

US3782014 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:45:10

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US3782014

Form: Participant Creation

Data signed: (b) (4) 26 Jan 2021 20:03:23

Generated On: 10 Jun 2021 09:45:10

[Participant ID](#)

US3782014

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

US3782014

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3782014

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3782014

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Condition	ASTHMA
Start date (dd MMM yyyy)	01 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Condition	TRANSIENT ISCHEMIC ATTACK
Start date (dd MMM yyyy)	02 FEB 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	02 FEB 2005
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2005
Start Year (derived)	2005
Stop Month and Year (derived)	FEB 2005
Stop Year (derived)	2005

US3782014

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 15:20
Height (xxx.x)	176 cm
Weight (xxx.x)	158.2 kg
BMI (xxx.x)	51.07180 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:03:30

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

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

Visit date (dd MMM yyyy)	13 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 143921

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 15:20
Temperature (xxx.x)	99.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	16:36 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 16:36
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3782014

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 16:04 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 16:04

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 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 AUG 2020
Collection time (00:00-23:59)	15:30 (24 HR)
Collection date and time (derived)	13 AUG 2020 15:30

US3782014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:34	13 AUG 2020 15:34
Nasopharyngeal Swab 2	No		

US3782014

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

13 AUG 2020 16:39

PC Open Date & Time

13 AUG 2020 16:24

PC Close Date & Time

13 AUG 2020 18:54

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	13 AUG 2020 20:59
PC Open Date & Time	13 AUG 2020 19:49
PC Close Date & Time	14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 21:23

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 22:25

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 21:56

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

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

97.7 °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

17 AUG 2020 22:03

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 22:13

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 21:46

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 16:40

PC Open Date & Time

13 AUG 2020 16:24

PC Close Date & Time

13 AUG 2020 18:54

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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

13 AUG 2020 21:00

PC Open Date & Time

13 AUG 2020 19:49

PC Close Date & Time

14 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 21:24

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 22:26

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 21:57

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 22:03

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 22:13

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 21:46

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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 ☐

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 16:40
PC Open Date & Time	13 AUG 2020 16:24
PC Close Date & Time	13 AUG 2020 18:54

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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 ☐

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 21:00
PC Open Date & Time	13 AUG 2020 19:49
PC Close Date & Time	14 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

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 ☒

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 21:25
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

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 ☒

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EAB) (1725)

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 22:26
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 4621

EAB) (1725)

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 21:57
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

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)

57 of 4621

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 22:03
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

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 ☒

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US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 22:14
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

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 ☒

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 21:47
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3782014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:20
Temperature (xxx.x)	99.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 14:43
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3782014

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3782014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 14:12 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 14:12

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

US3782014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

13:40 (24 HR)

Collection date and time (derived)

10 SEP 2020 13:40

US3782014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:42	10 SEP 2020 13:42
Nasopharyngeal Swab 2	No		

US3782014

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

10 SEP 2020 14:43

PC Open Date & Time

10 SEP 2020 14:32

PC Close Date & Time

10 SEP 2020 17:02

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °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	10 SEP 2020 21:51
PC Open Date & Time	10 SEP 2020 17:57
PC Close Date & Time	11 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

11 SEP 2020 22:52

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 20:39

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

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

98.1 °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

13 SEP 2020 20:35

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

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

97.1 °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

15 SEP 2020 05:44

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

15 SEP 2020 22:58

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 22:35

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 14:43

PC Open Date & Time

10 SEP 2020 14:32

PC Close Date & Time

10 SEP 2020 17:02

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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

10 SEP 2020 21:52

PC Open Date & Time

10 SEP 2020 17:57

PC Close Date & Time

11 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 22:50

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 20:39

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 20:36

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 05:45

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 22:59

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 22:36

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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 ☐

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 14:44
PC Open Date & Time	10 SEP 2020 14:32
PC Close Date & Time	10 SEP 2020 17:02

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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 ☐

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 21:52
PC Open Date & Time	10 SEP 2020 17:57
PC Close Date & Time	11 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

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 ☒

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 22:50
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 4621

EAB) (1725)

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 20:39
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

101 of 4621

EAB) (1725)

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 20:36
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

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 ☒

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 05:45
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

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 ☒

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 22:59
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

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 ☒

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 22:36
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3782014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	08:32 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 08:32
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3782014

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3782014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 OCT 2020

Collection time (00:00-23:59)

08:46 (24 HR)

Collection date and time (derived)

8 OCT 2020 08:46

US3782014

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:30

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 OCT 2020 07:38:35
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 07:42:37

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 08:10:07

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 92

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

No ☒

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 NOV 2020 06:22:46

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 09:12:29
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

23 NOV 2020 12:54:46

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

28 NOV 2020 07:37:41

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

05 DEC 2020 05:29:37

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

12 DEC 2020 08:09:05

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

19 DEC 2020 07:02:32

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

26 DEC 2020 06:37:24

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 06:58:50

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

09 JAN 2021 06:59:05

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

16 JAN 2021 04:04:55

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

23 JAN 2021 07:20:37

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

30 JAN 2021 07:29:29

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

06 FEB 2021 06:01:40

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

16 FEB 2021 16:03:32

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

20 FEB 2021 06:55:49

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

27 FEB 2021 12:05:39

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

06 MAR 2021 06:34:21

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	13 MAR 2021 07:48:50
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	23 MAR 2021 18:34:30
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	03 APR 2021 07:08:35
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 243

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 APR 2021 11:41:52

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

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

Date and time of submission

17 APR 2021 06:52:13

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

Date and time of submission

24 APR 2021 12:00:07

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 264

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

01 MAY 2021 06:35:00

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 278

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 292

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 306

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 439

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 502

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 509

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 516

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 579

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	02 APR 2022 00:01
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Patient Cloud Close Date & Time	06 APR 2022 23:59
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US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 677

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 698

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

DAY 747

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	01 OCT 2022 00:01
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Patient Cloud Close Date & Time	05 OCT 2022 23:59
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US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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

US3782014

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:45:10

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
No		02 MAR 2021 16:56:48

US3782014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:24:25

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:24:25

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 01:05:12

Generated On: 10 Jun 2021 09:45:10

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

Visit date (dd MMM yyyy)	10 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 01:05:12

Generated On: 10 Jun 2021 09:45:10

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3782014

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 MAR 2021

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

US3782014

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3782014

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3782014

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:45:10

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3782014

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

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3782014

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Date of updated informed consent (<i>dd MMM yyyy</i>)	8 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	8 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3782014

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3782014

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 JAN 2021
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 09:46
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	063 mmHg
Diastolic Blood Pressure units	MMHG

US3782014

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 JAN 2021
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 10:36
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3782014

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

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 JAN 2021

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

US3782014

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

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 8 JAN 2021

What was the treatment time? (00:00-23:59) 10:04 (24 HR)

Treatment Date and Time (derived) 8 JAN 2021 10:04

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

US3782014

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 JAN 2021

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

8 JAN 2021 09:40

US3782014

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00 - 23:59)	09:42
Collection Date and Time (derived)	8 JAN 2021 09:42

US3782014

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

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:03:29

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3782014

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 23:24:25

Generated On: 10 Jun 2021 09:45:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 23:24:25

Generated On: 10 Jun 2021 09:45:10

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	08:48 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 08:48
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 23:24:25

Generated On: 10 Jun 2021 09:45:10

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	09:33 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 09:33
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3782014

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 23:24:25

Generated On: 10 Jun 2021 09:45:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 FEB 2021

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

US3782014

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 23:24:25

Generated On: 10 Jun 2021 09:45:10

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 5 FEB 2021

What was the treatment time? (00:00-23:59) 08:59 (24 HR)

Treatment Date and Time (derived) 5 FEB 2021 08:59

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

US3782014

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:24:25

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:24:25

Generated On: 10 Jun 2021 09:45:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782014

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:24:25

Generated On: 10 Jun 2021 09:45:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782014

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3782014

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 MAR 2021

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

US3782014

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3782014

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Apr 2021 01:04:53

Generated On: 10 Jun 2021 09:45:10

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 17:29:26

Generated On: 10 Jun 2021 09:45:10

AEID	USA-US125-2021-MRNA-1273-P30 1000003
Adverse event	DRUG RASH
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	6 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	8 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	12 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 17:29:26

Generated On: 10 Jun 2021 09:45:10

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	DIFFUSE, NON-URTICARIAL RASH. TAKING CEFADROXIL POST-OP KNEE ARTHROPLASTY UNTIL 05-MAR-2021 (LIKELY ETIOLOGY)
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 17:29:26

Generated On: 10 Jun 2021 09:45:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 17:29:26

Generated On: 10 Jun 2021 09:45:10

AEID

Adverse event

FLATULENCE

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)

10 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 MAR 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

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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US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 17:29:26

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 17:29:26

Generated On: 10 Jun 2021 09:45:10

AEID	
Adverse event	HYPERGLYCEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 17:29:26

Generated On: 10 Jun 2021 09:45:10

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

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 17:29:26

Generated On: 10 Jun 2021 09:45:10

AEID	USA-US125-2021-MRNA-1273-P30 1000003
Adverse event	PERFORATED DUODENAL ULCER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	17 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	2 APR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 17:29:26

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Number of Days in ICU	12
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	IN PROCESS OF OBTAINING MEDICAL RECORD INFORMATION 08-APR-2021 - SEE CON MED LOGS FOR UPDATED INFORMATION
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 17:29:26

Generated On: 10 Jun 2021 09:45:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

1

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Jan 2021 20:03:24

Generated On: 10 Jun 2021 09:45:10

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

Yes ☒

No ☐

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

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication AZELASTINE 0.1%

Prophylaxis Yes ☐
No ☒

Indication OCC SINUS HEADACHE

Dose per administration 2

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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US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication FLUTICASONE

Prophylaxis Yes ☐
No ☒

Indication OCC SINUS HEADACHE

Dose per administration 2

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication CELECOXIB

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication PANIC DISORDER

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication AMLODIPINE/ BENAZEPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5/20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	17 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 FEB 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CV PROPHYLAXIS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ADVAIR
(FLUTICASONE/SALMETEROL)

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 115/21

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 FEB 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:42:02

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Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication CHOLEST OFF

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 2

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 2000

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN OCT 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SINUS HEADACHE

Dose per administration 1000

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		2 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		2 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 4000

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication OXYCONTIN

Prophylaxis Yes ☐
No ☒

Indication PRE-OPERATIVE SEDATION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication VANCOMYCIN

Prophylaxis Yes ☒
No ☐

Indication PRE-OPERATIVE INFECTION
PROPHYLAXIS

Dose per administration 2000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication PERI-OPERATIVE INFECTION
PROPHYLAXIS

Dose per administration 1000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication TRANEXAMIC ACID

Prophylaxis Yes ☒
No ☐

Indication INTRAOPERATIVE BLOOD LOSS
PREVENTION

Dose per administration 1950

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:42:02

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Name of Medication DECADRON

Prophylaxis Yes ☒
No ☐

Indication PERI-OPERATIVE
INFLAMMATION PROPHYLAXIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ATARAX

Prophylaxis Yes ☐
No ☒

Indication PRE-OPERATIVE SEDATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication CEFADROXIL

Prophylaxis Yes ☒
No ☐

Indication INFECTION PROPHYLAXIS

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication POST-OPERATIVE PAIN

Dose per administration 15

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication SENNOSIDES-DOCUSATE
SODIUM

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PROPHYLAXIS

Dose per administration 8.5/50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication POST-OPERATIVE EMBOLIC
PROPHYLAXIS

Dose per administration 81

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 21:42:02

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		7 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 21:42:02

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Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication R KNEE REPLACEMENT
POST-OPERATIVE PAIN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PLASMALYTE

Prophylaxis Yes ☐
No ☒

Indication INTRA-OPERATIVE FLUID
REPLACEMENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ROPIVACAINE

Prophylaxis Yes ☐
No ☒

Indication OPERATIVE ANESTHESIA

Dose per administration 40

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication EPINEPHRINE

Prophylaxis Yes ☐
No ☒

Indication OPERATIVE ANESTHESIA

Dose per administration 0.25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 21:42:02

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication KETAMINE

Prophylaxis Yes ☐
No ☒

Indication OPERATIVE ANESTHESIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication DRUG RASH

Dose per administration 20

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication KETORALAC

Prophylaxis Yes ☐
No ☒

Indication POST-OPERATIVE PAIN

Dose per administration 30

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		7 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication CETIRIZINE

Prophylaxis Yes ☐
No ☒

Indication DRUG RASH

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication DRUG RASH

Dose per administration 12.5-25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication TRIAMCINOLONE 0.1%

Prophylaxis Yes ☐
No ☒

Indication DRUG RASH

Dose per administration ONE

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

If dose unit is Other, specify APPLICATION

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA RELATED TO DRUG
RASH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication EMBOLIC PROPHYLAXIS

Dose per administration 40

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIOVASCULAR
PROPHYLAXIS

Dose per administration 81

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication MYLICON

Prophylaxis Yes ☐
No ☒

Indication FLATULENCE

Dose per administration 80

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication HUMOLOG INSULIN

Prophylaxis Yes ☐
No ☒

Indication HYPERGLYCEMIA

Dose per administration 1

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

If dose unit is Other, specify UNIT

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication SOLUCORTEF

Prophylaxis Yes ☐
No ☒

Indication DRUG RASH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	6 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication SOLUMEDROL

Prophylaxis Yes ☐
No ☒

Indication DRUG RASH

Dose per administration 125

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication DRUG RASH

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		7 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication DRUG RASH

Dose per administration 80

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	09 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	10 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication DRUG RASH

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication DRUG RASH

Dose per administration 40

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	17 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication DRUG RASH

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 18 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication CARAFATE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication MIRALAX

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication DULCOLAX

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input checked="" type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PROTONIX

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 40

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 5-7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

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Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 0.2

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication NEURONTIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PROCARDIA

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 30

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 21 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication SS HUMALOG INSULIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 1-21

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication GLARGINE INSULIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 15

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication	INSULIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PERFORATED DUODENAL ULCER
Dose per administration	3.3-12.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNITS/HOUR
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	CONTINUOUS INFUSION
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 2000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Data signed: (b) (4) 28 Apr 2021 21:42:02

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Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 1500

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 1000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 1250

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 3.375

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication VASOPRESSIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 0.03

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify PER HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Data signed: (b) (4) 28 Apr 2021 21:42:02

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Name of Medication VASOPRESSIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 2

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

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Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Data signed: (b) (4) 28 Apr 2021 21:42:02

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Name of Medication	DIPRIVAN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PERFORATED DUODENAL ULCER
Dose per administration	10-20
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MCG/KG/MIN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	CONTINUOUS INFUSION
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

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Name of Medication DIPRIVAN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 20-80

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 200

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication ROCURONIUM

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 20-80

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication NOREPINEPHRINE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 0-50

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

If dose unit is Other, specify

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

If frequency is Other, specify

CONTINUOUS DRIP

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication VERSED

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 0.5-2

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication KETAMINE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 25-50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication SOLU-CORTEF

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q 6-12 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 5000

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

PER HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication EPINEPHRINE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 0.4

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	SUBMUCOSAL INJECTION	
Start date (dd MMM yyyy)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication EPHEDRINE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 5-10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PRECEDEX
(DEXMEDETOMIDINE)

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 8-30

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication CALCIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication	TOTAL PARENTERAL NUTRITION (TPN)
--------------------	-------------------------------------

Prophylaxis	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Indication	PERFORATED DUODENAL ULCER
------------	------------------------------

Dose per administration	56-60
-------------------------	-------

Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input type="radio"/>
	unknown <input type="radio"/>
	other <input checked="" type="radio"/>

If frequency is Other, specify

PER HOUR

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication LIPIDS 20%

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

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Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PLASMALYTE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 70-125

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

PER HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 40-80

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 40

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

If dose unit is Other, specify MILLIEQUIVALENTS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 40

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

If dose unit is Other, specify MILLIEQUIVALENTS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication VITAMIN K1

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication LABETALOL

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication OMNIPAQUE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Data signed: (b) (4) 28 Apr 2021 21:42:02

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication OMNIPAQUE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication DIFLUCAN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Data signed: (b) (4) 28 Apr 2021 21:42:02

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication D50

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration UNK

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Data signed: (b) (4) 28 Apr 2021 21:42:02

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Name of Medication CALCIUM GLUCONATE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 2

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 ☐

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Name of Medication 5% HUMAN ALBUMIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication PANIC DISORDER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	12 APR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Name of Medication PACKED RED BLOOD CELLS

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 1

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

If dose unit is Other, specify UNIT

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 ☐

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 80

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

Q6H

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Name of Medication KETAMINE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Form: Prior/Concomitant Medication and Vaccination (103)

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Name of Medication KETAMINE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 10-15

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 ☐

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration UNK

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify TITRATED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		30 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Data signed: (b) (4) 28 Apr 2021 21:42:02

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Name of Medication ROBINUL

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 0.1

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 ☐

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Data signed: (b) (4) 28 Apr 2021 21:42:02

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Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

3 TIMES

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Name of Medication	PRECEDEX
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PERFORATED DUODENAL ULCER
Dose per administration	0.9
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MCG/KG/HR
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication	PRECEDEX
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PERFORATED DUODENAL ULCER
Dose per administration	0.9
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MCG/KG/HR
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication XANAX

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 0.25

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication SODIUM PHOSPHATE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 15

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

If dose unit is Other, specify MMOL

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication	MICROK+
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PERFORATED DUODENAL ULCER
Dose per administration	20
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MEQ
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication MICROK+

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 20

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

If dose unit is Other, specify MEQ

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication OMNIPAQUE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 350

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication DIPRIVAN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 30

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication DIPRIVAN

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 10-20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication POTASSIUM PHOSPHATE

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 15

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

If dose unit is Other, specify MMOL

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication PRILOSEC

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication VERSED

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication VERSED

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication FRESH FROZEN PLASMA

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 1

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

If dose unit is Other, specify UNIT

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	21 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication PERFORATED DUODENAL
ULCER

Dose per administration 40

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication AMLODIPINE/BENAZEPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5/20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication PANIC DISORDER

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Data signed: (b) (4) 28 Apr 2021 21:42:02

Generated On: 10 Jun 2021 09:45:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 01:04:57

Generated On: 10 Jun 2021 09:45:10

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 FEB 2021	ARTHROPLASTY TOTAL KNEE - RIGHT	Medical History	
18 MAR 2021	EXPLORATORY LAPAROTOMY WITH DUODENAL ULCER CAUTERIZATION	Adverse Event	
30 MAR 2021	GASTRODUODENAL ARTERY EMBOLIZATION	Adverse Event	

US3782014

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:45:10

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:45:10

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 ☐

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 16:24:31

Generated On: 10 Jun 2021 09:45:10

SAEID	USA-US125-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 16:24:31

Generated On: 10 Jun 2021 09:45:10

SAEID	USA-US125-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/MAR/2021 09:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 16:24:31

Generated On: 10 Jun 2021 09:45:10

SAEID	USA-US125-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/MAR/2021 13:56
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

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 16:24:31

Generated On: 10 Jun 2021 09:45:10

SAEID	USA-US125-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/MAR/2021 14:51
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.	True

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 16:24:31

Generated On: 10 Jun 2021 09:45:10

SAEID	USA-US125-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	25/MAR/2021 09:37
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

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 16:24:31

Generated On: 10 Jun 2021 09:45:10

SAEID	USA-US125-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	05/APR/2021 11:07
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.	True

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 16:24:31

Generated On: 10 Jun 2021 09:45:10

SAEID	USA-US125-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	09/APR/2021 13:21
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

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 30 Apr 2021 16:24:31

Generated On: 10 Jun 2021 09:45:10

SAEID	USA-US125-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	13/APR/2021 10:11
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

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 30 Apr 2021 16:24:31

Generated On: 10 Jun 2021 09:45:10

SAEID	USA-US125-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/APR/2021 12:13
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

US3782014 (Prod: Vanderbilt University Medical Center)

US3782014

Form: Participant Creation

Generated On: 10 Jun 2021 09:45:10

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'US3782014'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 19:24:22

US3782014

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:28:54

US3782014

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 19:24:23

US3782014

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:28:54

US3782014

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'SCRN'	System	13 Aug 2020 20:28:54

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 19:24:24

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '64'	(b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'YEARS'	System	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '64'	System	13 Aug 2020 20:29:52

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:10

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 20:29:26

US3782014

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:29:52

US3782014

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Aug 2020'	System	13 Aug 2020 20:29:52

US3782014

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '2020'	System	13 Aug 2020 20:29:52

US3782014

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:10

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	13 Aug 2020 20:29:52

US3782014

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:29:52

US3782014

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:29:52

US3782014

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:10

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:29:52

US3782014

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:10

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:29:52

US3782014

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:10

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 19:24:23

US3782014

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:10

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'I'	System	13 Aug 2020 20:30:07

US3782014

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:30:07

US3782014

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:45:10

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:30:15

US3782014

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Sinus headache, LLT: Sinus headache - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:12:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:12:59
Data point term sent to Coder	System	13 Aug 2020 22:11:50
User entered 'occasional sinus headache'	(b) (4), (b) (6)	13 Aug 2020 22:11:09

US3782014

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'UN UNK 2006'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:11:09

US3782014

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 22:11:09

US3782014

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:11:09

US3782014

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:11:09

US3782014

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 22:11:09

US3782014

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Jan 2006'	System	13 Aug 2020 22:11:09

US3782014

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '2006'	System	13 Aug 2020 22:11:09

US3782014

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:11:09

US3782014

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:11:09

US3782014

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:14:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:14:17
Data point term sent to Coder	System	13 Aug 2020 22:12:53
User entered 'vitamin D deficiency'	(b) (4), (b) (6)	13 Aug 2020 22:12:25

US3782014

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:12:25

US3782014

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:12:25

US3782014

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:12:25

US3782014

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:12:25

US3782014

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:12:25

US3782014

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Jan 2015'	System	13 Aug 2020 22:12:25

US3782014

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '2015'	System	13 Aug 2020 22:12:25

US3782014

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:12:25

US3782014

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:12:25

US3782014

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:15:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:15:18
Data point term sent to Coder	System	13 Aug 2020 22:13:55
User entered 'hyperlipidemia'	(b) (4), (b) (6)	13 Aug 2020 22:12:58

US3782014

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:12:58

US3782014

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:12:58

US3782014

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:12:58

US3782014

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:12:58

US3782014

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:12:58

US3782014

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Jan 2005'	System	13 Aug 2020 22:12:58

US3782014

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '2005'	System	13 Aug 2020 22:12:58

US3782014

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:12:58

US3782014

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:12:58

US3782014

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:15:19
Data point term sent to Coder	System	13 Aug 2020 22:13:56
User entered 'osteoarthritis'	(b) (4), (b) (6)	13 Aug 2020 22:13:50

US3782014

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:13:50

US3782014

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 22:13:50

US3782014

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:13:50

US3782014

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:13:50

US3782014

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 22:13:50

US3782014

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Jan 2015'	System	13 Aug 2020 22:13:50

US3782014

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '2015'	System	13 Aug 2020 22:13:50

US3782014

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:13:50

US3782014

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:13:50

US3782014

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Panic attacks and disorders, PT: Panic disorder, LLT: Panic disorder - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:15:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:15:20
Data point term sent to Coder	System	13 Aug 2020 22:14:57
User entered 'panic disorder'	(b) (4), (b) (6)	13 Aug 2020 22:14:33

US3782014

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:14:33

US3782014

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:14:33

US3782014

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:14:33

US3782014

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:14:33

US3782014

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 22:14:33

US3782014

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Jan 2018'	System	13 Aug 2020 22:14:33

US3782014

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '2018'	System	13 Aug 2020 22:14:33

US3782014

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:14:33

US3782014

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:14:33

US3782014

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:17:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:17:21
Data point term sent to Coder	System	13 Aug 2020 22:15:58
User entered 'hypertension'	(b) (4), (b) (6)	13 Aug 2020 22:15:07

US3782014

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'UN UNK 1975'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:15:07

US3782014

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:15:07

US3782014

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:15:07

US3782014

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:15:07

US3782014

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:15:07

US3782014

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Jan 1975'	System	13 Aug 2020 22:15:07

US3782014

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '1975'	System	13 Aug 2020 22:15:07

US3782014

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:15:07

US3782014

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:15:07

US3782014

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
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)	13 Aug 2020 22:17:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:17:21
Data point term sent to Coder	System	13 Aug 2020 22:15:58
User entered 'asthma'	(b) (4), (b) (6)	13 Aug 2020 22:15:36

US3782014

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '01 Feb 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:15:36

US3782014

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:15:36

US3782014

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:15:36

US3782014

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:15:36

US3782014

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:15:36

US3782014

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Feb 2020'	System	13 Aug 2020 22:15:36

US3782014

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '2020'	System	13 Aug 2020 22:15:36

US3782014

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:15:36

US3782014

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:15:36

US3782014

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Aug 2020 22:17:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 22:17:21
Data point term sent to Coder	System	13 Aug 2020 22:17:00
User entered 'obesity'	(b) (4), (b) (6)	13 Aug 2020 22:16:24

US3782014

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:16:24

US3782014

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:16:24

US3782014

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:16:24

US3782014

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:16:24

US3782014

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:16:24

US3782014

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Jan 2000'	System	13 Aug 2020 22:16:24

US3782014

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '2000'	System	13 Aug 2020 22:16:24

US3782014

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:16:24

US3782014

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	13 Aug 2020 22:16:24

US3782014

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User closed query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:48:22
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 18:19:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 18:19:35
Data point term sent to Coder	System	12 Sep 2020 18:18:29
Query 'Per MM, please expand the abbreviation ' answered with 'expanded abbreviation' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 18:17:45
Coding entries removed.	(b) (4), (b) (6)	12 Sep 2020 18:17:33
User entered 'Transient ischemic attack' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Sep 2020 18:17:33
User opened query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 23:30:15
Query 'Per MM, please expand the abbreviation ' canceled (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 23:30:10
User opened query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 23:30:09
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: TIA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 22:20:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 22:20:10
Data point term sent to Coder	System	13 Aug 2020 22:19:04
User entered 'TIA'	(b) (4), (b) (6)	13 Aug 2020 22:18:09

US3782014

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '02 Feb 2005'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:18:09

US3782014

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 22:18:09

US3782014

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:18:09

US3782014

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '02 Feb 2005'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:18:09

US3782014

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 22:18:09

US3782014

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Feb 2005'	System	13 Aug 2020 22:18:09

US3782014

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '2005'	System	13 Aug 2020 22:18:09

US3782014

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Feb 2005'	System	13 Aug 2020 22:18:09

US3782014

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '2005'	System	13 Aug 2020 22:18:09

US3782014

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
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)	03 Sep 2020 17:41:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 17:41:46
Data point term sent to Coder	System	03 Sep 2020 17:41:16
User entered 'seasonal allergies'	Carlton Griffin (b) (4)	03 Sep 2020 17:40:22

US3782014

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'UN UNK 1970'	(b) (4) Carlton Griffin (b) (4)	03 Sep 2020 17:40:22

US3782014

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) Carlton Griffin (b) (4)	03 Sep 2020 17:40:22

US3782014

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	03 Sep 2020 17:40:22

US3782014

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) Carlton Griffin (b) (4)	03 Sep 2020 17:40:22

US3782014

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4) Carlton Griffin (b) (4)	03 Sep 2020 17:40:22

US3782014

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'Jan 1970'	System	03 Sep 2020 17:40:22

US3782014

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '1970'	System	03 Sep 2020 17:40:22

US3782014

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	03 Sep 2020 17:40:22

US3782014

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	03 Sep 2020 17:40:22

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '15:20'	(b) (4), (b) (6)	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '13 Aug 2020 15:20'	System	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '176' cm	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 20:33:06
DataPoint set to visible.	System	13 Aug 2020 20:30:07

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '158.2' kg	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:33:06
DataPoint set to visible.	System	13 Aug 2020 20:30:07

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
Amendment Manager: User entered '51.07180'	System	16 Sep 2020 23:56:06
User entered '51.1'	System	13 Aug 2020 20:33:06
DataPoint set to visible.	System	13 Aug 2020 20:30:07

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'kg/m2'	System	13 Aug 2020 20:33:06
DataPoint set to visible.	System	13 Aug 2020 20:30:07

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 21:18:53
User entered '99.4' F	(b) (4), (b) (6)	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 21:18:53
User entered '64'	(b) (4), (b) (6)	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'bpm'	System	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 21:18:53
User entered '20'	(b) (4), (b) (6)	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'breaths/min'	System	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 21:18:53
User entered '154'	(b) (4), (b) (6)	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mmHg'	System	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 21:18:53
User entered '65'	(b) (4), (b) (6)	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mmHg'	System	13 Aug 2020 20:33:06

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18

US3782014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18

US3782014

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:43:38

US3782014

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:46:28
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 19:03:16
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 20:43:38

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

[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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

[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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

[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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

[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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

[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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 20:55:50

US3782014

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:56:17

US3782014

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:56:17

US3782014

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:56:17

US3782014

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'VISIT1'	System	13 Aug 2020 20:56:17

US3782014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 20:39:40

US3782014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:10

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:19:43
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:19:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 20:39:40
User entered '143921' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 20:39:40

US3782014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 20:39:40

US3782014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:10

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)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 20:57:01

US3782014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:10

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)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 20:57:01

US3782014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:57:01

US3782014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:57:01

US3782014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:10

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:57:01

US3782014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	Jenna Caserta (b) (4)	25 Sep 2020 18:15:43
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:08:22

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '15:20'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '13 Aug 2020 15:20'	System	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '99.4' F	(b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '64'	(b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'bpm'	System	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '20'	(b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'breaths/min'	System	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '154'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'mmHg'	System	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '65'	(b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'mmHg'	System	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:00:35
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minute minimum observation time. ' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 21:46:11
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 21:45:54
User entered '16:36'	(b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '13 Aug 2020 16:36'	System	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '98.3' F	(b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '55'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'bpm'	System	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '18'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'breaths/min'	System	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '151'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'mmHg'	System	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '73'	(b) (4), (b) (6)	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'mmHg'	System	13 Aug 2020 21:45:54

US3782014

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:57:53

US3782014

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 20:57:53

US3782014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:27:33

US3782014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:27:33

US3782014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:27:33

US3782014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 21:27:33

US3782014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:27:33

US3782014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '16:04'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:27:33

US3782014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '13 Aug 2020 16:04'	System	13 Aug 2020 21:27:33

US3782014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:27:33

US3782014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'ONCE'	System	13 Aug 2020 21:27:33

US3782014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 21:27:33

US3782014

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:58:38

US3782014

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:58:38

US3782014

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '15:30'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:58:38

US3782014

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '13 Aug 2020 15:30'	System	13 Aug 2020 20:58:38

US3782014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:45:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:59:11

US3782014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Aug 2020 20:59:11

US3782014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:59:11

US3782014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '15:34'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:59:11

US3782014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '13 Aug 2020 15:34'	System	13 Aug 2020 20:59:11

US3782014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Aug 2020 20:59:11

US3782014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:59:11

US3782014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:59:11

US3782014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered empty.	System	13 Aug 2020 20:59:11

US3782014

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:59:25

US3782014

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'I'	System	13 Aug 2020 20:59:25

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:38:55', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2f595c95-dbbd-496b-bcbe-44607fbbc4bf' User entered 'Yes (Y)'	System	13 Aug 2020 21:39:23
	System	13 Aug 2020 21:39:23

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:39:03', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2f595c95-dbbd-496b-bcbe-44607fbbc4bf' User entered '98.3'	System	13 Aug 2020 21:39:23
	System	13 Aug 2020 21:39:23

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:39:14', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2f595c95-dbbd-496b-bcbe-44607fbbc4bf'	System	13 Aug 2020 21:39:23
User entered 'No (N)'	System	13 Aug 2020 21:39:23

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:39:22', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2f595c95-dbbd-496b-bcbe-44607fbbc4bf' User entered '13 Aug 2020 16:39'	System	13 Aug 2020 21:39:23
	System	13 Aug 2020 21:39:23

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Aug 2020 16:24'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Aug 2020 18:54'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T20:58:44', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4308436f-99da-426d-aceb-910b8d484322' User entered 'Yes (Y)'	System	14 Aug 2020 01:59:38
	System	14 Aug 2020 01:59:38

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T20:59:26', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4308436f-99da-426d-aceb-910b8d484322' User entered '97.6'	System	14 Aug 2020 01:59:38
	System	14 Aug 2020 01:59:38

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T20:59:30', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4308436f-99da-426d-aceb-910b8d484322'	System	14 Aug 2020 01:59:38
User entered 'No (N)'	System	14 Aug 2020 01:59:38

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T20:59:35', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4308436f-99da-426d-aceb-910b8d484322'	System	14 Aug 2020 01:59:38
User entered '13 Aug 2020 20:59'	System	14 Aug 2020 01:59:38

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Aug 2020 19:49'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 2'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:23:38', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6126cbea-1a1f-4605-99cc-e2c5ecf627b6' User entered 'Yes (Y)'	System	15 Aug 2020 02:23:53
	System	15 Aug 2020 02:23:53

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:23:45', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6126cbea-1a1f-4605-99cc-e2c5ecf627b6' User entered '97.5'	System	15 Aug 2020 02:23:53
	System	15 Aug 2020 02:23:53

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:23:48', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6126cbea-1a1f-4605-99cc-e2c5ecf627b6'	System	15 Aug 2020 02:23:53
User entered 'No (N)'	System	15 Aug 2020 02:23:53

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:23:52', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6126cbea-1a1f-4605-99cc-e2c5ecf627b6' User entered '14 Aug 2020 21:23'	System	15 Aug 2020 02:23:53
	System	15 Aug 2020 02:23:53

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 3'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:25:42', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'ed654497-ca79-4e29-822f-d79b066ec03d' User entered 'Yes (Y)'	System	16 Aug 2020 03:26:02
	System	16 Aug 2020 03:26:02

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:25:49', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'ed654497-ca79-4e29-822f-d79b066ec03d' User entered '97.2'	System	16 Aug 2020 03:26:02
	System	16 Aug 2020 03:26:02

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:25:54', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'ed654497-ca79-4e29-822f-d79b066ec03d'	System	16 Aug 2020 03:26:02
User entered 'No (N)'	System	16 Aug 2020 03:26:02

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:25:57', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'ed654497-ca79-4e29-822f-d79b066ec03d' User entered '15 Aug 2020 22:25'	System	16 Aug 2020 03:26:02
	System	16 Aug 2020 03:26:02

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 4'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:56:41', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'c34c23e4-f9d8-441a-bfac-53213018a406'	System	17 Aug 2020 02:56:56
User entered 'Yes (Y)'	System	17 Aug 2020 02:56:56

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:56:45', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'c34c23e4-f9d8-441a-bfac-53213018a406'	System	17 Aug 2020 02:56:56
User entered '97.2'	System	17 Aug 2020 02:56:56

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:56:49', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'c34c23e4-f9d8-441a-bfac-53213018a406'	System	17 Aug 2020 02:56:56
User entered 'No (N)'	System	17 Aug 2020 02:56:56

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:56:52', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'c34c23e4-f9d8-441a-bfac-53213018a406'	System	17 Aug 2020 02:56:56
User entered '16 Aug 2020 21:56'	System	17 Aug 2020 02:56:56

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 5'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:02:51', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '44bb7e4c-7507-48d0-955f-7ea19db04833' User entered 'Yes (Y)'	System	18 Aug 2020 03:03:06
	System	18 Aug 2020 03:03:06

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:02:57', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '44bb7e4c-7507-48d0-955f-7ea19db04833' User entered '97.7'	System	18 Aug 2020 03:03:06
	System	18 Aug 2020 03:03:06

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '44bb7e4c-7507-48d0-955f-7ea19db04833'	System	18 Aug 2020 03:03:06
User entered 'No (N)'	System	18 Aug 2020 03:03:06

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:03', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '44bb7e4c-7507-48d0-955f-7ea19db04833' User entered '17 Aug 2020 22:03'	System	18 Aug 2020 03:03:06
	System	18 Aug 2020 03:03:06

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 6'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:02', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '53ade6ae-90de-4d0e-bf8f-4799d2527d0c' User entered 'Yes (Y)'	System	19 Aug 2020 03:13:18
	System	19 Aug 2020 03:13:18

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:08', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '53ade6ae-90de-4d0e-bf8f-4799d2527d0c' User entered '97.4'	System	19 Aug 2020 03:13:18
	System	19 Aug 2020 03:13:18

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:12', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '53ade6ae-90de-4d0e-bf8f-4799d2527d0c'	System	19 Aug 2020 03:13:18
User entered 'No (N)'	System	19 Aug 2020 03:13:18

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:15', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '53ade6ae-90de-4d0e-bf8f-4799d2527d0c' User entered '18 Aug 2020 22:13'	System	19 Aug 2020 03:13:18
	System	19 Aug 2020 03:13:18

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 7'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:46:30', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'f12f9fb9-c10a-4c80-8ecd-9e2967119fb0' User entered 'Yes (Y)'	System	20 Aug 2020 02:46:49
	System	20 Aug 2020 02:46:49

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:46:36', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'f12f9fb9-c10a-4c80-8ecd-9e2967119fb0' User entered '98.2'	System	20 Aug 2020 02:46:49
	System	20 Aug 2020 02:46:49

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:46:40', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'f12f9fb9-c10a-4c80-8ecd-9e2967119fb0'	System	20 Aug 2020 02:46:49
User entered 'No (N)'	System	20 Aug 2020 02:46:49

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:46:45', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'f12f9fb9-c10a-4c80-8ecd-9e2967119fb0' User entered '19 Aug 2020 21:46'	System	20 Aug 2020 02:46:49
	System	20 Aug 2020 02:46:49

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:39:34', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e829423d-71f3-4ea6-8382-0cdb65388ed3' User entered 'None (1)'	System	13 Aug 2020 21:40:06
	System	13 Aug 2020 21:40:06

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:39:47', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e829423d-71f3-4ea6-8382-0cdb65388ed3' User entered 'No (N)'	System	13 Aug 2020 21:40:06
	System	13 Aug 2020 21:40:06

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:39:52', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e829423d-71f3-4ea6-8382-0cdb65388ed3' User entered 'No (N)'	System	13 Aug 2020 21:40:06
	System	13 Aug 2020 21:40:06

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:39:59', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e829423d-71f3-4ea6-8382-0cdb65388ed3' User entered 'None (1)'	System	13 Aug 2020 21:40:06
	System	13 Aug 2020 21:40:06

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:40:02', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e829423d-71f3-4ea6-8382-0cdb65388ed3'	System	13 Aug 2020 21:40:06
User entered '13 Aug 2020 16:40'	System	13 Aug 2020 21:40:06

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Aug 2020 16:24'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Aug 2020 18:54'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T20:59:41', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '10b17162-13f6-45c3-8d15-42b0e025bed6' User entered 'None (1)'	System	14 Aug 2020 02:00:20
	System	14 Aug 2020 02:00:20

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:06', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '10b17162-13f6-45c3-8d15-42b0e025bed6' User entered 'No (N)'	System	14 Aug 2020 02:00:20
	System	14 Aug 2020 02:00:20

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:09', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '10b17162-13f6-45c3-8d15-42b0e025bed6' User entered 'No (N)'	System	14 Aug 2020 02:00:20
	System	14 Aug 2020 02:00:20

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:13', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '10b17162-13f6-45c3-8d15-42b0e025bed6' User entered 'None (1)'	System	14 Aug 2020 02:00:20
	System	14 Aug 2020 02:00:20

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:16', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '10b17162-13f6-45c3-8d15-42b0e025bed6' User entered '13 Aug 2020 21:00'	System	14 Aug 2020 02:00:20
	System	14 Aug 2020 02:00:20

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Aug 2020 19:49'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 2'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:24:44', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '57185aed-6c41-4a1c-8115-2d3b35a3dc16' User entered 'None (1)'	System	15 Aug 2020 02:25:00
	System	15 Aug 2020 02:25:00

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:24:47', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '57185aed-6c41-4a1c-8115-2d3b35a3dc16' User entered 'No (N)'	System	15 Aug 2020 02:25:00
	System	15 Aug 2020 02:25:00

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:24:51', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '57185aed-6c41-4a1c-8115-2d3b35a3dc16' User entered 'No (N)'	System	15 Aug 2020 02:25:00
	System	15 Aug 2020 02:25:00

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:24:54', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '57185aed-6c41-4a1c-8115-2d3b35a3dc16' User entered 'None (1)'	System	15 Aug 2020 02:25:00
	System	15 Aug 2020 02:25:00

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:24:57', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '57185aed-6c41-4a1c-8115-2d3b35a3dc16' User entered '14 Aug 2020 21:24'	System	15 Aug 2020 02:25:00
	System	15 Aug 2020 02:25:00

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 3'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:02', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '3f23759d-e79f-45ec-ae48-29c0ed6025bf' User entered 'None (1)'	System	16 Aug 2020 03:26:14
	System	16 Aug 2020 03:26:14

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:05', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '3f23759d-e79f-45ec-ae48-29c0ed6025bf' User entered 'No (N)'	System	16 Aug 2020 03:26:14
	System	16 Aug 2020 03:26:14

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:08', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '3f23759d-e79f-45ec-ae48-29c0ed6025bf' User entered 'No (N)'	System	16 Aug 2020 03:26:14
	System	16 Aug 2020 03:26:14

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:11', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '3f23759d-e79f-45ec-ae48-29c0ed6025bf' User entered 'None (1)'	System	16 Aug 2020 03:26:14
	System	16 Aug 2020 03:26:14

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:13', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '3f23759d-e79f-45ec-ae48-29c0ed6025bf' User entered '15 Aug 2020 22:26'	System	16 Aug 2020 03:26:14
	System	16 Aug 2020 03:26:14

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 4'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:56:57', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'd74c5896-72bc-4e0a-a92e-9e31c4dc91a7'	System	17 Aug 2020 02:57:09
User entered 'None (1)'	System	17 Aug 2020 02:57:09

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'd74c5896-72bc-4e0a-a92e-9e31c4dc91a7' User entered 'No (N)'	System	17 Aug 2020 02:57:09
	System	17 Aug 2020 02:57:09

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:03', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'd74c5896-72bc-4e0a-a92e-9e31c4dc91a7' User entered 'No (N)'	System	17 Aug 2020 02:57:09
	System	17 Aug 2020 02:57:09

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:06', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'd74c5896-72bc-4e0a-a92e-9e31c4dc91a7'	System	17 Aug 2020 02:57:09
User entered 'None (1)'	System	17 Aug 2020 02:57:09

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:08', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'd74c5896-72bc-4e0a-a92e-9e31c4dc91a7' User entered '16 Aug 2020 21:57'	System	17 Aug 2020 02:57:09
	System	17 Aug 2020 02:57:09

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 5'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:08', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4895cf85-3cc8-4687-980f-8517722c1071' User entered 'None (1)'	System	18 Aug 2020 03:03:32
	System	18 Aug 2020 03:03:32

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:11', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4895cf85-3cc8-4687-980f-8517722c1071' User entered 'No (N)'	System	18 Aug 2020 03:03:32
	System	18 Aug 2020 03:03:32

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:18', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4895cf85-3cc8-4687-980f-8517722c1071' User entered 'No (N)'	System	18 Aug 2020 03:03:32
	System	18 Aug 2020 03:03:32

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:25', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4895cf85-3cc8-4687-980f-8517722c1071' User entered 'None (1)'	System	18 Aug 2020 03:03:32
	System	18 Aug 2020 03:03:32

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:27', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4895cf85-3cc8-4687-980f-8517722c1071' User entered '17 Aug 2020 22:03'	System	18 Aug 2020 03:03:32
	System	18 Aug 2020 03:03:32

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 6'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:22', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '02fd29a0-32f9-45bc-a1c1-e96fe36f9778'	System	19 Aug 2020 03:13:45
User entered 'None (1)'	System	19 Aug 2020 03:13:45

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:25', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '02fd29a0-32f9-45bc-a1c1-e96fe36f9778' User entered 'No (N)'	System	19 Aug 2020 03:13:45
	System	19 Aug 2020 03:13:45

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:36', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '02fd29a0-32f9-45bc-a1c1-e96fe36f9778'	System	19 Aug 2020 03:13:45
User entered 'No (N)'	System	19 Aug 2020 03:13:45

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:38', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '02fd29a0-32f9-45bc-a1c1-e96fe36f9778'	System	19 Aug 2020 03:13:45
User entered 'None (1)'	System	19 Aug 2020 03:13:45

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:41', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '02fd29a0-32f9-45bc-a1c1-e96fe36f9778' User entered '18 Aug 2020 22:13'	System	19 Aug 2020 03:13:45
	System	19 Aug 2020 03:13:45

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 7'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:46:49', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '8112e48e-fb30-407c-8c77-5af10aadd71' User entered 'None (1)'	System	20 Aug 2020 02:47:00
	System	20 Aug 2020 02:47:00

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:46:51', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '8112e48e-fb30-407c-8c77-5af10aadd71' User entered 'No (N)'	System	20 Aug 2020 02:47:00
	System	20 Aug 2020 02:47:00

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:46:53', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '8112e48e-fb30-407c-8c77-5af10aadd71' User entered 'No (N)'	System	20 Aug 2020 02:47:00
	System	20 Aug 2020 02:47:00

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:46:56', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '8112e48e-fb30-407c-8c77-5af10aadd71' User entered 'None (1)'	System	20 Aug 2020 02:47:00
	System	20 Aug 2020 02:47:00

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:46:59', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '8112e48e-fb30-407c-8c77-5af10aadd71' User entered '19 Aug 2020 21:46'	System	20 Aug 2020 02:47:00
	System	20 Aug 2020 02:47:00

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:40:12', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '25f961dd-a357-41e8-9875-5cc1aebafa16' User entered 'None (0)'	System	13 Aug 2020 21:40:41
	System	13 Aug 2020 21:40:41

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:40:18', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '25f961dd-a357-41e8-9875-5cc1aebafa16' User entered 'None (0)'	System	13 Aug 2020 21:40:41
	System	13 Aug 2020 21:40:41

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:40:21', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '25f961dd-a357-41e8-9875-5cc1aebafa16' User entered 'None (0)'	System	13 Aug 2020 21:40:41
	System	13 Aug 2020 21:40:41

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:40:24', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '25f961dd-a357-41e8-9875-5cc1aebafa16' User entered 'None (0)'	System	13 Aug 2020 21:40:41
	System	13 Aug 2020 21:40:41

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:40:27', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '25f961dd-a357-41e8-9875-5cc1aebafa16' User entered 'None (0)'	System	13 Aug 2020 21:40:41
	System	13 Aug 2020 21:40:41

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:40:30', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '25f961dd-a357-41e8-9875-5cc1aebafa16' User entered 'None (0)'	System	13 Aug 2020 21:40:41
	System	13 Aug 2020 21:40:41

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:40:37', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '25f961dd-a357-41e8-9875-5cc1aebafa16'	System	13 Aug 2020 21:40:41
User entered 'No (N)'	System	13 Aug 2020 21:40:41

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T16:40:39', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '25f961dd-a357-41e8-9875-5cc1aebafa16'	System	13 Aug 2020 21:40:41
User entered '13 Aug 2020 16:40'	System	13 Aug 2020 21:40:41

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Aug 2020 16:24'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Aug 2020 18:54'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:23', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '004e6c44-b3ed-46a8-8272-0dd60afa05cb' User entered 'None (0)'	System	14 Aug 2020 02:00:53
	System	14 Aug 2020 02:00:53

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:26', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '004e6c44-b3ed-46a8-8272-0dd60afa05cb' User entered 'None (0)'	System	14 Aug 2020 02:00:53
	System	14 Aug 2020 02:00:53

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:32', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '004e6c44-b3ed-46a8-8272-0dd60afa05cb' User entered 'None (0)'	System	14 Aug 2020 02:00:53
	System	14 Aug 2020 02:00:53

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:34', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '004e6c44-b3ed-46a8-8272-0dd60afa05cb' User entered 'None (0)'	System	14 Aug 2020 02:00:53
	System	14 Aug 2020 02:00:53

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:36', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '004e6c44-b3ed-46a8-8272-0dd60afa05cb' User entered 'None (0)'	System	14 Aug 2020 02:00:53
	System	14 Aug 2020 02:00:53

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:39', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '004e6c44-b3ed-46a8-8272-0dd60afa05cb' User entered 'None (0)'	System	14 Aug 2020 02:00:53
	System	14 Aug 2020 02:00:53

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:49', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '004e6c44-b3ed-46a8-8272-0dd60afa05cb' User entered 'No (N)'	System	14 Aug 2020 02:00:53
	System	14 Aug 2020 02:00:53

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-13T21:00:51', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '004e6c44-b3ed-46a8-8272-0dd60afa05cb' User entered '13 Aug 2020 21:00'	System	14 Aug 2020 02:00:53
	System	14 Aug 2020 02:00:53

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Aug 2020 19:49'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 2'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:25:04', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1b06f34c-394f-4434-aba7-bdbd7d9e2f5f' User entered 'None (0)'	System	15 Aug 2020 02:25:29
	System	15 Aug 2020 02:25:29

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:25:07', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1b06f34c-394f-4434-aba7-bdbd7d9e2f5f' User entered 'None (0)'	System	15 Aug 2020 02:25:29
	System	15 Aug 2020 02:25:29

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:25:10', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1b06f34c-394f-4434-aba7-bdbd7d9e2f5f' User entered 'None (0)'	System	15 Aug 2020 02:25:29
	System	15 Aug 2020 02:25:29

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:25:12', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1b06f34c-394f-4434-aba7-bdbd7d9e2f5f' User entered 'None (0)'	System	15 Aug 2020 02:25:29
	System	15 Aug 2020 02:25:29

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:25:15', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1b06f34c-394f-4434-aba7-bdbd7d9e2f5f' User entered 'None (0)'	System	15 Aug 2020 02:25:29
	System	15 Aug 2020 02:25:29

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:25:17', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1b06f34c-394f-4434-aba7-bdbd7d9e2f5f' User entered 'None (0)'	System	15 Aug 2020 02:25:29
	System	15 Aug 2020 02:25:29

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:25:23', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1b06f34c-394f-4434-aba7-bdbd7d9e2f5f' User entered 'No (N)'	System	15 Aug 2020 02:25:29
	System	15 Aug 2020 02:25:29

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-14T21:25:25', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1b06f34c-394f-4434-aba7-bdbd7d9e2f5f' User entered '14 Aug 2020 21:25'	System	15 Aug 2020 02:25:29
	System	15 Aug 2020 02:25:29

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 3'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:18', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e1ddee12-2eeb-4863-98b1-af5dab0e4d3c' User entered 'None (0)'	System	16 Aug 2020 03:26:43
	System	16 Aug 2020 03:26:43

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:20', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e1ddee12-2eeb-4863-98b1-af5dab0e4d3c' User entered 'None (0)'	System	16 Aug 2020 03:26:43
	System	16 Aug 2020 03:26:43

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:22', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e1ddee12-2eeb-4863-98b1-af5dab0e4d3c' User entered 'None (0)'	System	16 Aug 2020 03:26:43
	System	16 Aug 2020 03:26:43

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:25', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e1ddee12-2eeb-4863-98b1-af5dab0e4d3c' User entered 'None (0)'	System	16 Aug 2020 03:26:43
	System	16 Aug 2020 03:26:43

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:27', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e1ddee12-2eeb-4863-98b1-af5dab0e4d3c' User entered 'None (0)'	System	16 Aug 2020 03:26:43
	System	16 Aug 2020 03:26:43

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:29', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e1ddee12-2eeb-4863-98b1-af5dab0e4d3c' User entered 'None (0)'	System	16 Aug 2020 03:26:43
	System	16 Aug 2020 03:26:43

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:36', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e1ddee12-2eeb-4863-98b1-af5dab0e4d3c' User entered 'No (N)'	System	16 Aug 2020 03:26:43
	System	16 Aug 2020 03:26:43

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-15T22:26:38', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e1ddee12-2eeb-4863-98b1-af5dab0e4d3c' User entered '15 Aug 2020 22:26'	System	16 Aug 2020 03:26:43
	System	16 Aug 2020 03:26:43

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 4'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:11', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5a0ea8ec-418b-4005-82d7-737353b3a942' User entered 'None (0)'	System	17 Aug 2020 02:57:32
	System	17 Aug 2020 02:57:32

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:14', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5a0ea8ec-418b-4005-82d7-737353b3a942' User entered 'None (0)'	System	17 Aug 2020 02:57:32
	System	17 Aug 2020 02:57:32

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:16', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5a0ea8ec-418b-4005-82d7-737353b3a942' User entered 'None (0)'	System	17 Aug 2020 02:57:32
	System	17 Aug 2020 02:57:32

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:18', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5a0ea8ec-418b-4005-82d7-737353b3a942' User entered 'None (0)'	System	17 Aug 2020 02:57:32
	System	17 Aug 2020 02:57:32

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:21', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5a0ea8ec-418b-4005-82d7-737353b3a942' User entered 'None (0)'	System	17 Aug 2020 02:57:32
	System	17 Aug 2020 02:57:32

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:23', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5a0ea8ec-418b-4005-82d7-737353b3a942' User entered 'None (0)'	System	17 Aug 2020 02:57:32
	System	17 Aug 2020 02:57:32

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:25', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5a0ea8ec-418b-4005-82d7-737353b3a942'	System	17 Aug 2020 02:57:32
User entered 'No (N)'	System	17 Aug 2020 02:57:32

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-16T21:57:27', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5a0ea8ec-418b-4005-82d7-737353b3a942'	System	17 Aug 2020 02:57:32
User entered '16 Aug 2020 21:57'	System	17 Aug 2020 02:57:32

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 5'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:32', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1310233d-1f62-4bfa-bc81-1c88eda8ce24' User entered 'None (0)'	System	18 Aug 2020 03:03:52
	System	18 Aug 2020 03:03:52

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:37', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1310233d-1f62-4bfa-bc81-1c88eda8ce24' User entered 'None (0)'	System	18 Aug 2020 03:03:52
	System	18 Aug 2020 03:03:52

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:39', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1310233d-1f62-4bfa-bc81-1c88eda8ce24' User entered 'None (0)'	System	18 Aug 2020 03:03:52
	System	18 Aug 2020 03:03:52

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:41', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1310233d-1f62-4bfa-bc81-1c88eda8ce24' User entered 'None (0)'	System	18 Aug 2020 03:03:52
	System	18 Aug 2020 03:03:52

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:43', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1310233d-1f62-4bfa-bc81-1c88eda8ce24' User entered 'None (0)'	System	18 Aug 2020 03:03:52
	System	18 Aug 2020 03:03:52

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:45', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1310233d-1f62-4bfa-bc81-1c88eda8ce24' User entered 'None (0)'	System	18 Aug 2020 03:03:52
	System	18 Aug 2020 03:03:52

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:47', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1310233d-1f62-4bfa-bc81-1c88eda8ce24' User entered 'No (N)'	System	18 Aug 2020 03:03:52
	System	18 Aug 2020 03:03:52

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-17T22:03:50', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1310233d-1f62-4bfa-bc81-1c88eda8ce24' User entered '17 Aug 2020 22:03'	System	18 Aug 2020 03:03:52
	System	18 Aug 2020 03:03:52

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 6'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:45', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '761632f3-26d4-427a-804c-6c46f9ee6968' User entered 'None (0)'	System	19 Aug 2020 03:14:06
	System	19 Aug 2020 03:14:06

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:48', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '761632f3-26d4-427a-804c-6c46f9ee6968' User entered 'None (0)'	System	19 Aug 2020 03:14:06
	System	19 Aug 2020 03:14:06

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:51', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '761632f3-26d4-427a-804c-6c46f9ee6968' User entered 'None (0)'	System	19 Aug 2020 03:14:06
	System	19 Aug 2020 03:14:06

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:54', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '761632f3-26d4-427a-804c-6c46f9ee6968' User entered 'None (0)'	System	19 Aug 2020 03:14:06
	System	19 Aug 2020 03:14:06

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:56', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '761632f3-26d4-427a-804c-6c46f9ee6968' User entered 'None (0)'	System	19 Aug 2020 03:14:06
	System	19 Aug 2020 03:14:06

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:13:58', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '761632f3-26d4-427a-804c-6c46f9ee6968' User entered 'None (0)'	System	19 Aug 2020 03:14:06
	System	19 Aug 2020 03:14:06

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:14:01', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '761632f3-26d4-427a-804c-6c46f9ee6968'	System	19 Aug 2020 03:14:06
User entered 'No (N)'	System	19 Aug 2020 03:14:06

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-18T22:14:03', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '761632f3-26d4-427a-804c-6c46f9ee6968'	System	19 Aug 2020 03:14:06
User entered '18 Aug 2020 22:14'	System	19 Aug 2020 03:14:06

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 7'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:47:02', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5e166be7-09b1-4060-b018-0b9e9b98a654' User entered 'None (0)'	System	20 Aug 2020 02:47:19
	System	20 Aug 2020 02:47:19

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:47:05', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5e166be7-09b1-4060-b018-0b9e9b98a654' User entered 'None (0)'	System	20 Aug 2020 02:47:19
	System	20 Aug 2020 02:47:19

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:47:07', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5e166be7-09b1-4060-b018-0b9e9b98a654' User entered 'None (0)'	System	20 Aug 2020 02:47:19
	System	20 Aug 2020 02:47:19

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:47:09', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5e166be7-09b1-4060-b018-0b9e9b98a654' User entered 'None (0)'	System	20 Aug 2020 02:47:19
	System	20 Aug 2020 02:47:19

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:47:10', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5e166be7-09b1-4060-b018-0b9e9b98a654' User entered 'None (0)'	System	20 Aug 2020 02:47:19
	System	20 Aug 2020 02:47:19

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:47:12', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5e166be7-09b1-4060-b018-0b9e9b98a654' User entered 'None (0)'	System	20 Aug 2020 02:47:19
	System	20 Aug 2020 02:47:19

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:47:14', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5e166be7-09b1-4060-b018-0b9e9b98a654'	System	20 Aug 2020 02:47:19
User entered 'No (N)'	System	20 Aug 2020 02:47:19

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-08-19T21:47:16', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5e166be7-09b1-4060-b018-0b9e9b98a654' User entered '19 Aug 2020 21:47'	System	20 Aug 2020 02:47:19
	System	20 Aug 2020 02:47:19

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 21:27:33

US3782014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	20 Aug 2020 19:27:36

US3782014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '20 Aug 2020'	(b) (4) Amber Massey (b) (4)	20 Aug 2020 19:27:36

US3782014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amber Massey (b) (4)	20 Aug 2020 19:27:36

US3782014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	20 Aug 2020 19:27:36

US3782014

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	20 Aug 2020 19:27:43

US3782014

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'I'	System	20 Aug 2020 19:27:43

US3782014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 13:38:20

US3782014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '27 Aug 2020'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 13:38:20

US3782014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 13:38:20

US3782014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 13:38:20

US3782014

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 13:38:27

US3782014

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User entered 'I'	System	27 Aug 2020 13:38:27

US3782014

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	03 Sep 2020 17:32:35

US3782014

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '3 Sep 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Sep 2020 17:32:35

US3782014

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	03 Sep 2020 17:32:35

US3782014

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Sep 2020 17:32:35

US3782014

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Sep 2020 17:32:40

US3782014

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User entered 'I'	System	03 Sep 2020 17:32:40

US3782014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:03:16

US3782014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:03:16

US3782014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:03:16

US3782014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'VISIT2'	System	10 Sep 2020 19:03:16

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13:20'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '10 Sep 2020 13:20'	System	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '99.9' F	(b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '64'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'bpm'	System	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '20'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'breaths/min'	System	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '134'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'mmHg'	System	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '60'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'mmHg'	System	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Sep 2020 19:50:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 19:50:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 19:50:39
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 19:50:33
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '14:43'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '10 Sep 2020 14:43'	System	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	10 Sep 2020 19:50:53
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 19:50:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Sep 2020 19:50:33
User entered '98.8' (non-conformant).	(b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '62'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'bpm'	System	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '20'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'breaths/min'	System	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '140'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'mmHg'	System	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '67'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'mmHg'	System	10 Sep 2020 19:50:33

US3782014

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:03:29

US3782014

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:03:29

US3782014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:32:59

US3782014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 19:32:59

US3782014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 19:32:59

US3782014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 19:32:59

US3782014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:32:59

US3782014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '14:12'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:32:59

US3782014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '10 Sep 2020 14:12'	System	10 Sep 2020 19:32:59

US3782014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:32:59

US3782014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'ONCE'	System	10 Sep 2020 19:32:59

US3782014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 19:32:59

US3782014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:04:05

US3782014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:04:05

US3782014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13:40'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:04:05

US3782014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '10 Sep 2020 13:40'	System	10 Sep 2020 19:04:05

US3782014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:45:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:04:29

US3782014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 19:04:29

US3782014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:04:29

US3782014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '13:42'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:04:29

US3782014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '10 Sep 2020 13:42'	System	10 Sep 2020 19:04:29

US3782014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 19:04:29

US3782014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:04:29

US3782014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:04:29

US3782014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered empty.	System	10 Sep 2020 19:04:29

US3782014

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:04:34

US3782014

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'I'	System	10 Sep 2020 19:04:34

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:43:18', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'bfb9a378-e447-4cc2-9926-a6d10b552dd7' User entered 'Yes (Y)'	System	10 Sep 2020 19:43:33
	System	10 Sep 2020 19:43:33

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:43:24', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'bfb9a378-e447-4cc2-9926-a6d10b552dd7' User entered '98.8'	System	10 Sep 2020 19:43:33
	System	10 Sep 2020 19:43:33

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:43:27', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'bfb9a378-e447-4cc2-9926-a6d10b552dd7'	System	10 Sep 2020 19:43:33
User entered 'No (N)'	System	10 Sep 2020 19:43:33

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:43:31', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'bfb9a378-e447-4cc2-9926-a6d10b552dd7' User entered '10 Sep 2020 14:43'	System	10 Sep 2020 19:43:33
	System	10 Sep 2020 19:43:33

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '10 Sep 2020 14:32'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '10 Sep 2020 17:02'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:50:01', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '85e33fcc-d286-4646-976d-e9355e01a595'	System	11 Sep 2020 02:51:45
User entered 'Yes (Y)'	System	11 Sep 2020 02:51:45

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:51:37', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '85e33fcc-d286-4646-976d-e9355e01a595' User entered '97.5'	System	11 Sep 2020 02:51:45
	System	11 Sep 2020 02:51:45

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:51:40', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '85e33fcc-d286-4646-976d-e9355e01a595'	System	11 Sep 2020 02:51:45
User entered 'No (N)'	System	11 Sep 2020 02:51:45

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:51:43', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '85e33fcc-d286-4646-976d-e9355e01a595'	System	11 Sep 2020 02:51:45
User entered '10 Sep 2020 21:51'	System	11 Sep 2020 02:51:45

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '10 Sep 2020 17:57'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 2'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:52:10', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '73e3b84d-74f9-4bb1-9437-792493438164' User entered 'Yes (Y)'	System	12 Sep 2020 03:52:26
	System	12 Sep 2020 03:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:52:16', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '73e3b84d-74f9-4bb1-9437-792493438164' User entered '97.0'	System	12 Sep 2020 03:52:26
	System	12 Sep 2020 03:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:52:20', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '73e3b84d-74f9-4bb1-9437-792493438164'	System	12 Sep 2020 03:52:26
User entered 'No (N)'	System	12 Sep 2020 03:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:52:22', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '73e3b84d-74f9-4bb1-9437-792493438164'	System	12 Sep 2020 03:52:26
User entered '11 Sep 2020 22:52'	System	12 Sep 2020 03:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 3'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:38:51', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1954e5de-f463-4298-abaf-8dc9e5f01b49' User entered 'Yes (Y)'	System	13 Sep 2020 01:39:07
	System	13 Sep 2020 01:39:07

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:38:56', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1954e5de-f463-4298-abaf-8dc9e5f01b49' User entered '97.4'	System	13 Sep 2020 01:39:07
	System	13 Sep 2020 01:39:07

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:38:59', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1954e5de-f463-4298-abaf-8dc9e5f01b49'	System	13 Sep 2020 01:39:07
User entered 'No (N)'	System	13 Sep 2020 01:39:07

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:02', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1954e5de-f463-4298-abaf-8dc9e5f01b49'	System	13 Sep 2020 01:39:07
User entered '12 Sep 2020 20:39'	System	13 Sep 2020 01:39:07

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 4'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:35:37', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '67d61686-ab73-4f4c-8759-9829e5caab5d' User entered 'Yes (Y)'	System	14 Sep 2020 01:35:51
	System	14 Sep 2020 01:35:51

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:35:41', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '67d61686-ab73-4f4c-8759-9829e5caab5d' User entered '98.1'	System	14 Sep 2020 01:35:51
	System	14 Sep 2020 01:35:51

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:35:44', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '67d61686-ab73-4f4c-8759-9829e5caab5d' User entered 'No (N)'	System	14 Sep 2020 01:35:51
	System	14 Sep 2020 01:35:51

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:35:47', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '67d61686-ab73-4f4c-8759-9829e5caab5d' User entered '13 Sep 2020 20:35'	System	14 Sep 2020 01:35:51
	System	14 Sep 2020 01:35:51

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 5'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:44:48', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'eb7cd1bb-5aa3-41df-9f4b-9df91ebbb6e6' User entered 'Yes (Y)'	System	15 Sep 2020 10:44:59
	System	15 Sep 2020 10:44:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:44:53', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'eb7cd1bb-5aa3-41df-9f4b-9df91ebbb6e6' User entered '97.1'	System	15 Sep 2020 10:44:59
	System	15 Sep 2020 10:44:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:44:56', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'eb7cd1bb-5aa3-41df-9f4b-9df91ebbb6e6'	System	15 Sep 2020 10:44:59
User entered 'No (N)'	System	15 Sep 2020 10:44:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:44:58', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'eb7cd1bb-5aa3-41df-9f4b-9df91ebbb6e6'	System	15 Sep 2020 10:44:59
User entered '15 Sep 2020 05:44'	System	15 Sep 2020 10:44:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 6'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:58:43', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '038eedce-fd73-434e-8a25-746936e124cc' User entered 'Yes (Y)'	System	16 Sep 2020 03:58:55
	System	16 Sep 2020 03:58:55

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:58:48', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '038eedce-fd73-434e-8a25-746936e124cc' User entered '97.9'	System	16 Sep 2020 03:58:55
	System	16 Sep 2020 03:58:55

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:58:51', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '038eedce-fd73-434e-8a25-746936e124cc'	System	16 Sep 2020 03:58:55
User entered 'No (N)'	System	16 Sep 2020 03:58:55

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:58:53', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '038eedce-fd73-434e-8a25-746936e124cc' User entered '15 Sep 2020 22:58'	System	16 Sep 2020 03:58:55
	System	16 Sep 2020 03:58:55

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 7'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:35:45', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'be111f6a-e1d7-4e6c-b32e-269b3b82bd84' User entered 'Yes (Y)'	System	17 Sep 2020 03:36:00
	System	17 Sep 2020 03:36:00

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:35:49', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'be111f6a-e1d7-4e6c-b32e-269b3b82bd84' User entered '97.9'	System	17 Sep 2020 03:36:00
	System	17 Sep 2020 03:36:00

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:35:54', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'be111f6a-e1d7-4e6c-b32e-269b3b82bd84' User entered 'No (N)'	System	17 Sep 2020 03:36:00
	System	17 Sep 2020 03:36:00

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:35:56', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'be111f6a-e1d7-4e6c-b32e-269b3b82bd84' User entered '16 Sep 2020 22:35'	System	17 Sep 2020 03:36:00
	System	17 Sep 2020 03:36:00

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:43:41', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6fe54fb6-22eb-4e5c-9ab1-09e8183d608b' User entered 'None (1)'	System	10 Sep 2020 19:43:54
	System	10 Sep 2020 19:43:54

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:43:45', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6fe54fb6-22eb-4e5c-9ab1-09e8183d608b' User entered 'No (N)'	System	10 Sep 2020 19:43:54
	System	10 Sep 2020 19:43:54

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:43:48', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6fe54fb6-22eb-4e5c-9ab1-09e8183d608b' User entered 'No (N)'	System	10 Sep 2020 19:43:54
	System	10 Sep 2020 19:43:54

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:43:50', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6fe54fb6-22eb-4e5c-9ab1-09e8183d608b' User entered 'None (1)'	System	10 Sep 2020 19:43:54
	System	10 Sep 2020 19:43:54

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:43:52', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6fe54fb6-22eb-4e5c-9ab1-09e8183d608b' User entered '10 Sep 2020 14:43'	System	10 Sep 2020 19:43:54
	System	10 Sep 2020 19:43:54

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '10 Sep 2020 14:32'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '10 Sep 2020 17:02'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:51:50', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0393fb57-4558-4e59-8290-f74c85fdd9bf' User entered 'None (1)'	System	11 Sep 2020 02:52:05
	System	11 Sep 2020 02:52:05

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:51:54', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0393fb57-4558-4e59-8290-f74c85fdd9bf' User entered 'No (N)'	System	11 Sep 2020 02:52:05
	System	11 Sep 2020 02:52:05

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:51:56', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0393fb57-4558-4e59-8290-f74c85fdd9bf' User entered 'No (N)'	System	11 Sep 2020 02:52:05
	System	11 Sep 2020 02:52:05

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:51:59', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0393fb57-4558-4e59-8290-f74c85fdd9bf' User entered 'None (1)'	System	11 Sep 2020 02:52:05
	System	11 Sep 2020 02:52:05

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:52:02', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0393fb57-4558-4e59-8290-f74c85fdd9bf' User entered '10 Sep 2020 21:52'	System	11 Sep 2020 02:52:05
	System	11 Sep 2020 02:52:05

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '10 Sep 2020 17:57'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 2'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:49:50', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '67d5a499-3dc6-4902-8ad9-b98c741813c4' User entered 'None (1)'	System	12 Sep 2020 03:50:07
	System	12 Sep 2020 03:50:07

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:49:54', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '67d5a499-3dc6-4902-8ad9-b98c741813c4' User entered 'No (N)'	System	12 Sep 2020 03:50:07
	System	12 Sep 2020 03:50:07

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:49:58', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '67d5a499-3dc6-4902-8ad9-b98c741813c4' User entered 'No (N)'	System	12 Sep 2020 03:50:07
	System	12 Sep 2020 03:50:07

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:50:01', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '67d5a499-3dc6-4902-8ad9-b98c741813c4' User entered 'None (1)'	System	12 Sep 2020 03:50:07
	System	12 Sep 2020 03:50:07

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:50:05', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '67d5a499-3dc6-4902-8ad9-b98c741813c4'	System	12 Sep 2020 03:50:07
User entered '11 Sep 2020 22:50'	System	12 Sep 2020 03:50:07

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 3'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:10', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '54d72575-03ad-4d3d-8baa-0e23b77a242b'	System	13 Sep 2020 01:39:26
User entered 'None (1)'	System	13 Sep 2020 01:39:26

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:14', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '54d72575-03ad-4d3d-8baa-0e23b77a242b' User entered 'No (N)'	System	13 Sep 2020 01:39:26
	System	13 Sep 2020 01:39:26

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:17', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '54d72575-03ad-4d3d-8baa-0e23b77a242b' User entered 'No (N)'	System	13 Sep 2020 01:39:26
	System	13 Sep 2020 01:39:26

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:21', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '54d72575-03ad-4d3d-8baa-0e23b77a242b'	System	13 Sep 2020 01:39:26
User entered 'None (1)'	System	13 Sep 2020 01:39:26

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:24', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '54d72575-03ad-4d3d-8baa-0e23b77a242b' User entered '12 Sep 2020 20:39'	System	13 Sep 2020 01:39:26
	System	13 Sep 2020 01:39:26

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 4'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:35:51', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b444a920-c177-4b1e-ba39-519403af4760' User entered 'None (1)'	System	14 Sep 2020 01:36:07
	System	14 Sep 2020 01:36:07

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:35:54', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b444a920-c177-4b1e-ba39-519403af4760' User entered 'No (N)'	System	14 Sep 2020 01:36:07
	System	14 Sep 2020 01:36:07

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:35:57', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b444a920-c177-4b1e-ba39-519403af4760' User entered 'No (N)'	System	14 Sep 2020 01:36:07
	System	14 Sep 2020 01:36:07

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:36:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b444a920-c177-4b1e-ba39-519403af4760' User entered 'None (1)'	System	14 Sep 2020 01:36:07
	System	14 Sep 2020 01:36:07

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:36:02', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b444a920-c177-4b1e-ba39-519403af4760'	System	14 Sep 2020 01:36:07
User entered '13 Sep 2020 20:36'	System	14 Sep 2020 01:36:07

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 5'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:02', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b4e7aedd-4334-4058-8753-12b0c1e13a41' User entered 'None (1)'	System	15 Sep 2020 10:45:14
	System	15 Sep 2020 10:45:14

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:06', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b4e7aedd-4334-4058-8753-12b0c1e13a41' User entered 'No (N)'	System	15 Sep 2020 10:45:14
	System	15 Sep 2020 10:45:14

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:08', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b4e7aedd-4334-4058-8753-12b0c1e13a41' User entered 'No (N)'	System	15 Sep 2020 10:45:14
	System	15 Sep 2020 10:45:14

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:10', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b4e7aedd-4334-4058-8753-12b0c1e13a41'	System	15 Sep 2020 10:45:14
User entered 'None (1)'	System	15 Sep 2020 10:45:14

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:12', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b4e7aedd-4334-4058-8753-12b0c1e13a41' User entered '15 Sep 2020 05:45'	System	15 Sep 2020 10:45:14
	System	15 Sep 2020 10:45:14

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 6'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:58:57', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '83e08009-256c-41ce-b829-d99a87e5b2fb' User entered 'None (1)'	System	16 Sep 2020 03:59:12
	System	16 Sep 2020 03:59:12

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:58:59', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '83e08009-256c-41ce-b829-d99a87e5b2fb' User entered 'No (N)'	System	16 Sep 2020 03:59:12
	System	16 Sep 2020 03:59:12

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:59:02', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '83e08009-256c-41ce-b829-d99a87e5b2fb' User entered 'No (N)'	System	16 Sep 2020 03:59:12
	System	16 Sep 2020 03:59:12

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:59:04', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '83e08009-256c-41ce-b829-d99a87e5b2fb' User entered 'None (1)'	System	16 Sep 2020 03:59:12
	System	16 Sep 2020 03:59:12

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:59:06', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '83e08009-256c-41ce-b829-d99a87e5b2fb' User entered '15 Sep 2020 22:59'	System	16 Sep 2020 03:59:12
	System	16 Sep 2020 03:59:12

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 7'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:11', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'd4cc6e8e-5869-405f-afad-82116ee52c45'	System	17 Sep 2020 03:36:27
User entered 'None (1)'	System	17 Sep 2020 03:36:27

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:14', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'd4cc6e8e-5869-405f-afad-82116ee52c45'	System	17 Sep 2020 03:36:27
User entered 'No (N)'	System	17 Sep 2020 03:36:27

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:16', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'd4cc6e8e-5869-405f-afad-82116ee52c45'	System	17 Sep 2020 03:36:27
User entered 'No (N)'	System	17 Sep 2020 03:36:27

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:18', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'd4cc6e8e-5869-405f-afad-82116ee52c45'	System	17 Sep 2020 03:36:27
User entered 'None (1)'	System	17 Sep 2020 03:36:27

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:22', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'd4cc6e8e-5869-405f-afad-82116ee52c45'	System	17 Sep 2020 03:36:27
User entered '16 Sep 2020 22:36'	System	17 Sep 2020 03:36:27

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:43:57', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '679b9d79-a6a4-43ce-8e91-f406dcc3c5ad' User entered 'None (0)'	System	10 Sep 2020 19:44:17
	System	10 Sep 2020 19:44:17

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:43:59', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '679b9d79-a6a4-43ce-8e91-f406dcc3c5ad' User entered 'None (0)'	System	10 Sep 2020 19:44:17
	System	10 Sep 2020 19:44:17

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:44:01', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '679b9d79-a6a4-43ce-8e91-f406dcc3c5ad' User entered 'None (0)'	System	10 Sep 2020 19:44:17
	System	10 Sep 2020 19:44:17

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:44:03', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '679b9d79-a6a4-43ce-8e91-f406dcc3c5ad' User entered 'None (0)'	System	10 Sep 2020 19:44:17
	System	10 Sep 2020 19:44:17

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:44:06', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '679b9d79-a6a4-43ce-8e91-f406dcc3c5ad' User entered 'None (0)'	System	10 Sep 2020 19:44:17
	System	10 Sep 2020 19:44:17

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:44:08', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '679b9d79-a6a4-43ce-8e91-f406dcc3c5ad' User entered 'None (0)'	System	10 Sep 2020 19:44:17
	System	10 Sep 2020 19:44:17

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:44:10', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '679b9d79-a6a4-43ce-8e91-f406dcc3c5ad' User entered 'No (N)'	System	10 Sep 2020 19:44:17
	System	10 Sep 2020 19:44:17

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T14:44:12', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '679b9d79-a6a4-43ce-8e91-f406dcc3c5ad' User entered '10 Sep 2020 14:44'	System	10 Sep 2020 19:44:17
	System	10 Sep 2020 19:44:17

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '10 Sep 2020 14:32'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '10 Sep 2020 17:02'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:52:06', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2395d26c-5545-4db0-bc32-02f8c29e865e' User entered 'None (0)'	System	11 Sep 2020 02:52:26
	System	11 Sep 2020 02:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:52:09', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2395d26c-5545-4db0-bc32-02f8c29e865e' User entered 'None (0)'	System	11 Sep 2020 02:52:26
	System	11 Sep 2020 02:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:52:11', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2395d26c-5545-4db0-bc32-02f8c29e865e' User entered 'None (0)'	System	11 Sep 2020 02:52:26
	System	11 Sep 2020 02:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:52:13', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2395d26c-5545-4db0-bc32-02f8c29e865e' User entered 'None (0)'	System	11 Sep 2020 02:52:26
	System	11 Sep 2020 02:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:52:15', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2395d26c-5545-4db0-bc32-02f8c29e865e' User entered 'None (0)'	System	11 Sep 2020 02:52:26
	System	11 Sep 2020 02:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:52:17', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2395d26c-5545-4db0-bc32-02f8c29e865e' User entered 'None (0)'	System	11 Sep 2020 02:52:26
	System	11 Sep 2020 02:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:52:20', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2395d26c-5545-4db0-bc32-02f8c29e865e' User entered 'No (N)'	System	11 Sep 2020 02:52:26
	System	11 Sep 2020 02:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-10T21:52:23', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2395d26c-5545-4db0-bc32-02f8c29e865e' User entered '10 Sep 2020 21:52'	System	11 Sep 2020 02:52:26
	System	11 Sep 2020 02:52:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '10 Sep 2020 17:57'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 2'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:50:09', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4cf493a8-55d0-4493-9a8f-2b9931eb8a92'	System	12 Sep 2020 03:50:31
User entered 'None (0)'	System	12 Sep 2020 03:50:31

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:50:12', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4cf493a8-55d0-4493-9a8f-2b9931eb8a92'	System	12 Sep 2020 03:50:31
User entered 'None (0)'	System	12 Sep 2020 03:50:31

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:50:15', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4cf493a8-55d0-4493-9a8f-2b9931eb8a92' User entered 'None (0)'	System	12 Sep 2020 03:50:31
	System	12 Sep 2020 03:50:31

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:50:17', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4cf493a8-55d0-4493-9a8f-2b9931eb8a92' User entered 'None (0)'	System	12 Sep 2020 03:50:31
	System	12 Sep 2020 03:50:31

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:50:19', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4cf493a8-55d0-4493-9a8f-2b9931eb8a92' User entered 'None (0)'	System	12 Sep 2020 03:50:31
	System	12 Sep 2020 03:50:31

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:50:21', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4cf493a8-55d0-4493-9a8f-2b9931eb8a92'	System	12 Sep 2020 03:50:31
User entered 'None (0)'	System	12 Sep 2020 03:50:31

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:50:24', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4cf493a8-55d0-4493-9a8f-2b9931eb8a92'	System	12 Sep 2020 03:50:31
User entered 'No (N)'	System	12 Sep 2020 03:50:31

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-11T22:50:26', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '4cf493a8-55d0-4493-9a8f-2b9931eb8a92'	System	12 Sep 2020 03:50:31
User entered '11 Sep 2020 22:50'	System	12 Sep 2020 03:50:31

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 3'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:27', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0864012c-1861-4031-9a5d-d0db5bb6e620' User entered 'None (0)'	System	13 Sep 2020 01:39:48
	System	13 Sep 2020 01:39:48

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:29', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0864012c-1861-4031-9a5d-d0db5bb6e620' User entered 'None (0)'	System	13 Sep 2020 01:39:48
	System	13 Sep 2020 01:39:48

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:32', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0864012c-1861-4031-9a5d-d0db5bb6e620' User entered 'None (0)'	System	13 Sep 2020 01:39:48
	System	13 Sep 2020 01:39:48

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:33', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0864012c-1861-4031-9a5d-d0db5bb6e620' User entered 'None (0)'	System	13 Sep 2020 01:39:48
	System	13 Sep 2020 01:39:48

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:36', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0864012c-1861-4031-9a5d-d0db5bb6e620' User entered 'None (0)'	System	13 Sep 2020 01:39:48
	System	13 Sep 2020 01:39:48

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:37', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0864012c-1861-4031-9a5d-d0db5bb6e620' User entered 'None (0)'	System	13 Sep 2020 01:39:48
	System	13 Sep 2020 01:39:48

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:43', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0864012c-1861-4031-9a5d-d0db5bb6e620' User entered 'No (N)'	System	13 Sep 2020 01:39:48
	System	13 Sep 2020 01:39:48

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-12T20:39:45', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0864012c-1861-4031-9a5d-d0db5bb6e620' User entered '12 Sep 2020 20:39'	System	13 Sep 2020 01:39:48
	System	13 Sep 2020 01:39:48

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 4'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:36:06', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6496c666-9dd8-4194-9d92-a23444fbc8d2' User entered 'None (0)'	System	14 Sep 2020 01:36:26
	System	14 Sep 2020 01:36:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:36:08', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6496c666-9dd8-4194-9d92-a23444fbc8d2' User entered 'None (0)'	System	14 Sep 2020 01:36:26
	System	14 Sep 2020 01:36:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:36:10', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6496c666-9dd8-4194-9d92-a23444fbc8d2' User entered 'None (0)'	System	14 Sep 2020 01:36:26
	System	14 Sep 2020 01:36:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:36:12', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6496c666-9dd8-4194-9d92-a23444fbc8d2' User entered 'None (0)'	System	14 Sep 2020 01:36:26
	System	14 Sep 2020 01:36:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:36:15', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6496c666-9dd8-4194-9d92-a23444fbc8d2' User entered 'None (0)'	System	14 Sep 2020 01:36:26
	System	14 Sep 2020 01:36:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:36:17', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6496c666-9dd8-4194-9d92-a23444fbc8d2' User entered 'None (0)'	System	14 Sep 2020 01:36:26
	System	14 Sep 2020 01:36:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:36:19', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6496c666-9dd8-4194-9d92-a23444fbc8d2' User entered 'No (N)'	System	14 Sep 2020 01:36:26
	System	14 Sep 2020 01:36:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-13T20:36:21', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '6496c666-9dd8-4194-9d92-a23444fbc8d2'	System	14 Sep 2020 01:36:26
User entered '13 Sep 2020 20:36'	System	14 Sep 2020 01:36:26

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 5'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:16', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1f7cb307-6649-47ef-b011-ec772bc1c902'	System	15 Sep 2020 10:45:35
User entered 'None (0)'	System	15 Sep 2020 10:45:35

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:18', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1f7cb307-6649-47ef-b011-ec772bc1c902' User entered 'None (0)'	System	15 Sep 2020 10:45:35
	System	15 Sep 2020 10:45:35

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:20', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1f7cb307-6649-47ef-b011-ec772bc1c902' User entered 'None (0)'	System	15 Sep 2020 10:45:35
	System	15 Sep 2020 10:45:35

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:21', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1f7cb307-6649-47ef-b011-ec772bc1c902' User entered 'None (0)'	System	15 Sep 2020 10:45:35
	System	15 Sep 2020 10:45:35

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:23', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1f7cb307-6649-47ef-b011-ec772bc1c902'	System	15 Sep 2020 10:45:35
User entered 'None (0)'	System	15 Sep 2020 10:45:35

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:25', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1f7cb307-6649-47ef-b011-ec772bc1c902' User entered 'None (0)'	System	15 Sep 2020 10:45:35
	System	15 Sep 2020 10:45:35

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:30', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1f7cb307-6649-47ef-b011-ec772bc1c902'	System	15 Sep 2020 10:45:35
User entered 'No (N)'	System	15 Sep 2020 10:45:35

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T05:45:33', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '1f7cb307-6649-47ef-b011-ec772bc1c902'	System	15 Sep 2020 10:45:35
User entered '15 Sep 2020 05:45'	System	15 Sep 2020 10:45:35

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 6'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:59:09', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '925ee0a8-9a6c-4822-855e-249613278ebe' User entered 'None (0)'	System	16 Sep 2020 03:59:29
	System	16 Sep 2020 03:59:29

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:59:11', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '925ee0a8-9a6c-4822-855e-249613278ebe' User entered 'None (0)'	System	16 Sep 2020 03:59:29
	System	16 Sep 2020 03:59:29

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:59:13', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '925ee0a8-9a6c-4822-855e-249613278ebe' User entered 'None (0)'	System	16 Sep 2020 03:59:29
	System	16 Sep 2020 03:59:29

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:59:15', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '925ee0a8-9a6c-4822-855e-249613278ebe' User entered 'None (0)'	System	16 Sep 2020 03:59:29
	System	16 Sep 2020 03:59:29

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:59:17', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '925ee0a8-9a6c-4822-855e-249613278ebe' User entered 'None (0)'	System	16 Sep 2020 03:59:29
	System	16 Sep 2020 03:59:29

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:59:19', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '925ee0a8-9a6c-4822-855e-249613278ebe' User entered 'None (0)'	System	16 Sep 2020 03:59:29
	System	16 Sep 2020 03:59:29

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:59:23', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '925ee0a8-9a6c-4822-855e-249613278ebe' User entered 'No (N)'	System	16 Sep 2020 03:59:29
	System	16 Sep 2020 03:59:29

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-15T22:59:25', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '925ee0a8-9a6c-4822-855e-249613278ebe' User entered '15 Sep 2020 22:59'	System	16 Sep 2020 03:59:29
	System	16 Sep 2020 03:59:29

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	10 Sep 2020 19:32:59
User entered 'Day 7'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:26', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '55744982-1f5b-4655-9514-737f1bac85f7' User entered 'None (0)'	System	17 Sep 2020 03:36:58
	System	17 Sep 2020 03:36:58

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:36', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '55744982-1f5b-4655-9514-737f1bac85f7' User entered 'None (0)'	System	17 Sep 2020 03:36:58
	System	17 Sep 2020 03:36:58

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:39', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '55744982-1f5b-4655-9514-737f1bac85f7' User entered 'None (0)'	System	17 Sep 2020 03:36:58
	System	17 Sep 2020 03:36:58

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:45', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '55744982-1f5b-4655-9514-737f1bac85f7' User entered 'None (0)'	System	17 Sep 2020 03:36:58
	System	17 Sep 2020 03:36:58

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:47', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '55744982-1f5b-4655-9514-737f1bac85f7' User entered 'None (0)'	System	17 Sep 2020 03:36:58
	System	17 Sep 2020 03:36:58

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:49', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '55744982-1f5b-4655-9514-737f1bac85f7' User entered 'None (0)'	System	17 Sep 2020 03:36:58
	System	17 Sep 2020 03:36:58

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

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 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:52', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '55744982-1f5b-4655-9514-737f1bac85f7' User entered 'No (N)'	System	17 Sep 2020 03:36:58
	System	17 Sep 2020 03:36:58

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-09-16T22:36:54', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '55744982-1f5b-4655-9514-737f1bac85f7' User entered '16 Sep 2020 22:36'	System	17 Sep 2020 03:36:58
	System	17 Sep 2020 03:36:58

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:32:59

US3782014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:32:59

US3782014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	17 Sep 2020 16:26:23

US3782014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '17 Sep 2020'	(b) (4) Amber Massey (b) (4)	17 Sep 2020 16:26:23

US3782014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amber Massey (b) (4)	17 Sep 2020 16:26:23

US3782014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	17 Sep 2020 16:26:23

US3782014

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	17 Sep 2020 16:26:29

US3782014

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User entered 'I'	System	17 Sep 2020 16:26:29

US3782014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	24 Sep 2020 12:58:08

US3782014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '24 Sep 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Sep 2020 12:58:08

US3782014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	24 Sep 2020 12:58:08

US3782014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) Carlton Griffin (b) (4)	24 Sep 2020 12:58:08
	(b) (4)	

US3782014

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	24 Sep 2020 12:58:14

US3782014

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:04:54
User entered 'I'	System	24 Sep 2020 12:58:14

US3782014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Amy Kerrigan (b) (4)	01 Oct 2020 16:02:37

US3782014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '1 Oct 2020'	(b) (4) Amy Kerrigan (b) (4) (b) (4)	01 Oct 2020 16:02:37

US3782014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Kerrigan (b) (4)	01 Oct 2020 16:02:37

US3782014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	Amy Kerrigan (b) (4)	01 Oct 2020 16:02:37

US3782014

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Amy Kerrigan (b) (4)	01 Oct 2020 16:02:42

US3782014

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'I'	System	01 Oct 2020 16:02:42

US3782014

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Amy Kerrigan (b) (4) (b) (4)	08 Oct 2020 14:08:01

US3782014

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '8 Oct 2020'	(b) (4) Amy Kerrigan (b) (4)	08 Oct 2020 14:08:01

US3782014

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Clinic (Clinic)'	Amy Kerrigan (b) (4)	08 Oct 2020 14:08:01

US3782014

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'VISIT3'	System	08 Oct 2020 14:08:01

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Amy Kerrigan (b) (4)	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '8 Oct 2020'	(b) (4) Amy Kerrigan (b) (4)	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '08:32'	(b) (4) Amy Kerrigan (b) (4) (b) (4)	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '8 Oct 2020 08:32'	System	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '97.9' F	(b) (4) Amy Kerrigan (b) (4)	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Oral (Oral)'	(b) (4) Amy Kerrigan (b) (4) (b) (4)	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) Amy Kerrigan (b) (4)	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '60'	Amy Kerrigan (b) (4)	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'bpm'	System	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '20'	(b) (4) Amy Kerrigan (b) (4) (b) (4)	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'breaths/min'	System	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '117'	(b) (4) Amy Kerrigan (b) (4) (b) (4)	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'mmHg'	System	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '61'	Amy Kerrigan (b) (4)	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'mmHg'	System	08 Oct 2020 14:09:27

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02

US3782014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02

US3782014

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Amy Kerrigan (b) (4)	08 Oct 2020 14:09:42

US3782014

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '8 Oct 2020'	(b) (4) Amy Kerrigan (b) (4) (b) (4)	08 Oct 2020 14:09:42

US3782014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Amy Kerrigan (b) (4)	08 Oct 2020 14:10:08

US3782014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '8 Oct 2020'	(b) (4) Amy Kerrigan (b) (4)	08 Oct 2020 14:10:08

US3782014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '08:46'	(b) (4) Amy Kerrigan (b) (4) (b) (4)	08 Oct 2020 14:10:08

US3782014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered '8 Oct 2020 08:46'	System	08 Oct 2020 14:10:08

US3782014

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) Amy Kerrigan (b) (4)	08 Oct 2020 14:10:16

US3782014

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'I'	System	08 Oct 2020 14:10:16

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 64'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-10-16T07:38:26', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b599b221-d3a0-4412-b8ba-7bc5bb865fd7'	System	16 Oct 2020 12:38:40
User entered 'No (N)'	System	16 Oct 2020 12:38:40

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-10-16T07:38:31', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b599b221-d3a0-4412-b8ba-7bc5bb865fd7'	System	16 Oct 2020 12:38:40
User entered 'No (N)'	System	16 Oct 2020 12:38:40

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-10-16T07:38:35', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b599b221-d3a0-4412-b8ba-7bc5bb865fd7' User entered '16 Oct 2020 07:38:35'	System	16 Oct 2020 12:38:40
	System	16 Oct 2020 12:38:40

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 71'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-10-20T07:42:24', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '73961e3b-357e-465f-91ef-be2bbd6acf9b' User entered 'No (N)'	System	20 Oct 2020 12:42:47
	System	20 Oct 2020 12:42:47

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-10-20T07:42:31', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '73961e3b-357e-465f-91ef-be2bbd6acf9b'	System	20 Oct 2020 12:42:47
User entered 'No (N)'	System	20 Oct 2020 12:42:47

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-10-20T07:42:37', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '73961e3b-357e-465f-91ef-be2bbd6acf9b' User entered '20 Oct 2020 07:42:37'	System	20 Oct 2020 12:42:47
	System	20 Oct 2020 12:42:47

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 78'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-10-27T08:09:55', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5481e04e-f296-4e56-bb32-16dbc887fa43' User entered 'No (N)'	System	27 Oct 2020 13:10:10
	System	27 Oct 2020 13:10:10

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-10-27T08:10:03', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5481e04e-f296-4e56-bb32-16dbc887fa43'	System	27 Oct 2020 13:10:10
User entered 'No (N)'	System	27 Oct 2020 13:10:10

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-10-27T08:10:07', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5481e04e-f296-4e56-bb32-16dbc887fa43' User entered '27 Oct 2020 08:10:07'	System	27 Oct 2020 13:10:10
	System	27 Oct 2020 13:10:10

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 92'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-10T06:22:34', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a0d1ba35-5747-454e-843f-8cf594e5e68c' User entered 'No (N)'	System	13 Nov 2020 13:49:50
	System	13 Nov 2020 13:49:50

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-10T06:22:40', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a0d1ba35-5747-454e-843f-8cf594e5e68c' User entered 'No (N)'	System	13 Nov 2020 13:49:50
	System	13 Nov 2020 13:49:50

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-10T06:22:46', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a0d1ba35-5747-454e-843f-8cf594e5e68c' User entered '10 Nov 2020 06:22:46'	System	13 Nov 2020 13:49:50
	System	13 Nov 2020 13:49:50

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered 'Day 99'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-17T09:12:21', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'aa3bbc93-0889-44c8-b600-6728518a8934' User entered 'No (N)'	System	17 Nov 2020 15:12:31
	System	17 Nov 2020 15:12:31

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-17T09:12:25', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'aa3bbc93-0889-44c8-b600-6728518a8934'	System	17 Nov 2020 15:12:31
User entered 'No (N)'	System	17 Nov 2020 15:12:31

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-17T09:12:29', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'aa3bbc93-0889-44c8-b600-6728518a8934' User entered '17 Nov 2020 09:12:29'	System	17 Nov 2020 15:12:31
	System	17 Nov 2020 15:12:31

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 21:27:33

US3782014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:44:35
Data entry locked.	System	13 Aug 2020 21:27:33
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 21:27:33

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-23T12:54:38', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e3c2c4b0-1aa7-48fd-beb6-e358427526aa' User entered 'No (N)'	System	23 Nov 2020 18:54:48
	System	23 Nov 2020 18:54:48

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-23T12:54:43', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e3c2c4b0-1aa7-48fd-beb6-e358427526aa' User entered 'No (N)'	System	23 Nov 2020 18:54:48

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-23T12:54:46', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'e3c2c4b0-1aa7-48fd-beb6-e358427526aa' User entered '23 Nov 2020 12:54:46'	System	23 Nov 2020 18:54:48
	System	23 Nov 2020 18:54:48

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-28T07:37:31', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '979be3d4-25e9-462f-8120-f20dda0f1919' User entered 'No (N)'	System	28 Nov 2020 13:37:43

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-28T07:37:37', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '979be3d4-25e9-462f-8120-f20dda0f1919' User entered 'No (N)'	System	28 Nov 2020 13:37:43

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-11-28T07:37:41', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '979be3d4-25e9-462f-8120-f20dda0f1919' User entered '28 Nov 2020 07:37:41'	System	28 Nov 2020 13:37:43
	System	28 Nov 2020 13:37:43

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-05T05:29:26', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '9b183e2c-36a6-4824-9629-2bc3ee513ec0' User entered 'No (N)'	System	05 Dec 2020 11:29:39
	System	05 Dec 2020 11:29:39

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-05T05:29:34', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '9b183e2c-36a6-4824-9629-2bc3ee513ec0' User entered 'No (N)'	System	05 Dec 2020 11:29:39
	System	05 Dec 2020 11:29:39

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-05T05:29:37', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '9b183e2c-36a6-4824-9629-2bc3ee513ec0' User entered '05 Dec 2020 05:29:37'	System	05 Dec 2020 11:29:39
	System	05 Dec 2020 11:29:39

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-12T08:08:57', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '9f6119de-90c5-42c3-8eb3-0ed200d1ab95'	System	12 Dec 2020 14:09:10
User entered 'No (N)'	System	12 Dec 2020 14:09:10

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-12T08:09:01', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '9f6119de-90c5-42c3-8eb3-0ed200d1ab95'	System	12 Dec 2020 14:09:10
User entered 'No (N)'	System	12 Dec 2020 14:09:10

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-12T08:09:05', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '9f6119de-90c5-42c3-8eb3-0ed200d1ab95'	System	12 Dec 2020 14:09:10
User entered '12 Dec 2020 08:09:05'	System	12 Dec 2020 14:09:10

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-19T07:02:23', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'db50b5eb-f2e9-4364-a58c-34832262638a' User entered 'No (N)'	System	19 Dec 2020 13:02:34
	System	19 Dec 2020 13:02:34

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-19T07:02:29', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'db50b5eb-f2e9-4364-a58c-34832262638a' User entered 'No (N)'	System	19 Dec 2020 13:02:34

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-19T07:02:32', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'db50b5eb-f2e9-4364-a58c-34832262638a' User entered '19 Dec 2020 07:02:32'	System	19 Dec 2020 13:02:34
	System	19 Dec 2020 13:02:34

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-26T06:37:14', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0578cd3b-341e-4a22-a7e2-b80004ce56a4' User entered 'No (N)'	System	26 Dec 2020 12:37:28
	System	26 Dec 2020 12:37:28

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-26T06:37:21', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0578cd3b-341e-4a22-a7e2-b80004ce56a4' User entered 'No (N)'	System	26 Dec 2020 12:37:28
	System	26 Dec 2020 12:37:28

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2020-12-26T06:37:24', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0578cd3b-341e-4a22-a7e2-b80004ce56a4' User entered '26 Dec 2020 06:37:24'	System	26 Dec 2020 12:37:28
	System	26 Dec 2020 12:37:28

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-02T06:58:33', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b3e79441-975f-40a1-9edd-2f3052084ddd' User entered 'No (N)'	System	02 Jan 2021 12:58:51

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-02T06:58:45', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b3e79441-975f-40a1-9edd-2f3052084ddd' User entered 'No (N)'	System	02 Jan 2021 12:58:51

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-02T06:58:50', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b3e79441-975f-40a1-9edd-2f3052084ddd' User entered '02 Jan 2021 06:58:50'	System	02 Jan 2021 12:58:51
	System	02 Jan 2021 12:58:51

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-09T06:58:53', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'bfaeec66-ae86-4e49-8c08-5abdf85a4f0b' User entered 'No (N)'	System	09 Jan 2021 12:59:08
	System	09 Jan 2021 12:59:08

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-09T06:59:01', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'bfaeec66-ae86-4e49-8c08-5abdf85a4f0b' User entered 'No (N)'	System	09 Jan 2021 12:59:08

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-09T06:59:05', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'bfaeec66-ae86-4e49-8c08-5abdf85a4f0b' User entered '09 Jan 2021 06:59:05'	System	09 Jan 2021 12:59:08
	System	09 Jan 2021 12:59:08

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-16T04:04:46', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'ce32a460-7096-4679-91cf-7131b14fa66d' User entered 'No (N)'	System	16 Jan 2021 10:05:00
	System	16 Jan 2021 10:05:00

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-16T04:04:52', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'ce32a460-7096-4679-91cf-7131b14fa66d' User entered 'No (N)'	System	16 Jan 2021 10:05:00

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-16T04:04:55', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'ce32a460-7096-4679-91cf-7131b14fa66d' User entered '16 Jan 2021 04:04:55'	System	16 Jan 2021 10:05:00
	System	16 Jan 2021 10:05:00

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-23T07:20:29', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '8c2c3f3a-d32a-4914-a200-b7e6afde27b2' User entered 'No (N)'	System	23 Jan 2021 13:20:39
	System	23 Jan 2021 13:20:39

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-23T07:20:34', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '8c2c3f3a-d32a-4914-a200-b7e6afde27b2'	System	23 Jan 2021 13:20:39
User entered 'No (N)'	System	23 Jan 2021 13:20:39

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-23T07:20:37', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '8c2c3f3a-d32a-4914-a200-b7e6afde27b2' User entered '23 Jan 2021 07:20:37'	System	23 Jan 2021 13:20:39
	System	23 Jan 2021 13:20:39

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-30T07:29:22', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'c18d567d-6f7f-4395-82b5-969322f14510'	System	30 Jan 2021 12:29:31
User entered 'No (N)'	System	30 Jan 2021 12:29:31

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-30T07:29:25', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'c18d567d-6f7f-4395-82b5-969322f14510'	System	30 Jan 2021 12:29:31
User entered 'No (N)'	System	30 Jan 2021 12:29:31

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-01-30T07:29:29', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'c18d567d-6f7f-4395-82b5-969322f14510' User entered '30 Jan 2021 07:29:29'	System	30 Jan 2021 12:29:31
	System	30 Jan 2021 12:29:31

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-06T06:01:30', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'f1ea133b-9c95-4bd3-bffb-996f5e99896d' User entered 'No (N)'	System	06 Feb 2021 12:01:44
	System	06 Feb 2021 12:01:44

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-06T06:01:37', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'f1ea133b-9c95-4bd3-bffb-996f5e99896d' User entered 'No (N)'	System	06 Feb 2021 12:01:44

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-06T06:01:40', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'f1ea133b-9c95-4bd3-bffb-996f5e99896d' User entered '06 Feb 2021 06:01:40'	System	06 Feb 2021 12:01:44
	System	06 Feb 2021 12:01:44

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-16T16:03:26', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '226838f6-083a-46a1-a247-77a3184f73d4' User entered 'No (N)'	System	16 Feb 2021 22:03:33
	System	16 Feb 2021 22:03:33

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-16T16:03:29', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '226838f6-083a-46a1-a247-77a3184f73d4' User entered 'No (N)'	System	16 Feb 2021 22:03:33

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-16T16:03:32', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '226838f6-083a-46a1-a247-77a3184f73d4' User entered '16 Feb 2021 16:03:32'	System	16 Feb 2021 22:03:33
	System	16 Feb 2021 22:03:33

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-20T06:55:32', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '18d7a2bd-b1c1-4e6b-bb86-c00eb9874144'	System	20 Feb 2021 12:55:52
User entered 'No (N)'	System	20 Feb 2021 12:55:52

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-20T06:55:41', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '18d7a2bd-b1c1-4e6b-bb86-c00eb9874144'	System	20 Feb 2021 12:55:52
User entered 'No (N)'	System	20 Feb 2021 12:55:52

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-20T06:55:49', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '18d7a2bd-b1c1-4e6b-bb86-c00eb9874144' User entered '20 Feb 2021 06:55:49'	System	20 Feb 2021 12:55:52
	System	20 Feb 2021 12:55:52

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-27T06:05:30-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a3997849-5123-4330-8bf8-dd8e01db828e'	System	27 Feb 2021 12:05:40
User entered 'No (N)'	System	27 Feb 2021 12:05:40

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-27T06:05:36-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a3997849-5123-4330-8bf8-dd8e01db828e'	System	27 Feb 2021 12:05:40
User entered 'No (N)'	System	27 Feb 2021 12:05:40

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-02-27T06:05:39-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a3997849-5123-4330-8bf8-dd8e01db828e'	System	27 Feb 2021 12:05:40
User entered '27 Feb 2021 12:05:39'	System	27 Feb 2021 12:05:40

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-06T06:34:14-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '86362b3f-eb60-4729-9ab0-d582fdadc106'	System	06 Mar 2021 12:34:24
User entered 'No (N)'	System	06 Mar 2021 12:34:24

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-06T06:34:19-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '86362b3f-eb60-4729-9ab0-d582fdadc106'	System	06 Mar 2021 12:34:24
User entered 'No (N)'	System	06 Mar 2021 12:34:24

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-06T06:34:21-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '86362b3f-eb60-4729-9ab0-d582fdadc106'	System	06 Mar 2021 12:34:24
User entered '06 Mar 2021 06:34:21'	System	06 Mar 2021 12:34:24

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-13T07:47:43-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a30268d2-2bf1-44bc-9999-af2be2914999'	System	13 Mar 2021 13:48:59
User entered 'Yes (Y)'	System	13 Mar 2021 13:48:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-13T07:47:48-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a30268d2-2bf1-44bc-9999-af2be2914999'	System	13 Mar 2021 13:48:59
User entered 'No (N)'	System	13 Mar 2021 13:48:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-13T07:47:54-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a30268d2-2bf1-44bc-9999-af2be2914999'	System	13 Mar 2021 13:48:59
User entered 'No (N)'	System	13 Mar 2021 13:48:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-13T07:48:11-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a30268d2-2bf1-44bc-9999-af2be2914999'	System	13 Mar 2021 13:48:59
User entered 'Yes (Y)'	System	13 Mar 2021 13:48:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Please 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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-13T07:48:28-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a30268d2-2bf1-44bc-9999-af2be2914999'	System	13 Mar 2021 13:48:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Mar 2021 13:48:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-13T07:48:50-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'a30268d2-2bf1-44bc-9999-af2be2914999'	System	13 Mar 2021 13:48:59
User entered '13 Mar 2021 07:48:50'	System	13 Mar 2021 13:48:59

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-23T18:34:03-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '61dc4672-099e-48cb-899b-7c894e70e398'	System	23 Mar 2021 23:34:42
User entered 'Yes (Y)'	System	23 Mar 2021 23:34:42

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-23T18:34:06-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '61dc4672-099e-48cb-899b-7c894e70e398'	System	23 Mar 2021 23:34:42
User entered 'No (N)'	System	23 Mar 2021 23:34:42

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-23T18:34:16-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '61dc4672-099e-48cb-899b-7c894e70e398'	System	23 Mar 2021 23:34:42
User entered 'No (N)'	System	23 Mar 2021 23:34:42

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-23T18:34:19-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '61dc4672-099e-48cb-899b-7c894e70e398'	System	23 Mar 2021 23:34:42
User entered 'Yes (Y)'	System	23 Mar 2021 23:34:42

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Please 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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-23T18:34:27-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '61dc4672-099e-48cb-899b-7c894e70e398'	System	23 Mar 2021 23:34:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Mar 2021 23:34:42

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-23T18:34:30-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '61dc4672-099e-48cb-899b-7c894e70e398'	System	23 Mar 2021 23:34:42
User entered '23 Mar 2021 18:34:30'	System	23 Mar 2021 23:34:42

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-03T07:08:10-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0921d0d5-e35a-4801-b90c-47bf3066b587'	System	03 Apr 2021 12:08:48
User entered 'Yes (Y)'	System	03 Apr 2021 12:08:48

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-03T07:08:14-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0921d0d5-e35a-4801-b90c-47bf3066b587'	System	03 Apr 2021 12:08:48
User entered 'No (N)'	System	03 Apr 2021 12:08:48

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-03T07:08:19-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0921d0d5-e35a-4801-b90c-47bf3066b587'	System	03 Apr 2021 12:08:48
User entered 'No (N)'	System	03 Apr 2021 12:08:48

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-03T07:08:27-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0921d0d5-e35a-4801-b90c-47bf3066b587'	System	03 Apr 2021 12:08:48
User entered 'Yes (Y)'	System	03 Apr 2021 12:08:48

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

Please 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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-03T07:08:31-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0921d0d5-e35a-4801-b90c-47bf3066b587'	System	03 Apr 2021 12:08:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Apr 2021 12:08:48

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-03T07:08:35-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '0921d0d5-e35a-4801-b90c-47bf3066b587'	System	03 Apr 2021 12:08:48
User entered '03 Apr 2021 07:08:35'	System	03 Apr 2021 12:08:48

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-12T11:41:46-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2772f948-4d5f-4f7e-b6ec-339604365a16'	System	12 Apr 2021 16:41:55
User entered 'No (N)'	System	12 Apr 2021 16:41:55

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-12T11:41:49-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2772f948-4d5f-4f7e-b6ec-339604365a16'	System	12 Apr 2021 16:41:55
User entered 'No (N)'	System	12 Apr 2021 16:41:55

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-12T11:41:52-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '2772f948-4d5f-4f7e-b6ec-339604365a16'	System	12 Apr 2021 16:41:55
User entered '12 Apr 2021 11:41:52'	System	12 Apr 2021 16:41:55

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-17T06:52:06-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'ce295166-5f71-4211-a0a9-08c749a23d03'	System	17 Apr 2021 11:52:16
User entered 'No (N)'	System	17 Apr 2021 11:52:16

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-17T06:52:10-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'ce295166-5f71-4211-a0a9-08c749a23d03'	System	17 Apr 2021 11:52:16
User entered 'No (N)'	System	17 Apr 2021 11:52:16

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-17T06:52:13-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'ce295166-5f71-4211-a0a9-08c749a23d03'	System	17 Apr 2021 11:52:16
User entered '17 Apr 2021 06:52:13'	System	17 Apr 2021 11:52:16

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-24T12:00:00-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5632779e-36b9-43bd-8ebd-a832ddac4a78'	System	24 Apr 2021 17:00:09
User entered 'No (N)'	System	24 Apr 2021 17:00:09

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-24T12:00:04-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5632779e-36b9-43bd-8ebd-a832ddac4a78'	System	24 Apr 2021 17:00:09
User entered 'No (N)'	System	24 Apr 2021 17:00:09

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-04-24T12:00:07-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '5632779e-36b9-43bd-8ebd-a832ddac4a78'	System	24 Apr 2021 17:00:09
User entered '24 Apr 2021 12:00:07'	System	24 Apr 2021 17:00:09

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-05-01T06:34:54-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b298cc78-69fe-43d6-bf27-43a5cb8d7cff'	System	01 May 2021 11:35:02
User entered 'No (N)'	System	01 May 2021 11:35:02

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

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 (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-05-01T06:34:56-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b298cc78-69fe-43d6-bf27-43a5cb8d7cff'	System	01 May 2021 11:35:02
User entered 'No (N)'	System	01 May 2021 11:35:02

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-05-01T06:35:00-05:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: 'b298cc78-69fe-43d6-bf27-43a5cb8d7cff'	System	01 May 2021 11:35:02
User entered '01 May 2021 06:35:00'	System	01 May 2021 11:35:02

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:40:30

US3782014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:40:30
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:40:30

US3782014

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:45:10

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)	30 Apr 2021 21:58:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-02T16:56:43-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '122e8c11-2da3-4405-b27b-33a80267bbca' User entered 'No (N)'	System	02 Mar 2021 22:56:52
	System	02 Mar 2021 22:56:52

US3782014

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:45:10

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:58:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BC69EE9-4A01-4EE0-A28C-4F6B4A41C2F1)', Time: '2021-03-02T16:56:48-06:00', User OID: 'PatientReportedOutcome (US3782014)', ODM File OID: '122e8c11-2da3-4405-b27b-33a80267bbca' User entered '02 Mar 2021 16:56:48'	System	02 Mar 2021 22:56:52
	System	02 Mar 2021 22:56:52

US3782014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:48:09

US3782014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:48:09

US3782014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:48:09

US3782014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:48:09

US3782014

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:48:13

US3782014

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:05:02
User entered 'I'	System	06 Nov 2020 15:48:13

US3782014

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	09 Dec 2020 17:14:39
	(b) (4)	

US3782014

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered '9 Dec 2020'	Carlton Griffin (b) (4)	09 Dec 2020 17:14:39
	(b) (4)	

US3782014

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	09 Dec 2020 17:14:39
	(b) (4)	

US3782014

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	09 Dec 2020 17:14:39
	(b) (4)	

US3782014

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	09 Dec 2020 17:14:47
	(b) (4)	

US3782014

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User entered 'I'	System	09 Dec 2020 17:14:47

US3782014

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	08 Jan 2021 16:25:12
	(b) (4)	

US3782014

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered '8 Jan 2021'	Carlton Griffin (b) (4)	08 Jan 2021 16:25:12
	(b) (4)	

US3782014

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	08 Jan 2021 16:25:12
	(b) (4)	

US3782014

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	08 Jan 2021 16:25:12
	(b) (4)	

US3782014

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	08 Jan 2021 16:25:19
	(b) (4)	

US3782014

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User entered 'I'	System	08 Jan 2021 16:25:19

US3782014

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 16:04:30

US3782014

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
	(b) (4)	
User entered '5 Feb 2021'	(b) (4), (b) (6)	05 Feb 2021 16:04:30

US3782014

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Feb 2021 16:04:30

US3782014

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 16:04:30

US3782014

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 16:04:22

US3782014

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:49:52
User entered 'I'	System	05 Feb 2021 16:04:22

US3782014

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	10 Mar 2021 16:50:41

US3782014

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered '10 Mar 2021'	Carlton Griffin (b) (4)	10 Mar 2021 16:50:41

US3782014

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4)	10 Mar 2021 16:50:41

US3782014

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User entered 'VISIT4'	System	10 Mar 2021 16:50:41

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered 'No (N)'	Carlton Griffin (b) (4)	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User entered empty.	System	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User entered empty.	System	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User entered empty.	System	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User entered empty.	System	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:12
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User entered empty.	System	30 Mar 2021 13:50:25

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59

US3782014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59

US3782014

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	10 Mar 2021 16:50:52

US3782014

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '10 Mar 2021'	Carlton Griffin (b) (4)	10 Mar 2021 16:50:52

US3782014

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	10 Mar 2021 16:51:02

US3782014

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:51:02

US3782014

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:51:02

US3782014

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User entered empty.	System	10 Mar 2021 16:51:02

US3782014

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	10 Mar 2021 16:51:14

US3782014

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:11:59
User entered 'I'	System	10 Mar 2021 16:51:14

US3782014

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:43:24

US3782014

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '8 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:43:24

US3782014

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:43:24

US3782014

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:43:24

US3782014

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:43:30

US3782014

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:37
User entered 'I'	System	08 Apr 2021 13:43:30

US3782014

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

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	08 Jan 2021 15:36:10

US3782014

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

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '8 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	08 Jan 2021 15:36:10

US3782014

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

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 15:36:10

US3782014

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

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 15:36:10

US3782014

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:10

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:14:46

US3782014

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:10

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:45:20

US3782014

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:10

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:14:46

US3782014

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:10

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:45:20

US3782014

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:10

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 16:14:46

US3782014

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:10

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:14:46

US3782014

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:10

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:53:24
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Jan 2021 16:14:46

US3782014

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:10

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 11:53:24
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Jan 2021 16:14:46

US3782014

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:10

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:14:46

US3782014

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:10

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '1'	System	08 Jan 2021 16:14:46

US3782014

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:10

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'I'	System	08 Jan 2021 16:14:46

US3782014

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	08 Jan 2021 16:16:27
DataPoint set to visible.	System	08 Jan 2021 16:14:46

US3782014

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	08 Jan 2021 16:16:27
DataPoint set to visible.	System	08 Jan 2021 16:14:46

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '09:46'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '8 Jan 2021 09:46'	System	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '98.1' F	(b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '63'	(b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'bpm'	System	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '20'	(b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'breaths/min'	System	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '121'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mmHg'	System	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '063'	(b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mmHg'	System	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:16:27

US3782014

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered empty.	System	08 Jan 2021 16:16:27
DataPoint set to visible.	System	08 Jan 2021 16:14:46

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User accepted default value 'Post-Dose (POSTDOSE)'	Trudy Sullivan (b) (4) (b) (4)	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) Trudy Sullivan (b) (4)	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '8 Jan 2021'	(b) (4) Trudy Sullivan (b) (4)	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '10:36'	(b) (4) Trudy Sullivan (b) (4) (b) (4)	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '8 Jan 2021 10:36'	System	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '97.8' F	Trudy Sullivan (b) (4)	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Oral (Oral)'	(b) (4) Trudy Sullivan (b) (4) (b) (4)	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '58'	(b) (4) Trudy Sullivan (b) (4)	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'bpm'	System	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '20'	Trudy Sullivan (b) (4)	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'breaths/min'	System	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '120'	Trudy Sullivan (b) (4)	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mmHg'	System	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '60'	Trudy Sullivan (b) (4)	08 Jan 2021 16:44:49

US3782014

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mmHg'	System	08 Jan 2021 16:44:49

US3782014

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:14:55

US3782014

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:14:55

US3782014

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:15:11

US3782014

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 16:15:11

US3782014

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 16:15:11

US3782014

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mRNA-1273'	System	08 Jan 2021 16:15:11
DataPoint set to visible.	System	08 Jan 2021 16:14:46

US3782014

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:15:11

US3782014

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '10:04'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:15:11

US3782014

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '8 Jan 2021 10:04'	System	08 Jan 2021 16:15:11

US3782014

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:15:11

US3782014

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'ONCE'	System	08 Jan 2021 16:15:11

US3782014

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 16:15:11

US3782014

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:15:23

US3782014

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 16:15:23

US3782014

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '09:40'	(b) (4), (b) (6)	08 Jan 2021 16:15:23

US3782014

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '8 Jan 2021 09:40'	System	08 Jan 2021 16:15:23

US3782014

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:15:36

US3782014

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 16:15:36

US3782014

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '09:42'	(b) (4), (b) (6)	08 Jan 2021 16:15:36

US3782014

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '8 Jan 2021 09:42'	System	08 Jan 2021 16:15:36

US3782014

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

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:15:41

US3782014

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

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'I'	System	08 Jan 2021 16:15:41

US3782014

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:48
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	15 Jan 2021 14:42:44

US3782014

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:48
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered '15 Jan 2021'	Carlton Griffin (b) (4)	15 Jan 2021 14:42:44

US3782014

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:48
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	15 Jan 2021 14:42:44

US3782014

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:48
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered empty.	Carlton Griffin (b) (4)	15 Jan 2021 14:42:44

US3782014

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:48
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:31
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	15 Jan 2021 14:42:35

US3782014

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:48
User entered 'I'	System	15 Jan 2021 14:42:35

US3782014

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:48
User entered '1'	System	15 Jan 2021 14:42:35
DataPoint set to visible.	System	15 Jan 2021 14:42:35

US3782014

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 14:47:33

US3782014

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '5 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 14:47:33

US3782014

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[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 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	05 Feb 2021 14:47:33

US3782014

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'OLD29'	System	05 Feb 2021 14:47:33

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User accepted default value 'Pre-Dose (PREDOSE)'	Carlton Griffin (b) (4) (b) (4)	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '5 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	05 Feb 2021 15:03:47
data change (Site from System).		05 Feb 2021 15:03:47
User entered '08:48' reason for change: Data Entry	Carlton Griffin (b) (4)	05 Feb 2021 15:03:47
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 15:03:31
User entered empty.	Carlton Griffin (b) (4)	05 Feb 2021 15:03:31
	(b) (4)	

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '5 Feb 2021 08:48'	System	05 Feb 2021 15:03:47
User entered empty.	System	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '98.3' F	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Oral (Oral)'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:03:31
	(b) (4)	

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered empty.	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '84'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'bpm'	System	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '16'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'breaths/min'	System	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '135'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mmHg'	System	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '85'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mmHg'	System	05 Feb 2021 15:03:31

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User accepted default value 'Post-Dose (POSTDOSE)'	Trudy Sullivan (b) (4) (b) (4)	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Yes (Y)'	(b) (4) Trudy Sullivan (b) (4)	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '5 Feb 2021'	(b) (4) Trudy Sullivan (b) (4)	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '09:33'	Trudy Sullivan (b) (4)	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '5 Feb 2021 09:33'	System	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '98.2' F	Trudy Sullivan (b) (4)	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Oral (Oral)'	(b) (4) Trudy Sullivan (b) (4)	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered empty.	Trudy Sullivan (b) (4)	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '53'	Trudy Sullivan (b) (4)	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'bpm'	System	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '16'	Trudy Sullivan (b) (4)	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'breaths/min'	System	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '125'	Trudy Sullivan (b) (4)	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mmHg'	System	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '63'	Trudy Sullivan (b) (4)	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mmHg'	System	05 Feb 2021 15:40:34

US3782014

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 14:48:48

US3782014

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '5 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 14:48:48

US3782014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:02:44

US3782014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered empty.	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:02:44

US3782014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered empty.	Carlton Griffin (b) (4)	05 Feb 2021 15:02:44

US3782014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'mRNA-1273'	System	05 Feb 2021 15:02:44
DataPoint set to visible.	System	15 Jan 2021 14:42:35

US3782014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '5 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:02:44

US3782014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '08:59'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:02:44

US3782014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered '5 Feb 2021 08:59'	System	05 Feb 2021 15:02:44

US3782014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 15:02:44

US3782014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'ONCE'	System	05 Feb 2021 15:02:44

US3782014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 15:02:44

US3782014

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Feb 2021 14:48:53

US3782014

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:35:18
User entered 'I'	System	05 Feb 2021 14:48:53

US3782014

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:16
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:41:32

US3782014

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:16
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:41:32

US3782014

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:16
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:41:32

US3782014

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:16
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:41:32

US3782014

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:16
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:41:37

US3782014

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:16
User entered 'I'	System	12 Feb 2021 14:41:37

US3782014

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:39
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	10 Mar 2021 16:51:26
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:39
User entered '10 Mar 2021'	Carlton Griffin (b) (4)	10 Mar 2021 16:51:26
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:39
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4)	10 Mar 2021 16:51:26
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User entered 'OLD57'	System	10 Mar 2021 16:51:26

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:48
User entered 'No (N)'	Carlton Griffin (b) (4)	10 Mar 2021 16:51:42
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:48
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:51:42
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:48
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:51:42
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User entered empty.	System	10 Mar 2021 16:51:42

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:48
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:51:42
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:48
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:51:42
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:48
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:51:42
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:48
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:51:42
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User entered empty.	System	10 Mar 2021 16:51:42

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:48
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:51:42
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User entered empty.	System	10 Mar 2021 16:51:42

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:48
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:51:42
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User entered empty.	System	10 Mar 2021 16:51:42

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:48
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:51:42
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User entered empty.	System	10 Mar 2021 16:51:42

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13

US3782014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13

US3782014

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:59
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	10 Mar 2021 16:51:57
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:10

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:10:59
User entered '10 Mar 2021'	Carlton Griffin (b) (4)	10 Mar 2021 16:51:57
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:11:23
User entered 'No (N)'	Carlton Griffin (b) (4)	10 Mar 2021 16:52:04
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:11:23
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:52:04
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:11:23
User entered empty.	Carlton Griffin (b) (4)	10 Mar 2021 16:52:04
	(b) (4)	

US3782014

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:13
User entered empty.	System	10 Mar 2021 16:52:04

US3782014

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:45:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:50:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:39
Signature has been broken.	(b) (4), (b) (6)	12 Mar 2021 21:46:19
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	12 Mar 2021 21:46:19
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	19 Feb 2021 19:12:43

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:22:08
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:29
User entered 'USA-US125-2021-mRNA-1273-P301000003'	System	15 Mar 2021 14:51:24
User entered 'New'	(b) (4), (b) (6)	15 Mar 2021 14:51:24

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:45:11
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User closed query 'Per DM CLR: Please review and reflect the specific DRUG that caused this RASH, the anatomical location (e.g., Right deltoid, etc) and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:54:08
Query 'Per DM CLR: Please review and reflect the specific DRUG that caused this RASH, the anatomical location (e.g., Right deltoid, etc) and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'diffuse and non-urticarial added to the narrative. not adding to AE term since it is a descriptor. ' (Site from DM).	Carlton Griffin (b) (4)	02 Apr 2021 17:07:28
	(b) (4)	
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Drug rash - version MedDRA\23.0.	Coder Import (b) (4)	02 Apr 2021 17:06:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Apr 2021 17:06:39
	(b) (4)	
Data point term sent to Coder	System	02 Apr 2021 17:05:53
User entered 'DRUG RASH' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	02 Apr 2021 17:05:51
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	02 Apr 2021 17:04:56
	(b) (4)	
Coding entries removed.	Carlton Griffin (b) (4)	02 Apr 2021 17:04:56
	(b) (4)	
User entered 'NON-URTICARIAL, DIFFUSE DRUG RASH' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	02 Apr 2021 17:04:56
	(b) (4)	

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and reflect the specific DRUG that caused this RASH, the anatomical location (e.g., Right deltoid, etc) and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	27 Mar 2021 04:18:10
	(b) (4), (b) (6)	16 Mar 2021 16:22:15
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Drug rash - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 21:50:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Mar 2021 21:50:56
Data point term sent to Coder	System	12 Mar 2021 21:50:29
User entered 'drug rash'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:22:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:22:27
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:22:30
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:22:44
User entered '6 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:22:46
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 16:00:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:00:10
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Carlton Griffin (b) (4)	02 Apr 2021 17:04:05
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	02 Apr 2021 17:03:05
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	02 Apr 2021 17:03:05
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 20:02:46
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:22:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:45:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	02 Apr 2021 17:03:05
	(b) (4)	
User entered '18 Mar 2021' reason for change: New Information	Carlton Griffin (b) (4)	02 Apr 2021 17:03:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:22:52
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:22:58
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:51:47
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 16:25:55
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 16:25:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:23:03
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:23:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:23:13
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:23:20
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:23:24
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
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. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:00:20
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. [mRNA-1273 protocols where subject was hospitalization during study participation]' answered with 'sent with records already' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	02 Apr 2021 17:03:57
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. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 13:46:56
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).	(b) (4), (b) (6)	24 Mar 2021 19:06:15
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 'sent' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	22 Mar 2021 15:44:04
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)	19 Mar 2021 20:02:32

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:23:30
User entered '8 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:00:36
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'records sent already' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	02 Apr 2021 17:03:50
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 13:45:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:23:33
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:23:35
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:23:37
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:23:55
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:23:57
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:24:09
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:24:11
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:24:13
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:24:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:24:18
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
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) (4), (b) (6)	05 Apr 2021 15:04:55
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 'meds already in con med forms' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	02 Apr 2021 17:03:41
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)	01 Apr 2021 13:47:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:24:21
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:24:29
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:45:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:05:15
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Carlton Griffin (b) (4)	02 Apr 2021 17:03:15
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	02 Apr 2021 17:03:05
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Carlton Griffin (b) (4)	02 Apr 2021 17:03:05
New Information	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 20:02:57
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:24:32
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:24:35
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:45:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	02 Apr 2021 17:06:43
	(b) (4)	
User entered 'diffuse, non-urticarial rash. TAKING CEFADROXIL POST-OP KNEE ARTHROPLASTY UNTIL 05-MAR-2021 (LIKELY ETIOLOGY)' reason for change: Data Entry Error	Carlton Griffin (b) (4)	02 Apr 2021 17:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:24:38
User entered 'taking Cefadroxil post-op knee arthroplasty until 05-MAR-2021 (likely etiology)'	(b) (4), (b) (6)	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 21:49:50

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:42:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Flatulence, bloating and distension, PT: Flatulence, LLT: Flatulence - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 21:52:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 21:52:51
Data point term sent to Coder	System	12 Mar 2021 21:51:30
User entered 'flatulence'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:42:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:42:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:42:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:42:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '10 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:42:57
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
User entered empty.	System	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:42:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 21:51:38
User entered 'No (N)' reason for change: Data Entry Error	System	12 Mar 2021 21:51:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 21:51:29
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
User entered empty.	System	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:15
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:33
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:39
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:43:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:44:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:44:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'l'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:44:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:44:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:44:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:44:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
User entered '0'	System	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11
User entered '1'	System	12 Mar 2021 21:51:29

US3782014

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:11

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:38:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 21:52:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 21:52:51
Data point term sent to Coder	System	12 Mar 2021 21:52:31
User entered 'hyperglycemia'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:38:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:38:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:38:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:38:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '10 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:38:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
User entered empty.	System	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:38:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:39:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '11 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:39:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
User entered empty.	System	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:39:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:39:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:39:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:39:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:39:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:40:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:40:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:40:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:40:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:32
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:39
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'l'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:50
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:41:52
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
User entered '0'	System	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26
User entered 'I'	System	12 Mar 2021 21:52:19

US3782014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:26

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:52:32
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:36:59
User entered 'USA-US125-2021-mRNA-1273-P301000003'	(b) (4), (b) (6)	25 Mar 2021 13:36:54

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 16:52:36
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Duodenal ulcers and perforation, PT: Duodenal ulcer perforation, LLT: Duodenal ulcer perforated - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 16:40:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 16:40:36
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 16:25:22
User entered 'perforated duodenal ulcer'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:52:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:52:40
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:52:49
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:52:52
User entered '17 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:52:54
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	29 Apr 2021 20:09:32
DataPoint Verified.	Spyros Kalams (b) (4) (b) (4)	29 Apr 2021 17:29:27
	(b) (4), (b) (6)	29 Apr 2021 15:59:37
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'this is now supplied. And per (b) (6), it's okay to have con meds continuing for this AE even though the AE is resolved, so do not QC for that.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:15:58
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 15:14:46
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 15:14:46
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 15:14:46
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	12 Apr 2021 12:50:13
DataPoint Verified.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:05:01
	(b) (4), (b) (6)	29 Mar 2021 16:52:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	29 Apr 2021 17:29:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:59:38
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 15:14:46
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 15:14:46
User entered '30 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 15:14:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:52:59
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:01
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:02
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:08
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:11
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 03:06:23
	(b) (4), (b) (6)	29 Mar 2021 16:53:13
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'admitted to ICUD is marked yes, and hosp admission date is also entered. He is not yet discharged. Not sure why this query popped up' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 16:25:13
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	24 Mar 2021 16:24:22
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:16
User entered '17 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	29 Apr 2021 17:29:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:59:53
User closed query 'PV Query: Please send a hospital discharge summary for event of perforated duodenal ulcer and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 13:56:39
Query 'PV Query: Please send a hospital discharge summary for event of perforated duodenal ulcer and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'records sent' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	13 Apr 2021 14:44:58
DataPoint Un-verified.	Carlton Griffin (b) (4) (b) (4)	12 Apr 2021 14:49:23
Signature has been broken.	Carlton Griffin (b) (4) (b) (4)	12 Apr 2021 14:49:23
User entered '2 Apr 2021' reason for change: New Information	Carlton Griffin (b) (4) (b) (4)	12 Apr 2021 14:49:23
User opened query 'PV Query: Please send a hospital discharge summary for event of perforated duodenal ulcer and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:50:46
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:05:01

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:53:18
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:16:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 14:01:54
User entered '12' reason for change: New Information	(b) (4), (b) (6)	08 Apr 2021 14:01:54
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 03:06:29
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:53:23
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'still in ICU - do not know this number as of yet' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 16:25:28
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	24 Mar 2021 16:24:22
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:26
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:28
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:29
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:38
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:44
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:53:50
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Concomitant Medication](#)

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)	13 Apr 2021 14:09:13
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 'see con med eCRF. medications already added. see con procedures eCRF. already added' (Site from Safety).	Carlton Griffin (b) (4)	12 Apr 2021 16:12:48
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 Apr 2021 12:51:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:53:54
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:54:01
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:09:39
User signature succeeded.	Spyros Kalams (b) (4)	29 Apr 2021 17:29:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:16:47
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:16:08
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 15:14:46
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 15:14:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 15:14:46
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:49:52
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:54:02
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:54:04
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:16:49
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).	(b) (4), (b) (6)	13 Apr 2021 14:09:38
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 'sars-cov-2 PCR test result not detected on 3/17/2021' (Site from Safety).	Carlton Griffin (b) (4)	12 Apr 2021 16:16:36
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).	(b) (4), (b) (6)	12 Apr 2021 12:51:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 14:01:54
User entered 'IN PROCESS OF OBTAINING MEDICAL RECORD INFORMATION 08-apr-2021 - see con med logs for updated information' reason for change: New Information	(b) (4), (b) (6)	08 Apr 2021 14:01:54
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:54:06
User entered 'in process of obtaining medical record information'	(b) (4), (b) (6)	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 16:24:22

US3782014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 16:24:22

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:45:10

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:50:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:25:12
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 22:20:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 06:23:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:23:09
Data point term sent to Coder	System	13 Aug 2020 22:27:25
User entered 'azelastine 0.1%'	(b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'occ sinus headache'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Signature has been broken.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:34:20
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '2'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'puff (PUFF)' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	28 Aug 2020 20:20:51
	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User closed query 'Per CDM: Please select ' PUFF' from the drop down list for SPRAY. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:00:49
Query 'Per CDM: Please select ' PUFF' from the drop down list for SPRAY. Thank you.' answered with 'per query resolution' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	28 Aug 2020 20:20:58
User entered empty; reason for change Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	28 Aug 2020 20:20:51
User opened query 'Per CDM: Please select ' PUFF' from the drop down list for SPRAY. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 09:16:40
User entered 'spray'	(b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Nasal (NASAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 22:26:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 06:45:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:45:11
Data point term sent to Coder	System	13 Aug 2020 22:28:29
User entered 'fluticasone'	(b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'occ sinus headache'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '2'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'puff (PUFF)' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	28 Aug 2020 20:21:16
	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User closed query 'Per CDM: Please select ' PUFF' from the drop down list for SPRAY. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:00:53
Query 'Per CDM: Please select ' PUFF' from the drop down list for SPRAY. Thank you.' answered with 'per query resolution' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	28 Aug 2020 20:21:20
User entered empty; reason for change Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	28 Aug 2020 20:21:16
User opened query 'Per CDM: Please select ' PUFF' from the drop down list for SPRAY. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 09:24:07
User entered 'sprays'	(b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Nasal (NASAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 22:28:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 22:31:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 22:31:10
Data point term sent to Coder	System	13 Aug 2020 22:30:33
User entered 'celecoxib'	(b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'osteoarthritis'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '100'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:08:44
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'medical condition is recorded on MH form #4. revised start date of medication ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 17:07:53
User entered 'UN UNK 2015' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 17:06:31
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 06:49:12
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 09:17:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 22:30:32
User entered 'UN UNK 2000'	(b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	08 Jan 2021 16:17:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4)	08 Jan 2021 16:17:08
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User entered '2'	System	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User entered '1'	System	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:33
User entered '804 (804)'	System	13 Aug 2020 22:30:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 22:33:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 22:33:11
Data point term sent to Coder	System	13 Aug 2020 22:32:36
User entered 'rosuvastatin'	(b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'hyperlipidemia'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '40'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 09:17:27
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 22:32:07
User entered 'UN UNK 2018'	(b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	14 Aug 2020 12:44:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		14 Aug 2020 12:44:21
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		13 Aug 2020 22:32:07
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 22:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 23:34:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 23:34:15
Data point term sent to Coder	System	13 Aug 2020 22:34:37
User entered 'citalopram'	(b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'panic disorder'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '20'	(b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4)	
	(b) (4), (b) (6)	14 Aug 2020 09:17:31
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 22:33:52
User entered 'UN UNK 2018'	(b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Signature has been broken.	Carlton Griffin (b) (4)	31 Mar 2021 16:43:48
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	31 Mar 2021 16:43:48
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Signature has been broken.	Carlton Griffin (b) (4)	31 Mar 2021 16:43:48
User entered '26 Mar 2021' reason for change: New Information	Carlton Griffin (b) (4)	31 Mar 2021 16:43:48
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User entered '1'	System	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User entered '1'	System	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:41
User entered '804 (804)'	System	13 Aug 2020 22:33:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS, PRODUCT: AMLODIPINE;BENAZEPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 22:43:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 22:43:12
Data point term sent to Coder	System	13 Aug 2020 22:35:40
User entered 'amlodipine/ benazepril'	(b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '5/20'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4)	
	(b) (4), (b) (6)	14 Aug 2020 09:17:35
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 22:35:23
User entered 'UN UNK 2008'	(b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 15:54:49
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	25 Mar 2021 15:54:49
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:54:49
User entered '17 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	25 Mar 2021 15:54:49
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User entered '1'	System	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User entered '1'	System	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:46
User entered '804 (804)'	System	13 Aug 2020 22:35:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 23:37:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 23:37:08
Data point term sent to Coder	System	13 Aug 2020 23:36:31
User entered 'Atenolol'	(b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '50'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 09:17:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 23:36:10
User entered 'UN UNK 2008'	(b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 23:36:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 23:39:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 23:39:08
Data point term sent to Coder	System	13 Aug 2020 23:38:35
User entered 'Albuterol Inhaler'	(b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'asthma'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '2'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 09:17:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 23:37:48
User entered '01 Feb 2020'	(b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 23:37:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 04:29:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 04:29:19
Data point term sent to Coder	System	13 Aug 2020 23:40:38
User entered 'Aspirin'	(b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'CV prophylaxis'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '325'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:59:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'med ongoing within 28 days of vaccination ' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 12:46:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 12:46:22
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 12:46:22
User entered 'UN UNK 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 12:46:22
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 23:39:53
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:22:59
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Mar 2021 15:22:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Signature has been broken.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:22:59
User entered '23 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	09 Mar 2021 15:22:59
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:03:25
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	14 Aug 2020 12:46:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 12:46:22
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	13 Aug 2020 23:39:53
User entered 'UN UNK 2019'	(b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User entered '1'	System	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User entered '1'	System	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:24
User entered '804 (804)'	System	13 Aug 2020 23:39:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 20:04:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:04:24
Data point term sent to Coder	System	06 Oct 2020 13:23:56
Coding entries removed.	(b) (4), (b) (6)	06 Oct 2020 13:23:35
User entered 'ADVAIR (fluticasone/salmeterol)' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Oct 2020 13:23:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 23:42:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 23:42:07
Data point term sent to Coder	System	13 Aug 2020 23:41:40
User entered 'Advair'	(b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 12:47:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 12:47:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 12:47:41
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 23:40:57
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'asthma'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User closed query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/160; Dose Unit = mg) as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:35:33
Query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/160; Dose Unit = mg) as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 13:24:25
User entered '115/21' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 13:23:35
User opened query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/160; Dose Unit = mg) as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 07:46:30
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'ug (ug)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:23:35
User entered 'puff (PUFF)'	(b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 09:17:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 23:40:57
User entered '01 Feb 2020'	(b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 23:40:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
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.	(b) (4) Coder Import (b) (4)	13 Aug 2020 23:48:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 23:48:09
Data point term sent to Coder	System	13 Aug 2020 23:46:49
User entered 'multivitamin'	(b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'general health'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 09:17:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 23:46:15
User entered 'UN UNK 2010'	(b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 23:46:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: SITOSTEROL, PRODUCTSYNONYM: CHOLEST-OFF - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 06:52:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:52:18
Data point term sent to Coder	System	13 Aug 2020 23:47:51
User entered 'Cholest Off'	(b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'hyperlipidemia'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '2'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'capsule (CAPSULE)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 09:18:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 23:47:41
User entered 'UN UNK 2018'	(b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 23:47:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 23:50:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 23:50:12
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 23:48:52
User entered 'vitamin D'	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'vitamin D deficiency'	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered '2000'	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'IU (IU)'	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 09:18:08
User entered 'UN UNK 2015'	System	13 Aug 2020 23:48:45
	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Amy Kerrigan (b) (4)	08 Oct 2020 14:19:05
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).		08 Oct 2020 14:19:05
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	08 Oct 2020 14:18:41
User entered 'UN Oct 2020' reason for change: New Information	Amy Kerrigan (b) (4)	08 Oct 2020 14:18:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User entered '1'	System	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User entered '1'	System	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:00:50
User entered '804 (804)'	System	13 Aug 2020 23:48:45

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 17:43:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:43:47
Data point term sent to Coder	System	03 Sep 2020 17:43:18
User entered 'mucinex'	Carlton Griffin (b) (4) (b) (4)	03 Sep 2020 17:42:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'seasonal allergies'	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered '600'	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:03:25
User entered empty.	Carlton Griffin (b) (4) (b) (4)	03 Sep 2020 17:42:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
Signature has been broken.	Carlton Griffin (b) (4)	08 Apr 2021 13:44:03
	(b) (4)	
User entered 'as needed (PRN)' reason for change: New Information	Carlton Griffin (b) (4)	08 Apr 2021 13:44:03
	(b) (4)	
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'other (OTHER)'	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
Signature has been broken.	Carlton Griffin (b) (4)	08 Apr 2021 13:44:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	Carlton Griffin (b) (4)	08 Apr 2021 13:44:03
	(b) (4)	
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'q12h'	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered '29 Aug 2020'	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:03:25
User entered empty.	Carlton Griffin (b) (4) (b) (4)	03 Sep 2020 17:42:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	03 Sep 2020 17:42:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 17:42:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 17:42:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 17:42:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 19:08:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 19:08:40
Data point term sent to Coder	System	10 Sep 2020 19:07:59
User entered 'Tylenol'	(b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'sinus headache'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '1000'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:45:10
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2006). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:00:29
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2006). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	02 Jan 2021 19:20:53
User entered 'UN UNK 2006' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	02 Jan 2021 19:20:46
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2006). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Jan 2021 19:15:55
User entered 'un UNK 1970'	(b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the SINUS HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SINUS HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:21:09
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the SINUS HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SINUS HEADACHE did not meet the AE reporting criteria. ' answered with 'Updated - thanks' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 18:14:00
User entered 'No (N)' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 18:13:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the SINUS HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SINUS HEADACHE did not meet the AE reporting criteria. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 06:49:35
	(b) (4), (b) (6) (b) (4), (b) (6)	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 19:07:26

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 14:07:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 14:07:30
Data point term sent to Coder	System	06 Oct 2020 13:25:59
User entered 'Influenza vaccination'	(b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'influenza prophylaxis'	(b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0.5'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User entered empty.	System	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User entered empty.	System	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:16
User entered empty.	System	06 Oct 2020 13:25:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Oct 2020 20:58:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 20:58:00
Data point term sent to Coder	System	08 Oct 2020 14:21:38
User entered 'Vitamin D'	Amy Kerrigan (b) (4) (b) (4)	08 Oct 2020 14:20:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'No (N)'	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Vitamin D Deficiency'	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered '4000'	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'IU (IU)'	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:03:25
User entered empty.	Amy Kerrigan (b) (4) (b) (4)	08 Oct 2020 14:20:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'once daily (QD)'	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered empty.	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Oral (ORAL)'	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:03:25
User entered empty.	Amy Kerrigan (b) (4) (b) (4)	08 Oct 2020 14:20:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'UN Oct 2020'	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered '0'	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'Yes (Y)'	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered empty.	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:03:25
	(b) (4)	
User entered 'No (N)'	Amy Kerrigan (b) (4)	08 Oct 2020 14:20:53
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:20:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:20:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 14:20:53

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Mar 2021 15:40:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 15:40:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 15:25:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 15:25:57
Data point term sent to Coder	System	09 Mar 2021 15:24:47
User entered 'oxycontin'	(b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'pre-operative sedation'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '10'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '22 Feb 2021'	(b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '22 Feb 2021'	(b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:24:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 07:07:47
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 07:07:47
Data point term sent to Coder	System	09 Mar 2021 15:26:54
User entered 'Vancomycin'	(b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'pre-operative infection prophylaxis'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '2000'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User entered empty.	System	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User entered empty.	System	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:35
User entered empty.	System	09 Mar 2021 15:25:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 11:26:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 11:26:53
Data point term sent to Coder	System	09 Mar 2021 15:26:54
User entered 'Cefazolin'	(b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'peri-operative infection prophylaxis'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '1000'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4)	(b) (4), (b) (6)
		09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User entered '2'	System	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User entered '1'	System	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:21
User entered '804 (804)'	System	09 Mar 2021 15:26:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 07:15:40
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 07:15:40
Data point term sent to Coder	System	09 Mar 2021 15:27:55
User entered 'tranexamic acid'	(b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'intraoperative blood loss prevention'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '1950'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User entered empty.	System	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User entered empty.	System	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:49
User entered empty.	System	09 Mar 2021 15:27:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 10:29:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 10:29:43
Data point term sent to Coder	System	09 Mar 2021 15:28:56
User entered 'decadron'	(b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'peri-operative inflammation prophylaxis'	(b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '10'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User entered empty.	System	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User entered empty.	System	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:45
User entered empty.	System	09 Mar 2021 15:28:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: ATARAX [ALPRAZOLAM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Mar 2021 11:03:49
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 11:03:49
Data point term sent to Coder	System	09 Mar 2021 15:28:56
User entered 'atarax'	(b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'pre-operative sedation'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '25'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User entered empty.	System	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User entered empty.	System	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:55
User entered empty.	System	09 Mar 2021 15:28:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFADROXIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 11:26:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 11:26:53
Data point term sent to Coder	System	09 Mar 2021 15:29:57
User entered 'cefadroxil'	(b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'infection prophylaxis'	(b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '500'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User entered '2'	System	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User entered '1'	System	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:28
User entered '804 (804)'	System	09 Mar 2021 15:29:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Mar 2021 12:08:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:08:38
Data point term sent to Coder	System	09 Mar 2021 15:30:58
User entered 'oxycodone'	(b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'post-operative pain'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '15'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User entered empty.	System	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User entered empty.	System	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:10
User entered empty.	System	09 Mar 2021 15:30:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM;SENNOSIDE A+B - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 09:37:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 09:37:32
Data point term sent to Coder	System	09 Mar 2021 15:30:58
User entered 'sennosides-docusate sodium'	(b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'constipation prophylaxis'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '8.5/50'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '08 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User entered '2'	System	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User entered '1'	System	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:13
User entered '804 (804)'	System	09 Mar 2021 15:30:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 11:00:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 11:00:49
Data point term sent to Coder	System	09 Mar 2021 15:31:59
User entered 'aspirin'	(b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'post-operative embolic prophylaxis'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '81'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:18:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '7 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	12 Mar 2021 21:18:28
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User entered '2'	System	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User entered '1'	System	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:17
User entered '804 (804)'	System	09 Mar 2021 15:31:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 09:57:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 09:57:51
Data point term sent to Coder	System	07 Apr 2021 15:26:42
Coding entries removed.	Carlton Griffin (b) (4)	07 Apr 2021 15:26:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:08:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:08:38
Data point term sent to Coder	System	09 Mar 2021 15:33:02
User entered 'oxycodone'	(b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
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 if appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:36:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
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 if appropriate. ' answered with 'no AE is needed for this. medication was taken for a procedure. see con procedure form ' (Site from DM).	(b) (4) Carlton Griffin (b) (4)	07 Apr 2021 15:26:32
User entered 'R KNEE REPLACEMENT POST-OPERATIVE PAIN' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	07 Apr 2021 15:26:00
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 if appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:58:58
User entered 'post-operative pain'	(b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '10'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	25 Mar 2021 15:13:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '17 Mar 2021' reason for change: New Information	(b) (4)	25 Mar 2021 15:13:05
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User entered empty.	System	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User entered empty.	System	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:44
User entered empty.	System	09 Mar 2021 15:32:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCONATE SODIUM;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE, PRODUCTSYNONYM: PLASMALYTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 15:36:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 15:36:58
Data point term sent to Coder	System	09 Mar 2021 15:36:05
User entered 'plasmalyte'	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'intra-operative fluid replacement'	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '500'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mL (mL)'	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User entered empty.	System	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User entered empty.	System	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:49
User entered empty.	System	09 Mar 2021 15:35:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Mar 2021 15:34:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: ROPIVACAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 07:29:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:29:49
Data point term sent to Coder	System	09 Mar 2021 15:36:05
User entered 'ropivacaine' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 15:36:01
Data point term sent to Coder	System	09 Mar 2021 15:33:02
User entered 'plasmalyte'	(b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'operative anesthesia' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:36:01
User entered 'intra-operative fluid replacement'	(b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '40' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:36:01
User entered '500'	(b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User entered empty.	System	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User entered empty.	System	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:56
User entered empty.	System	09 Mar 2021 15:32:55

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 07:11:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:11:54
Data point term sent to Coder	System	09 Mar 2021 15:37:07
User entered 'epinephrine' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 15:36:33
Data point term sent to Coder	System	09 Mar 2021 15:34:03
User entered 'Ropivacaine'	(b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'operative anesthesia'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0.25' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:36:33
User entered '40'	(b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:36:33
User entered 'mL (mL)'	(b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User entered empty.	System	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User entered empty.	System	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User entered empty.	System	09 Mar 2021 15:33:33

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 07:52:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:52:53
Data point term sent to Coder	System	12 Mar 2021 21:20:28
User entered 'Ketamine'	(b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'operative anesthesia'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '50'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User entered empty.	System	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User entered empty.	System	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:01
User entered empty.	System	12 Mar 2021 21:20:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 10:17:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 10:17:37
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:27:10
Data point term sent to Coder	System	12 Mar 2021 21:21:30
User entered 'pepcid' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:21:15
Data point term sent to Coder	System	09 Mar 2021 15:38:08
User entered 'ketamine'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:27:13
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User closed query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:36:33
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' answered with 'the rash is diffuse and non-urticarial. this is in the narrative of the AE, but is not an AE term because they are descriptors- will not be adding to AE term or indication for con med. ' (Site from DM).	(b) (4) Carlton Griffin (b) (4)	07 Apr 2021 15:30:27
User opened query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:58:13
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:27:15
User entered 'drug rash' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:21:15
User entered 'operative anesthesia'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:27:19
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:21:15
User entered '50'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:27:21
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:27:23
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:27:25
User entered 'twice daily (BID)' reason for change:	(b) (4), (b) (6)	12 Mar 2021 21:21:15
Data Entry Error		
User entered 'once (ONCE)'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:27:27
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:27:29
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:21:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:27:31
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:54:08
User closed query 'Source indicates start date for CM as 06MAR2021. Please confirm and update as needed.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 15:53:21
Query 'Source indicates start date for CM as 06MAR2021. Please confirm and update as needed.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:59:45
User entered '6 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 17:59:16
User opened query 'Source indicates start date for CM as 06MAR2021. Please confirm and update as needed.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 16:28:20
User entered '6 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:21:15
User entered '22 Feb 2021'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:06
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:58:37
DataPoint Un-verified.	Carlton Griffin (b) (4)	25 Mar 2021 15:14:49
User entered 'No (N)' reason for change: New Information	(b) (4) Carlton Griffin (b) (4)	25 Mar 2021 15:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:21:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:58:52
DataPoint Un-verified.	Carlton Griffin (b) (4)	25 Mar 2021 15:14:49
User entered '18 Mar 2021' reason for change: New Information	(b) (4) Carlton Griffin (b) (4)	25 Mar 2021 15:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:21:15
User entered '22 Feb 2021'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:30:14
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User entered '2'	System	12 Mar 2021 21:21:15
User entered empty.	System	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User entered '1'	System	12 Mar 2021 21:21:15
User entered empty.	System	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:07
User entered '804 (804)'	System	12 Mar 2021 21:21:15
User entered empty.	System	09 Mar 2021 15:37:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 08:15:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:15:01
Data point term sent to Coder	System	12 Mar 2021 21:22:30
User entered 'ketoralac'	(b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'post-operative pain'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '30'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '07 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '7 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User entered empty.	System	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User entered empty.	System	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:36
User entered empty.	System	12 Mar 2021 21:21:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:30:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Mar 2021 13:50:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Mar 2021 13:50:37
Data point term sent to Coder	System	12 Mar 2021 21:23:32
User entered 'cetirizine'	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:30:56
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User closed query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:36:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' answered with 'the rash is diffuse and non-urticarial. this is in the narrative of the AE, but is not an AE term because they are descriptors- will not be adding to AE term or indication for con med. ' (Site from DM).	(b) (4) Carlton Griffin (b) (4)	07 Apr 2021 15:30:51
User opened query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:58:29
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:30:58
User entered 'drug rash'	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:31:00
User entered '20'	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:31:02
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:31:04
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:33:37
User entered 'twice daily (BID)'	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:33:42
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:33:45
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:36:24
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:37:38
User entered '08 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:37:40
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:59:49
DataPoint Un-verified.	Carlton Griffin (b) (4)	25 Mar 2021 15:13:57
User entered 'No (N)' reason for change: New Information	(b) (4) Carlton Griffin (b) (4)	25 Mar 2021 15:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:37:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:59:50
DataPoint Un-verified.	Carlton Griffin (b) (4)	25 Mar 2021 15:13:57
User entered '18 Mar 2021' reason for change: New Information	(b) (4) Carlton Griffin (b) (4)	25 Mar 2021 15:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:37:46
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:37:48
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User entered '2'	System	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User entered '1'	System	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:20
User entered '804 (804)'	System	12 Mar 2021 21:22:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:41:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 22:37:59
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 22:37:59
Data point term sent to Coder	System	12 Mar 2021 21:23:32
User entered 'benadryl'	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:41:17
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User closed query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:36:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' answered with 'the rash is diffuse and non-urticarial. this is in the narrative of the AE, but is not an AE term because they are descriptors- will not be adding to AE term or indication for con med. ' (Site from DM).	(b) (4) Carlton Griffin (b) (4)	07 Apr 2021 15:30:57
User opened query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:58:38
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:41:19
User entered 'drug rash'	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:41:29
User entered '12.5-25'	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:41:33
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:41:40
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:41:42
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:41:45
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:41:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:41:50
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:41:53
User entered '06 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:41:55
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:00:38
DataPoint Un-verified.	Carlton Griffin (b) (4)	25 Mar 2021 15:14:20
User entered 'No (N)' reason for change: New Information	(b) (4) Carlton Griffin (b) (4)	25 Mar 2021 15:14:20
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:41:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:00:40
DataPoint Un-verified.	Carlton Griffin (b) (4)	25 Mar 2021 15:14:20
User entered '18 Mar 2021' reason for change: New Information	(b) (4) Carlton Griffin (b) (4)	25 Mar 2021 15:14:20
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:02
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:42:08
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User entered empty.	System	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User entered empty.	System	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:43
User entered empty.	System	12 Mar 2021 21:23:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:42:42
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 15:15:55
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 15:15:55
Data point term sent to Coder	System	12 Mar 2021 21:24:32
User entered 'triamcinolone 0.1%'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:42:47
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:42:49
User entered 'drug rash'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:43:04
User entered 'one'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:43:06
User entered 'Other (OTHER)'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:43:09
User entered 'application'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:43:11
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:54:04
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:54:11
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:54:19
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:54:21
User entered '8 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:54:26
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Un-verified.	(b) (4)	
	Carlton Griffin (b) (4)	02 Apr 2021 17:01:55
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Carlton Griffin (b) (4)	02 Apr 2021 17:01:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:54:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Un-verified.	(b) (4)	
	Carlton Griffin (b) (4)	02 Apr 2021 17:01:55
User entered '18 Mar 2021' reason for change: New Information	(b) (4)	02 Apr 2021 17:01:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:54:30
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:54:33
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User entered empty.	System	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User entered empty.	System	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:49
User entered empty.	System	12 Mar 2021 21:24:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:55:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 01:17:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 01:17:48
Data point term sent to Coder	System	12 Mar 2021 21:25:39
User entered 'zofran'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:55:46
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:55:50
User entered 'nausea related to drug rash'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:55:52
User entered '4'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:55:54
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:55:56
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:55:58
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:56:00
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:56:02
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:56:06
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:56:11
User entered '08 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:56:13
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:56:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:56:19
User entered '8 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:56:21
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User entered empty.	System	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User entered empty.	System	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:13
User entered empty.	System	12 Mar 2021 21:24:51

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 13:54:44
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 13:54:44
Data point term sent to Coder	System	12 Mar 2021 21:25:39
User entered 'Lovenox'	(b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'embolic prophylaxis'	(b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '40'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '08 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User entered '2'	System	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User entered '1'	System	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:20
User entered '804 (804)'	System	12 Mar 2021 21:25:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 21:44:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 21:44:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 21:29:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 21:29:49
Data point term sent to Coder User entered 'Aspirin'	System	12 Mar 2021 21:28:58
	(b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Cardiovascular prophylaxis'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '81'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	25 Mar 2021 15:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '17 Mar 2021' reason for change: New Information	(b) (4)	25 Mar 2021 15:16:55
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User entered '2'	System	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User entered '1'	System	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:56
User entered '804 (804)'	System	12 Mar 2021 21:28:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, PRODUCT: SIMETICONE, PRODUCTSYNONYM: MYLICON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 21:47:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 21:47:50
Data point term sent to Coder	System	12 Mar 2021 21:32:03
User entered 'Mylicon'	(b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'flatulence'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '80'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User entered empty.	System	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User entered empty.	System	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:02
User entered empty.	System	12 Mar 2021 21:31:52

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Mar 2021 07:59:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:59:02
Data point term sent to Coder	System	12 Mar 2021 21:33:04
User entered 'Humolog insulin'	(b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'hyperglycemia'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User closed query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:27:36
Query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' answered with 'insulin is measured as "unit" not IU. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 14:01:57
User opened query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:21:07
User entered 'unit'	(b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User entered empty.	System	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User entered empty.	System	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:29
User entered empty.	System	12 Mar 2021 21:32:43

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:56:51
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: HYDROCORTISONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUCORTEF - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:12:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:12:58
Data point term sent to Coder	System	12 Mar 2021 21:40:10
User entered 'solucortef'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:56:53
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:56:56
User entered 'drug rash'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:22:12
User entered '100'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:22:20
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:22:29
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:22:32
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:22:43
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:22:46
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:22:48
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:22:52
User entered '06 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:23:15
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:23:18
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:23:34
User entered '6 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:23:40
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User entered empty.	System	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User entered empty.	System	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:14
User entered empty.	System	12 Mar 2021 21:39:14

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:24:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:12:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:12:57
Data point term sent to Coder	System	12 Mar 2021 21:40:12
User entered 'solumedrol'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:24:08
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:24:32
User entered 'drug rash'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:24:47
User entered '125'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:24:51
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:24:53
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:24:55
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:24:58
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:25:02
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:25:04
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:25:07
User entered '8 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:25:09
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:25:12
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:25:15
User entered '8 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:25:47
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User entered empty.	System	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User entered empty.	System	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:28
User entered empty.	System	12 Mar 2021 21:39:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 12:51:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	19 Mar 2021 12:51:32
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:26:07
Data point term sent to Coder	System	12 Mar 2021 21:41:13
User entered 'prednisone'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:09
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:11
User entered 'drug rash'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:13
User entered '60'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:15
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:18
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:22
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:23
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:29
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:30
User entered '07 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:33
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:35
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:37
User entered '7 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:38
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User entered empty.	System	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User entered empty.	System	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:08
User entered empty.	System	12 Mar 2021 21:40:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 12:51:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	19 Mar 2021 12:51:32
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:26:44
Data point term sent to Coder	System	12 Mar 2021 21:41:13
User entered 'prednisone'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:46
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:50
User entered 'drug rash'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:53
User entered '80'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:55
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:57
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:26:59
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:27:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:27:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:27:04
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:27:07
User entered '09 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:27:14
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:27:43
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:28:05
User entered '10 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:28:10
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User entered '1'	System	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User entered '1'	System	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:13:54
User entered '804 (804)'	System	12 Mar 2021 21:40:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 12:51:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	19 Mar 2021 12:51:33
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:30:14
Data point term sent to Coder User entered 'prednisone'	System	12 Mar 2021 21:42:16
	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:30:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User closed query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:36:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' answered with 'the rash is diffuse and non-urticarial. this is in the narrative of the AE, but is not an AE term because they are descriptors- will not be adding to AE term or indication for con med. ' (Site from DM).	(b) (4) Carlton Griffin (b) (4)	07 Apr 2021 15:31:49
User opened query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:59:21
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:30:18
User entered 'drug rash'	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:30:20
User entered '60'	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:30:22
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:32:12
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:32:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:32:21
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:32:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:32:28
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:32:30
User entered '11 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:32:33
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:02:04
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 15:27:10
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	25 Mar 2021 15:27:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:32:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:02:06
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 15:27:10
User entered '14 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	25 Mar 2021 15:27:10
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:32:38
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:32:39
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User entered '1'	System	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User entered '1'	System	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:14:01
User entered '804 (804)'	System	12 Mar 2021 21:41:18

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:09
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:44:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:44:29
Data point term sent to Coder	System	25 Mar 2021 15:28:58
User entered 'prednisone'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User closed query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:37:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' answered with 'the rash is diffuse and non-urticarial. this is in the narrative of the AE, but is not an AE term because they are descriptors- will not be adding to AE term or indication for con med. ' (Site from DM).	(b) (4) Carlton Griffin (b) (4)	07 Apr 2021 15:31:55
User opened query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:59:30
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:05:16
User entered 'drug rash'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:19
User entered '40'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:20
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:23
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:26
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:31
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:34
User entered '15 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:36
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:37
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:41
User entered '17 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:05:43
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User entered '1'	System	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User entered '1'	System	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:25
User entered '804 (804)'	System	25 Mar 2021 15:28:02

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:29:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:29:27
Data point term sent to Coder	System	25 Mar 2021 15:28:57
User entered 'prednisone'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:04
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User closed query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:37:15
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' answered with 'the rash is diffuse and non-urticarial. this is in the narrative of the AE, but is not an AE term because they are descriptors- will not be adding to AE term or indication for con med. ' (Site from DM).	(b) (4) Carlton Griffin (b) (4)	07 Apr 2021 15:32:01
User opened query 'Per DM CLR: Please review and update the ConMed reason for medication to reflect the location and of type of rash (e.g., pruritic, macular). Please reconcile with the AE or medical history eCRFs so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:59:38
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:06:07
User entered 'drug rash'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:10
User entered '20'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:12
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:14
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:16
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:18
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:39
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:41
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:43
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:46
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:54
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:06:58
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User entered '1'	System	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User entered '1'	System	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:30
User entered '804 (804)'	System	25 Mar 2021 15:28:41

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:08:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE, PRODUCTSYNONYM: CARAFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:04:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:04:17
Data point term sent to Coder	System	25 Mar 2021 16:05:07
User entered 'Carafate'	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:08:31
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:08:33
User entered 'perforated duodenal ulcer'	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:08:40
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:08:47
User entered 'g (g)'	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:08:55
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:08:58
User entered 'three times daily (TID)'	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:01
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:08
User entered '20 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:11
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:17
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:19
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 16:04:46

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:07:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:07:28
Data point term sent to Coder	System	25 Mar 2021 16:06:08
User entered 'Miralax'	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:38
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:43
User entered 'perforated duodenal ulcer'	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:49
User entered '17'	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:59
User entered 'g (g)'	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:09:57
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Un-verified.	(b) (4)	
	Carlton Griffin (b) (4)	08 Apr 2021 13:44:44
User entered 'once (ONCE)' reason for change: New Information	(b) (4)	08 Apr 2021 13:44:44
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:10:01
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:05
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:10
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:13
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:15
User entered '24 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:20
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Un-verified.	(b) (4)	
	Carlton Griffin (b) (4)	08 Apr 2021 13:44:44
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Carlton Griffin (b) (4)	08 Apr 2021 13:44:44
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:10:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Un-verified.	(b) (4)	
	Carlton Griffin (b) (4)	08 Apr 2021 13:44:44
User entered '24 Mar 2021' reason for change: New Information	(b) (4)	08 Apr 2021 13:44:44
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:10:24
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:25
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User entered empty.	System	08 Apr 2021 13:44:44
User entered '1'	System	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User entered empty.	System	08 Apr 2021 13:44:44
User entered '1'	System	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:19
User entered empty.	System	08 Apr 2021 13:44:44
User entered '804 (804)'	System	25 Mar 2021 16:06:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 12:34:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 12:34:40
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:10:35
Data point term sent to Coder	System	25 Mar 2021 16:07:10
User entered 'Dulcolax'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:37
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:38
User entered 'perforated duodenal ulcer'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:42
User entered '10'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:44
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:46
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:48
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:50
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:51
User entered 'Rectal (RECTAL)'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:54
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:10:59
User entered '23 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:00
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:02
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:05
User entered '23 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:07
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User entered empty.	System	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User entered empty.	System	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:58
User entered empty.	System	25 Mar 2021 16:06:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:22:42
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 Mar 2021 11:22:42
Data point term sent to Coder	System	25 Mar 2021 16:08:11
User entered 'Protonix'	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:21
User entered 'perforated duodenal ulcer'	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:24
User entered '40'	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:26
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:28
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:30
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:32
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:36
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:42
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:47
User entered '17 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:48
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	31 Mar 2021 16:42:16
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	31 Mar 2021 16:42:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:11:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	31 Mar 2021 16:42:16
	(b) (4)	
User entered '30 Mar 2021' reason for change: New Information	Carlton Griffin (b) (4)	31 Mar 2021 16:42:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:11:54
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:11:55
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 16:07:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:12:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:52:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:52:07
Data point term sent to Coder	System	25 Mar 2021 16:08:11
User entered 'oxycodone'	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:12:32
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:12:34
User entered 'perforated duodenal ulcer'	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:12:39
User entered '5-7.5'	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:12:41
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:39:31
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:39:34
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:39:42
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:39:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:39:49
User entered '24 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:39:52
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	31 Mar 2021 16:42:36
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	31 Mar 2021 16:42:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	31 Mar 2021 16:42:36
	(b) (4)	
User entered '29 Mar 2021' reason for change: New Information	Carlton Griffin (b) (4)	31 Mar 2021 16:42:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:39:56
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:39:58
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 16:07:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:09:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:09:28
Data point term sent to Coder	System	25 Mar 2021 16:09:13
User entered 'dilaudid'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:30
User entered 'perforated duodenal ulcer'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:32
User entered 'l'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:34
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:38
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:39
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:41
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:43
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:46
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:49
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:53
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:40:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:00
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User entered empty.	System	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User entered empty.	System	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:06
User entered empty.	System	25 Mar 2021 16:08:24

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 22:33:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 22:33:31
Data point term sent to Coder	System	25 Mar 2021 22:32:16
User entered 'Dilaudid'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:51
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:53
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:57
User entered '0.2'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:59
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:42:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:42:09
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:42:11
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:42:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:42:15
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:42:19
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:42:21
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:42:22
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:42:24
User entered '24 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:42:26
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User entered empty.	System	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User entered empty.	System	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:12:12
User entered empty.	System	25 Mar 2021 22:32:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN, PRODUCTSYNONYM: NEURONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 10:46:46
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 Mar 2021 10:46:46
Data point term sent to Coder	System	25 Mar 2021 22:33:17
User entered 'Neurontin'	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:18
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:20
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:24
User entered '100'	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:25
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:28
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:29
User entered 'three times daily (TID)'	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:31
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:32
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:34
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:37
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:38
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	08 Apr 2021 13:45:09
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	08 Apr 2021 13:45:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:43:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	08 Apr 2021 13:45:09
	(b) (4)	
User entered '01 Apr 2021' reason for change: New Information	Carlton Griffin (b) (4)	08 Apr 2021 13:45:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:43:42
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 22:32:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 08:38:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 08:38:52
Data point term sent to Coder	System	25 Mar 2021 22:34:17
User entered 'Zofran'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:56
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:58
User entered '4'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:00
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:02
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:04
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:05
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:07
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:09
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:11
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:18
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:26
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:28
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:32
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User entered empty.	System	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User entered empty.	System	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:37
User entered empty.	System	25 Mar 2021 22:33:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: NIFEDIPINE, PRODUCTSYNONYM: PROCARDIA [NIFEDIPINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:15:44
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 Mar 2021 11:15:44
Data point term sent to Coder	System	25 Mar 2021 22:34:17
User entered 'Procardia'	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:42
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:45
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:48
User entered '30'	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:51
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:52
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:55
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:57
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:44:59
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:00
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:02
User entered '22 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:04
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	08 Apr 2021 13:45:32
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	08 Apr 2021 13:45:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:45:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	08 Apr 2021 13:45:32
	(b) (4)	
User entered '01 Apr 2021' reason for change: New Information	Carlton Griffin (b) (4)	08 Apr 2021 13:45:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:45:08
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:10
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 22:34:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 15:34:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	07 Apr 2021 15:34:41
Data point term sent to Coder Coding entries removed.	System Carlton Griffin (b) (4)	07 Apr 2021 15:33:49 07 Apr 2021 15:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 12:06:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	26 Mar 2021 12:06:43
Data point term sent to Coder User entered 'Amlodipine'	System (b) (4), (b) (6)	25 Mar 2021 22:35:18 25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual 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)	23 Apr 2021 07:37:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4)	07 Apr 2021 15:34:07
DataPoint Un-verified.	Carlton Griffin (b) (4)	07 Apr 2021 15:33:41
User entered 'hypertension' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	07 Apr 2021 15:33:41
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual 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)	07 Apr 2021 08:57:51
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:45:22
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:25
User entered '10'	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:26
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:28
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:35
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:38
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:41
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:48
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:50
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:45:54
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:46:03
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:46:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User entered empty.	System	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User entered empty.	System	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:44
User entered empty.	System	25 Mar 2021 22:34:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 10:48:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 10:48:31
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:46:21
Data point term sent to Coder	System	25 Mar 2021 22:36:19
User entered 'SS Humalog insulin'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:46:24
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:49:58
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:50:03
User entered '1-21'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:50:06
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:50:10
User entered 'units'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:50:26
User entered 'four times daily (QID)'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:50:28
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:50:43
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 18:50:40
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:50:36
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:50:47
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:03
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:05
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:07
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:09
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User entered '4'	System	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User entered '1'	System	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:25
User entered '804 (804)'	System	25 Mar 2021 22:36:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Mar 2021 14:18:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:38
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:51:24
Data point term sent to Coder User entered 'Glargine insulin'	System (b) (4), (b) (6)	25 Mar 2021 22:40:21 25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:25
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:27
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:30
User entered '15'	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:39
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:40
User entered 'units'	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:42
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:45
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:48
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:50
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:54
User entered '20 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:51:56
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	31 Mar 2021 16:43:22
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	31 Mar 2021 16:43:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:51:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
DataPoint Un-verified.	Carlton Griffin (b) (4)	31 Mar 2021 16:43:22
	(b) (4)	
User entered '29 Mar 2021' reason for change: New Information	Carlton Griffin (b) (4)	31 Mar 2021 16:43:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:52:01
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:52:04
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 22:40:06

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 10:28:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 10:28:37
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:52:13
Data point term sent to Coder	System	25 Mar 2021 22:47:28
User entered 'INSULIN' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 22:47:24
Data point term sent to Coder	System	25 Mar 2021 22:41:23
User entered 'Insuling'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:52:22
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:52:26
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:52:32
User entered '3.3-12.5'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:52:39
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:52:41
User entered 'units/hour'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:53:37
User entered 'other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:53:44
User entered 'continuous infusion'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:53:47
User entered 'Intravenous Drip (INTRAVENOUS DRIP)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 22:47:24
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:53:49
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:53:53
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:53:54
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:53:57
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:53:59
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:01
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User entered empty.	System	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User entered empty.	System	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:31
User entered empty.	System	25 Mar 2021 22:41:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:44
Data point term sent to Coder	System	25 Mar 2021 22:42:24
User entered 'Vancomycin'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:11
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:13
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:17
User entered '2000'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:18
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:20
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:22
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:24
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:36
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:40
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:43
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:45
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:46
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:48
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User entered empty.	System	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User entered empty.	System	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:08
User entered empty.	System	25 Mar 2021 22:41:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:54:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:44
Data point term sent to Coder	System	25 Mar 2021 22:43:24
User entered 'Vancomycin'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:00
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:02
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:06
User entered '1500'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:09
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:12
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:15
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:17
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:25
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:29
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:31
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:33
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:35
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:55:37
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User entered empty.	System	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User entered empty.	System	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:01
User entered empty.	System	25 Mar 2021 22:42:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:44
Data point term sent to Coder	System	25 Mar 2021 22:43:25
User entered 'vancomycin'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:02
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:03
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:05
User entered '1000'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:07
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:09
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:13
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:12
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:16
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:18
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:23
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:25
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:27
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:34
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:30
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User entered '2'	System	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User entered '1'	System	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:06
User entered '804 (804)'	System	25 Mar 2021 22:42:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:45
Data point term sent to Coder	System	25 Mar 2021 22:44:26
User entered 'vancomycin'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:50
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:51
User entered '1250'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:53
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:57:55
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:01
User entered 'three times daily (TID)'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:05
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:10
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:12
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:15
User entered '22 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:17
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:19
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:21
User entered '22 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:22
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User entered '3'	System	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User entered '1'	System	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:40
User entered '804 (804)'	System	25 Mar 2021 22:43:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 22:45:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 22:45:31
Data point term sent to Coder	System	25 Mar 2021 22:44:26
User entered 'Zosyn'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:32
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:34
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:40
User entered '3.375'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:43
User entered 'g (g)'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:45
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:48
User entered 'three times daily (TID)'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:51
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:58:57
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:00
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:02
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:07
User entered '22 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:09
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User entered '3'	System	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User entered '1'	System	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:48
User entered '804 (804)'	System	25 Mar 2021 22:44:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:16
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: VASOPRESSIN AND ANALOGUES, PRODUCT: VASOPRESSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:38
Data point term sent to Coder	System	25 Mar 2021 22:48:29
Data point term sent to Coder	System	25 Mar 2021 22:45:26
User entered 'Vasopressin'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:18
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:20
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:23
User entered '0.03'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:25
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:28
User entered 'units'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:30
User entered 'other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:34
User entered 'per hour'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:36
User entered 'Intravenous Drip (INTRAVENOUS DRIP)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 22:47:42
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:38
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:41
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:42
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:45
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:48
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:59:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User entered empty.	System	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User entered empty.	System	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:47
User entered empty.	System	25 Mar 2021 22:45:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: VASOPRESSIN AND ANALOGUES, PRODUCT: VASOPRESSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:38
Data point term sent to Coder	System	25 Mar 2021 22:46:27
User entered 'vasopressin'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:07
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:09
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:14
User entered '2'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:16
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:19
User entered 'units'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:21
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:23
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:30
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:35
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:37
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:40
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:43
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:00:46
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User entered empty.	System	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User entered empty.	System	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:35:53
User entered empty.	System	25 Mar 2021 22:45:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:01:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL, PRODUCTSYNONYM: DIPRIVAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 22:48:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 22:48:31
Data point term sent to Coder	System	25 Mar 2021 22:47:27
User entered 'Diprivan'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:01:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:01:46
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:01:52
User entered '10-20'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:01:54
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:01:56
User entered 'mcg/kg/min'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:02:00
User entered 'other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:02:03
User entered 'continuous infusion'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:02:04
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:02:07
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:02:10
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:02:12
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:02:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:02:17
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:02:18
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User entered empty.	System	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User entered empty.	System	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:40
User entered empty.	System	25 Mar 2021 22:46:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:03:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL, PRODUCTSYNONYM: DIPRIVAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 22:50:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 22:50:31
Data point term sent to Coder	System	25 Mar 2021 22:49:30
User entered 'Diprivan'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:03:32
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:03:36
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:03:43
User entered '20-80'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:03:51
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:03:57
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:03:58
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:04:01
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:06:06
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:06:08
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:06:10
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:06:12
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:06:15
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:06:18
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:06:21
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User entered empty.	System	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User entered empty.	System	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:18
User entered empty.	System	25 Mar 2021 22:48:38

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:09:42
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 Mar 2021 11:09:42
Data point term sent to Coder	System	25 Mar 2021 22:50:31
User entered 'Phenylephrine'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:09
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:12
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:14
User entered '200'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:16
User entered 'ug (ug)'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:18
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:20
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:22
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:24
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:26
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:29
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:31
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:10:33
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:12:48
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:12:50
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User entered empty.	System	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User entered empty.	System	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:22
User entered empty.	System	25 Mar 2021 22:49:42

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:54:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:54:43
Data point term sent to Coder	System	25 Mar 2021 22:50:31
User entered 'rocuronium'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:09
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:11
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:14
User entered '20-80'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:17
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:19
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:21
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:24
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:28
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:46
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:13:50
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:15
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:17
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:19
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User entered empty.	System	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User entered empty.	System	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:30
User entered empty.	System	25 Mar 2021 22:50:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 10:35:42
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 Mar 2021 10:35:42
Data point term sent to Coder	System	25 Mar 2021 22:51:32
User entered 'norepinephrine'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:32
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:34
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:39
User entered '0-50'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:40
User entered 'ug (ug)'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:42
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:51
User entered 'other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:54
User entered 'continuous drip'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:14:59
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:15:02
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:15:07
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:15:09
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:15:11
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:15:14
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:15:16
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User entered empty.	System	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User entered empty.	System	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:37
User entered empty.	System	25 Mar 2021 22:51:01

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:15:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:39
Data point term sent to Coder	System	25 Mar 2021 22:52:33
User entered 'versed'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:15:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:15:31
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:15:57
User entered '0.5-2'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:16:33
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:16:49
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:16:57
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:06
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:08
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:13
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:14
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:28
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:31
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User entered empty.	System	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User entered empty.	System	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:27
User entered empty.	System	25 Mar 2021 22:51:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 14:19:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:19:38
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:17:47
Data point term sent to Coder	System	25 Mar 2021 22:52:32
User entered 'Ketamine'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:49
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:51
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:54
User entered '25-50'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:17:59
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:05
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:07
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:09
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:11
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:14
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:17
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:22
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:25
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User entered empty.	System	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User entered empty.	System	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:56
User entered empty.	System	25 Mar 2021 22:52:12

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:45
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: HYDROCORTISONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLU-CORTEF - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:54:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:54:04
Data point term sent to Coder	System	25 Mar 2021 22:53:33
User entered 'solu-cortef'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:49
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:52
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:18:56
User entered '50'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:12
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:46
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:52
User entered 'other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:58
User entered 'q 6-12 hours'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:03
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:05
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:08
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:10
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:13
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:15
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User entered empty.	System	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User entered empty.	System	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:07
User entered empty.	System	25 Mar 2021 22:53:20

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:29:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:29:21
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:20:31
Data point term sent to Coder	System	25 Mar 2021 22:54:34
User entered 'heparin'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:32
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:41
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:45
User entered '5000'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:49
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:55
User entered 'units'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:59
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:02
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:03
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:10
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:17
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:19
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:21
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:23
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User entered empty.	System	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User entered empty.	System	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:45
User entered empty.	System	25 Mar 2021 22:53:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:21
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:21:30
Data point term sent to Coder	System	25 Mar 2021 22:55:34
User entered 'fentanyl'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:32
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:34
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:36
User entered '50'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:21:39
User entered 'ug (ug)'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:22:50
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:22:55
User entered 'other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:22:58
User entered 'per hour'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:16
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:18
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:26
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:30
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:31
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:33
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:34
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User entered empty.	System	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User entered empty.	System	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:42
User entered empty.	System	25 Mar 2021 22:54:36

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 13:26:37
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 13:26:37
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:23:44
Data point term sent to Coder User entered 'epinephrine'	System (b) (4), (b) (6)	25 Mar 2021 22:55:34 25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:45
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:47
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:50
User entered '0.4'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:52
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:54
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:56
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:23:58
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:24:01
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:29:18
User entered 'submucosal injection'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:29:20
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:29:22
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:29:25
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:29:26
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:29:30
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User entered empty.	System	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User entered empty.	System	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:56
User entered empty.	System	25 Mar 2021 22:55:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPHEDRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:00
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:29:48
Data point term sent to Coder User entered 'ephedrine'	System	25 Mar 2021 22:56:35
	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:29:50
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:29:52
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:29:54
User entered '5-10'	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:29:57
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:29:58
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:01
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:06
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:08
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:10
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:13
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:16
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:23
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User entered empty.	System	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User entered empty.	System	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:06
User entered empty.	System	25 Mar 2021 22:56:00

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE HYDROCHLORIDE, PRODUCTSYNONYM: PRECEDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:44:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:44:44
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:30:33
Data point term sent to Coder	System	26 Mar 2021 13:30:24
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	26 Mar 2021 13:30:23
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	Carlton Griffin (b) (4)	26 Mar 2021 13:30:23
Data point term sent to Coder	System	26 Mar 2021 13:29:20
User entered 'PRECEDEX (Dexmedetomidine)' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	26 Mar 2021 13:29:12
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	26 Mar 2021 10:55:43
Data point term sent to Coder	System	25 Mar 2021 22:57:37

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'percedex'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:36
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:38
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:44
User entered '8-30'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:49
User entered 'ug (ug)'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:51
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:52
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:55
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:57
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:30:58
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:31:04
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:31:06
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:31:09
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:31:12
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:31:13
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User entered empty.	System	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User entered empty.	System	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:19
User entered empty.	System	25 Mar 2021 22:56:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:43:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: CALCIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:01:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:01:21
Data point term sent to Coder	System	25 Mar 2021 22:57:35
User entered 'calcium chloride'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:43:55
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:43:57
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:00
User entered '500'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:02
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:05
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:08
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:11
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:12
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:15
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:18
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:20
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:23
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:25
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:27
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User entered empty.	System	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User entered empty.	System	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:34
User entered empty.	System	25 Mar 2021 22:57:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: SOLUTIONS FOR PARENTERAL NUTRITION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:21:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:21:31
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:44:51
Data point term sent to Coder	System	25 Mar 2021 22:58:38
User entered 'total parenteral nutrition (TPN)'	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:56
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:44:58
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:04
User entered '56-60'	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:07
User entered 'mL (mL)'	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:08
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:10
User entered 'other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:12
User entered 'per hour'	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:17
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:19
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:26
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:28
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 22:58:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 22:58:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 22:58:20
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 22:58:10
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:30
User entered '24 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 22:58:20
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:35
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 22:58:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 22:58:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 22:58:20
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 22:58:10
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User entered empty.	System	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User entered empty.	System	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:26
User entered empty.	System	25 Mar 2021 22:58:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: LIPIDS NOS, PRODUCTSYNONYM: LIPIDS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 07:35:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 07:35:35
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:45:43
Data point term sent to Coder	System	25 Mar 2021 22:59:38
User entered 'Lipids 20%'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:46
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:48
User entered '50'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:49
User entered 'g (g)'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:52
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:45:55
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:46:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:46:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:46:24
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:46:32
User entered '22 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:46:36
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:46:40
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:46:41
User entered '24 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:46:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User entered '1'	System	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User entered '1'	System	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:46
User entered '804 (804)'	System	25 Mar 2021 22:58:57

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCONATE SODIUM;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE, PRODUCTSYNONYM: PLASMALYTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 23:00:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 23:00:33
Data point term sent to Coder	System	25 Mar 2021 22:59:39
User entered 'plasmalyte'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:08
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:09
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:12
User entered '70-125'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:14
User entered 'mL (mL)'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:17
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:19
User entered 'other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:23
User entered 'per hour'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:27
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:28
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:31
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:33
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:37
User entered '20 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:38
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User entered empty.	System	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User entered empty.	System	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:58
User entered empty.	System	25 Mar 2021 22:59:34

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 14:02:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 14:02:33
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:49:20
Data point term sent to Coder User entered 'Lasix'	System	25 Mar 2021 23:00:39
	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:22
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:24
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:27
User entered '40-80'	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:29
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:31
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:33
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:35
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:39
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:42
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:45
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:46
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:48
User entered '24 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:49
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User entered '1'	System	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User entered '1'	System	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:04
User entered '804 (804)'	System	25 Mar 2021 23:00:07

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:18:42
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 Mar 2021 11:18:42
Data point term sent to Coder	System	25 Mar 2021 23:01:40
User entered 'Potassium'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:50:01
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:51:32
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:51:36
User entered '40'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:51:39
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:51:43
User entered 'milliequivalents'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:51:51
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:51:53
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:51:55
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:51:57
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:51:59
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:01
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:02
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:04
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:06
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User entered empty.	System	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User entered empty.	System	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:10
User entered empty.	System	25 Mar 2021 23:01:04

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:18:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:18:43
Data point term sent to Coder	System	25 Mar 2021 23:01:40
User entered 'potassium'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:16
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:18
User entered '40'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:25
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:26
User entered 'milliequivalents'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:29
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:32
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:36
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:38
User entered '23 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:50
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:52
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:55
User entered '24 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:52:57
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User entered '1'	System	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User entered '1'	System	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:51
User entered '804 (804)'	System	25 Mar 2021 23:01:39

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: VITAMIN K, PRODUCT: PHYTOMENADIONE, PRODUCTSYNONYM: VITAMIN K1 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:30
Data point term sent to Coder	System	25 Mar 2021 23:02:41
User entered 'vitamin K1'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:08
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:10
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:18
User entered '10'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:21
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:25
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:29
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:42
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:46
User entered '20 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:49
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:55
User entered '20 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:53:57
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User entered empty.	System	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User entered empty.	System	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:18
User entered empty.	System	25 Mar 2021 23:02:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 15:44:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:44:33
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:54:40
Data point term sent to Coder User entered 'labetalol'	System (b) (4), (b) (6)	25 Mar 2021 23:03:42 25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:54:42
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:54:44
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:54:53
User entered '10'	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:54:55
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:54:57
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:55:00
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:55:02
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:55:04
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:55:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:55:08
User entered '20 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:55:10
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:55:31
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:55:44
User entered '20 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:55:46
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User entered '2'	System	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User entered '1'	System	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:38
User entered '804 (804)'	System	25 Mar 2021 23:02:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:55:55
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 23:04:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 23:04:32
Data point term sent to Coder	System	25 Mar 2021 23:03:42
User entered 'omnipaque'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:01
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:08
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:10
User entered '100'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:12
User entered 'mL (mL)'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:16
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:18
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:20
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:26
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:31
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:35
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:37
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:43
User entered '18 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:45
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User entered empty.	System	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User entered empty.	System	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:45
User entered empty.	System	25 Mar 2021 23:03:21

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:53
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 23:05:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 23:05:32
Data point term sent to Coder	System	25 Mar 2021 23:04:43
User entered 'omnipaque'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:55
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:57
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:56:59
User entered '100'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:06
User entered 'mL (mL)'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:08
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:10
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:12
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:20
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:25
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:30
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:32
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:34
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:57:36
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User entered empty.	System	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User entered empty.	System	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:51
User entered empty.	System	25 Mar 2021 23:03:59

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE, PRODUCTSYNONYM: DIFLUCAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:45:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:45:21
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:58:03
Data point term sent to Coder	System	25 Mar 2021 23:04:43
User entered 'diflucan'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:07
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:08
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:10
User entered '800'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:13
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:17
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:19
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:23
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:29
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:31
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:34
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:36
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:38
User entered '21 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:58:40
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User entered '1'	System	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User entered '1'	System	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:07:26
User entered '804 (804)'	System	25 Mar 2021 23:04:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 10:18:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 10:18:35
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:59:10
Data point term sent to Coder	System	25 Mar 2021 23:06:44
User entered 'D50'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:11
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:13
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:15
User entered 'UNK'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:21
User entered 'mL (mL)'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:26
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:29
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:30
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:34
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:36
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:39
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:41
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:43
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:59:46
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User entered empty.	System	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User entered empty.	System	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User entered empty.	System	25 Mar 2021 23:05:48

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:00:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: CALCIUM GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:02:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:02:08
Data point term sent to Coder	System	25 Mar 2021 23:06:48
User entered 'Calcium gluconate'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:00:43
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:00:45
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:00:46
User entered '2'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:03:45
User entered 'g (g)'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:03:48
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:03:49
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:03:51
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:03:52
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:03:54
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:03:56
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:03:57
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:03:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:00
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:02
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User entered empty.	System	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User entered empty.	System	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User entered empty.	System	25 Mar 2021 23:06:31

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN HUMAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 01:45:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 01:45:39
Data point term sent to Coder	System	25 Mar 2021 23:07:49
User entered '5% human albumin'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:14
User entered 'PERFORATED DUODENAL ULCER'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:16
User entered '25'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:19
User entered 'g (g)'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:20
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:22
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:38
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:40
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:04:47
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:05:01
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:05:03
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:05:06
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:05:08
User entered '19 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:05:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User entered empty.	System	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User entered empty.	System	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:27
User entered empty.	System	25 Mar 2021 23:07:03

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Mar 2021 16:53:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 16:53:23
Data point term sent to Coder	System	31 Mar 2021 16:52:00
User entered 'citalopram'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 16:51:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'panic disorder'	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '10'	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once daily (QD)'	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '27 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
Signature has been broken.	Carlton Griffin (b) (4)	21 Apr 2021 15:34:31
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	21 Apr 2021 15:34:31
	(b) (4)	
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
Signature has been broken.	Carlton Griffin (b) (4)	21 Apr 2021 15:34:31
	(b) (4)	
User entered '12 Apr 2021' reason for change: New Information	Carlton Griffin (b) (4)	21 Apr 2021 15:34:31
	(b) (4)	
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:51:35
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 16:51:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 16:51:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Mar 2021 16:51:35

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 06:58:34
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 Apr 2021 06:58:34
Data point term sent to Coder	System	31 Mar 2021 16:54:01
User entered 'packed red blood cells'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 16:53:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '1'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'unit'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'as needed (PRN)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '18 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:10
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:53:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:53:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:53:10

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Mar 2021 16:55:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 16:55:08
Data point term sent to Coder	System	31 Mar 2021 16:54:01
User entered 'lasix'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '80'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'q6h'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '25 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '26 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User entered empty.	System	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User entered empty.	System	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:41
User entered empty.	System	31 Mar 2021 16:53:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 14:19:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:19:38
Data point term sent to Coder	System	31 Mar 2021 16:55:02
User entered 'ketamine'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 16:54:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '50'	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 16:54:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '27 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '27 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:54:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:54:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:54:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:54:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 14:19:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:19:38
Data point term sent to Coder	System	31 Mar 2021 16:56:03
User entered 'ketamine'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 16:55:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '10-15'	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'as needed (PRN)'	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '29 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '29 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:55:29
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:55:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:55:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:55:29

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 11:04:21
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 Apr 2021 11:04:21
Data point term sent to Coder	System	31 Mar 2021 16:59:06
User entered 'heparin'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 16:58:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'unk'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'units'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'titrated'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 16:58:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '30 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '30 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 16:58:25
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:58:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:58:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:58:25

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: GLYCOPYRRONIUM BROMIDE, PRODUCTSYNONYM: ROBINUL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 08:34:30
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 Apr 2021 08:34:30
Data point term sent to Coder	System	31 Mar 2021 18:17:48
User entered 'robinul'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:17:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0.1'	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '29 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '29 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:17:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:17:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:17:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:17:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Mar 2021 18:20:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:20:09
Data point term sent to Coder	System	31 Mar 2021 18:18:53
User entered 'fentanyl'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:18:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '50'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'ug (ug)'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '3 times'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '30 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '30 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:18:44
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:18:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:18:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:18:44

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE HYDROCHLORIDE, PRODUCTSYNONYM: PRECEDEX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Mar 2021 18:21:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:21:11
Data point term sent to Coder	System	31 Mar 2021 18:19:54
User entered 'precedex'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:19:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0.9'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mcg/kg/hr'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '27 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '27 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:19:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:19:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:19:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:19:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE HYDROCHLORIDE, PRODUCTSYNONYM: PRECEDEX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Mar 2021 18:22:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:22:01
Data point term sent to Coder	System	31 Mar 2021 18:20:56
User entered 'precedex'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:20:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0.9'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mcg/kg/hr'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '29 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '29 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:15
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:20:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:20:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:20:15

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Mar 2021 18:22:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:22:02
Data point term sent to Coder	System	31 Mar 2021 18:20:55
User entered 'xanax'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:20:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0.25'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'as needed (PRN)'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '26 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:20:40
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:20:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:20:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:20:40

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM PHOSPHATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 10:11:33
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 Apr 2021 10:11:33
Data point term sent to Coder	System	31 Mar 2021 18:21:56
User entered 'sodium phosphate'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '15'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mmol'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '26 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '26 Mar 2021'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:21:11
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User entered empty.	System	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User entered empty.	System	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:14
User entered empty.	System	31 Mar 2021 18:21:11

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE, PRODUCTSYNONYM: MICRO K - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 08:26:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:26:42
Data point term sent to Coder	System	31 Mar 2021 18:21:56
User entered 'MicroK+'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '20'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'meq'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '26 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '26 Mar 2021'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:21:50
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User entered empty.	System	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User entered empty.	System	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:24
User entered empty.	System	31 Mar 2021 18:21:50

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE, PRODUCTSYNONYM: MICRO K - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 08:26:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:26:42
Data point term sent to Coder	System	31 Mar 2021 18:22:57
User entered 'microk+'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:22:19

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '20'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'meq'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '31 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '31 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:19
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:22:19

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:22:19

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:22:19

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:16:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:16:28
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:48:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:48:45
Data point term sent to Coder	System	31 Mar 2021 18:22:57
User entered 'magnesium sulfate'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '4'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '26 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '26 Mar 2021'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:22:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User entered empty.	System	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User entered empty.	System	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User entered empty.	System	31 Mar 2021 18:22:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:16:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:16:28
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:48:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:48:46
Data point term sent to Coder	System	31 Mar 2021 18:23:59
User entered 'magnesium sulfate'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:23:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '4'	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '31 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '31 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:23:32
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:23:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:23:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:23:32

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Mar 2021 18:26:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:26:08
Data point term sent to Coder	System	31 Mar 2021 18:24:59
User entered 'omnipaque'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:24:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '350'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once daily (QD)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '26 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '27 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:30
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 18:24:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 18:24:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Mar 2021 18:24:30

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL, PRODUCTSYNONYM: DIPRIVAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Mar 2021 18:26:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:26:08
Data point term sent to Coder	System	31 Mar 2021 18:25:00
User entered 'diprivan'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:24:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '30'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:24:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '27 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '27 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:24:56
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:24:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:24:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (116)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:24:56

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL, PRODUCTSYNONYM: DIPRIVAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Mar 2021 18:27:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:27:06
Data point term sent to Coder	System	31 Mar 2021 18:26:01
User entered 'diprivan'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:25:27

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '10-20'	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:25:27

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'as needed (PRN)'	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '29 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '29 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:25:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:25:27

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:25:27

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:25:27

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM PHOSPHATE DIBASIC - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 07:04:04
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 Apr 2021 07:04:04
Data point term sent to Coder	System	31 Mar 2021 18:27:03
User entered 'potassium phosphate'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:26:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '15'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mmol'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '31 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '31 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:05
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:26:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:26:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:26:05

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 07:08:33
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 Apr 2021 07:08:33
Data point term sent to Coder	System	31 Mar 2021 18:27:03
User entered 'prilosec'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:26:28

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '20'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:26:28

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'twice daily (BID)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '31 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:28
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Mar 2021 18:26:28

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 18:26:28

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Mar 2021 18:26:28

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Mar 2021 18:28:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:28:09
Data point term sent to Coder	System	31 Mar 2021 18:27:03
User entered 'versed'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:26:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '2'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '27 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '27 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:26:54
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:26:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:26:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:26:54

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Mar 2021 18:29:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:29:13
Data point term sent to Coder	System	31 Mar 2021 18:28:04
User entered 'versed'	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:27:27

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '2'	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:27:27

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '29 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '29 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:27:27
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:27:27

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:27:27

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:27:27

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: PLASMA, PRODUCTSYNONYM: FRESH FROZEN PLASMA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 18:30:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 18:30:15
Data point term sent to Coder	System	31 Mar 2021 18:29:06
User entered 'fresh frozen plasma'	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'I'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'unit'	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'once daily (QD)'	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '20 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '0'	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '21 Mar 2021'	(b) (4) Carlton Griffin (b) (4)	31 Mar 2021 18:28:08
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'No (N)'	Carlton Griffin (b) (4)	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User entered '1'	System	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User entered '1'	System	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:54
User entered '804 (804)'	System	31 Mar 2021 18:28:08

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 13:48:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 13:48:47
Data point term sent to Coder	System	08 Apr 2021 13:47:26
User entered 'lasix'	Carlton Griffin (b) (4) (b) (4)	08 Apr 2021 13:47:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'perforated duodenal ulcer'	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '40'	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '01 Apr 2021'	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '01 Apr 2021'	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	08 Apr 2021 13:47:23
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 13:47:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 13:47:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 13:47:23

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS, PRODUCT: AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE, PRODUCTSYNONYM: AMLODIPINE/BENAZEPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 13:49:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 13:49:52
Data point term sent to Coder	System	08 Apr 2021 13:48:36
User entered 'amlodipine/benazepril'	Carlton Griffin (b) (4) (b) (4)	08 Apr 2021 13:48:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'hypertension'	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '5/20'	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'once daily (QD)'	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '02 Apr 2021'	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	08 Apr 2021 13:48:09
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 13:48:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 13:48:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 13:48:09

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Apr 2021 15:38:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 15:38:30
Data point term sent to Coder	System	21 Apr 2021 15:35:51
User entered 'citalopram'	Carlton Griffin (b) (4) (b) (4)	21 Apr 2021 15:35:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	21 Apr 2021 15:35:47
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
User entered 'panic disorder'	Carlton Griffin (b) (4)	21 Apr 2021 15:35:47
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
User entered '20'	Carlton Griffin (b) (4)	21 Apr 2021 15:35:47
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	21 Apr 2021 15:35:47
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:42:02
User entered empty.	Carlton Griffin (b) (4) (b) (4)	21 Apr 2021 15:35:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
User entered 'once daily (QD)'	Carlton Griffin (b) (4)	21 Apr 2021 15:35:47
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:42:02
User entered empty.	Carlton Griffin (b) (4) (b) (4)	21 Apr 2021 15:35:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	21 Apr 2021 15:35:47
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	21 Apr 2021 15:35:47
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
User entered '13 Apr 2021'	Carlton Griffin (b) (4)	21 Apr 2021 15:35:47
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	21 Apr 2021 15:35:47
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	21 Apr 2021 15:35:47
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:42:02
User entered empty.	Carlton Griffin (b) (4) (b) (4)	21 Apr 2021 15:35:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	21 Apr 2021 15:35:47
	(b) (4)	

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 15:35:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 15:35:47

US3782014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 10 Jun 2021 09:45:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 15:35:47

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:45:10

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:50:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:10:51
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 15:22:07
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	09 Mar 2021 15:22:07
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:24:25
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	19 Feb 2021 20:37:51

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:22:29

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'arthroplasty total knee - right'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:22:29

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:22:29

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:22:29

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:12:03
User entered '18 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 16:35:25

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:12:08
User entered 'exploratory laparotomy with duodenal ulcer cauterization'	(b) (4), (b) (6)	24 Mar 2021 16:35:25

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:12:09
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	24 Mar 2021 16:35:25

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:38:42
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:12:11
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 16:35:25

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:45:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered '30 Mar 2021'	Carlton Griffin (b) (4)	31 Mar 2021 18:41:07
	(b) (4)	

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:45:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'gastroduodenal artery embolization'	Carlton Griffin (b) (4)	31 Mar 2021 18:41:07
	(b) (4)	

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:45:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
	(b) (4)	
User entered 'Adverse Event (AE)'	Carlton Griffin (b) (4)	31 Mar 2021 18:41:07
	(b) (4)	

US3782014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:45:10

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:05:01
User entered empty.	Carlton Griffin (b) (4) (b) (4)	31 Mar 2021 18:41:07

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'USA-US125-2021-MRNA-1273-P301000003'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:56
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Spyros'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Kalams'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '1161 21st Avenue South'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Nashville'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '37232'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:53
User entered 'US'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 19:13:16
User entered '7'	System	13 Apr 2021 14:11:38
User entered '6'	System	09 Apr 2021 13:21:28
User entered '5'	System	05 Apr 2021 15:07:03
User entered '4'	System	25 Mar 2021 13:37:25
User entered '3'	System	23 Mar 2021 18:52:00
User entered '2'	System	15 Mar 2021 18:56:14
User entered '1'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'USA-US125-2021-MRNA-1273-P301000003'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:56
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Spyros'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Kalams'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '1161 21st Avenue South'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Nashville'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '37232'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:53
User entered 'US'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 19:13:16
User entered '7'	System	13 Apr 2021 14:11:38
User entered '6'	System	09 Apr 2021 13:21:28
User entered '5'	System	05 Apr 2021 15:07:03
User entered '4'	System	25 Mar 2021 13:37:25
User entered '3'	System	23 Mar 2021 18:52:00
User entered '2'	System	15 Mar 2021 18:56:14
User entered '1'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
User entered '15/Mar/2021 09:51'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:10

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)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:53
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'USA-US125-2021-MRNA-1273-P301000003'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:56
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Spyros'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Kalams'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '1161 21st Avenue South'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Nashville'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '37232'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:53
User entered 'US'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 19:13:16
User entered '7'	System	13 Apr 2021 14:11:38
User entered '6'	System	09 Apr 2021 13:21:28
User entered '5'	System	05 Apr 2021 15:07:03
User entered '4'	System	25 Mar 2021 13:37:25
User entered '3'	System	23 Mar 2021 18:52:00
User entered '2'	System	15 Mar 2021 18:56:14
User entered '1'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:45:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
User entered '15/Mar/2021 13:56'	System	15 Mar 2021 18:56:14

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:45:10

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)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:21:30
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 18:56:14

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'USA-US125-2021-MRNA-1273-P301000003'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:56
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Spyros'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Kalams'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '1161 21st Avenue South'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Nashville'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '37232'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:53
User entered 'US'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 19:13:16
User entered '7'	System	13 Apr 2021 14:11:38
User entered '6'	System	09 Apr 2021 13:21:28
User entered '5'	System	05 Apr 2021 15:07:03
User entered '4'	System	25 Mar 2021 13:37:25
User entered '3'	System	23 Mar 2021 18:52:00
User entered '2'	System	15 Mar 2021 18:56:14
User entered '1'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:45:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:50:19
User entered '23/Mar/2021 14:51'	System	23 Mar 2021 18:52:00

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:45:10

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)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:50:20
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 18:52:04
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 18:52:00

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'USA-US125-2021-MRNA-1273-P301000003'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:56
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Spyros'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Kalams'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '1161 21st Avenue South'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Nashville'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '37232'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:53
User entered 'US'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 19:13:16
User entered '7'	System	13 Apr 2021 14:11:38
User entered '6'	System	09 Apr 2021 13:21:28
User entered '5'	System	05 Apr 2021 15:07:03
User entered '4'	System	25 Mar 2021 13:37:25
User entered '3'	System	23 Mar 2021 18:52:00
User entered '2'	System	15 Mar 2021 18:56:14
User entered '1'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:45:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:50:43
User entered '25/Mar/2021 09:37'	System	25 Mar 2021 13:37:25

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:45:10

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)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:07:07
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:50:34
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 13:37:25

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'USA-US125-2021-MRNA-1273-P301000003'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:56
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Spyros'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Kalams'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '1161 21st Avenue South'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Nashville'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '37232'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:53
User entered 'US'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 19:13:16
User entered '7'	System	13 Apr 2021 14:11:38
User entered '6'	System	09 Apr 2021 13:21:28
User entered '5'	System	05 Apr 2021 15:07:03
User entered '4'	System	25 Mar 2021 13:37:25
User entered '3'	System	23 Mar 2021 18:52:00
User entered '2'	System	15 Mar 2021 18:56:14
User entered '1'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:45:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
User entered '05/Apr/2021 11:07'	(b) (4) System	05 Apr 2021 15:07:03

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:45:10

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)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 15:07:07
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 15:07:03

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'USA-US125-2021-MRNA-1273-P301000003'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:56
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Spyros'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Kalams'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '1161 21st Avenue South'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Nashville'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '37232'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:53
User entered 'US'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 19:13:16
User entered '7'	System	13 Apr 2021 14:11:38
User entered '6'	System	09 Apr 2021 13:21:28
User entered '5'	System	05 Apr 2021 15:07:03
User entered '4'	System	25 Mar 2021 13:37:25
User entered '3'	System	23 Mar 2021 18:52:00
User entered '2'	System	15 Mar 2021 18:56:14
User entered '1'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:45:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
User entered '09/Apr/2021 13:21'	(b) (4) System	09 Apr 2021 13:21:28

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:45:10

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)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:11:52
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 13:21:28

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'USA-US125-2021-MRNA-1273-P301000003'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:56
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Spyros'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Kalams'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '1161 21st Avenue South'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Nashville'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '37232'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:53
User entered 'US'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 19:13:16
User entered '7'	System	13 Apr 2021 14:11:38
User entered '6'	System	09 Apr 2021 13:21:28
User entered '5'	System	05 Apr 2021 15:07:03
User entered '4'	System	25 Mar 2021 13:37:25
User entered '3'	System	23 Mar 2021 18:52:00
User entered '2'	System	15 Mar 2021 18:56:14
User entered '1'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:45:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
User entered '13/Apr/2021 10:11'	(b) (4) System	13 Apr 2021 14:11:38

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:45:10

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)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:02
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 14:11:52
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 14:11:38

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'USA-US125-2021-MRNA-1273-P301000003'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Yes (Y)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:56
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'No (N)'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Spyros'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Kalams'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '1161 21st Avenue South'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered 'Nashville'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:51:45
User entered '37232'	System	15 Mar 2021 14:51:24

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:05:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:21:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:53
User entered 'US'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 19:13:16
User entered '7'	System	13 Apr 2021 14:11:38
User entered '6'	System	09 Apr 2021 13:21:28
User entered '5'	System	05 Apr 2021 15:07:03
User entered '4'	System	25 Mar 2021 13:37:25
User entered '3'	System	23 Mar 2021 18:52:00
User entered '2'	System	15 Mar 2021 18:56:14
User entered '1'	System	15 Mar 2021 14:51:51

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:45:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	30 Apr 2021 16:24:31
User entered '29/Apr/2021 12:13'	(b) (4) System	29 Apr 2021 19:13:16

US3782014

Folder: SAE USA-US125-2021-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:45:10

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)
User signature succeeded.	Spyros Kalams (b) (4)	30 Apr 2021 16:24:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:13:16