EudraCT Results Form

Trial Information

A. Trial Identification

Full title of the trial

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of SEP-4199 for the Treatment of Major Depressive Episode Associated with Bipolar I Disorder (Bipolar I Depression)

EudraCT Number	2018-000103-16
Sponsor Protocol Code	SEP380-201
ISRCTN Number	
ClinicalTrials.gov identifier (NCT Number)	NCT03543410
WHO Universal Trial Reference Number (UTRN)	

Other trial identifiers

Other identifier name	Other identifier code
Japan jRCT2031220302	

B. Paediatric Regulatory Details

Is the trial part of an agreed Paediatric Investigation Plan (PIP)?	No
Paediatric Investigation Plan(s) **Enter the EMA paediatric Investigation plan number(s) (PIP) using the following format: EMEA-999999-PIP99-99, where 9 is a number (0-9 inclusive).**	EMA Decision number of Paediatric Investigation Plan(s)
Does Article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does Article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

C. Sponsor Details

Name	Scientific Contact	Public Contact
Organisation name: Sunovion Pharmaceuticals Inc. **Street Address:** 84 Waterford Drive **Town/City:** Marlboro **Country:** United States **Post code:** 01752	**Functional contact name:** CNS Medical Director **Organisation name:** Sunovion Pharmaceuticals Inc. **Country code:** 01 **Phone Number:** 18665036351 **Email address:** ClinicalTrialDisclosure@sunovion.com	**Functional contact name:** CNS Medical Director **Organisation name:** Sunovion Pharmaceuticals Inc. **Country code:** 01 **Phone Number:** 18665036351 **Email address:** ClinicalTrialDisclosure@sunovion.com

D. Results Analysis Stage

Analysis Stage	Final
Date of Interim/Final Analysis	2020-04-23
Is this the analysis of the primary completion data?	Yes
Primary completion date	2020-04-23
Global end of trial date reached?	Yes
Global end of trial date	2020-04-23
Was the trial ended prematurely?	No

E. General Information About Trial

Main objective of Trial

To evaluate the efficacy of SEP-4199 200 mg/day and 400 mg/day compared with

placebo for major depressive episode associated with bipolar I disorder (diagnosed by

DSM-5 criteria) as measured by Montgomery-Asberg Depression Rating Scale

(MADRS) total score

The actual start date of recruitment must be the current date or a date in the past.

Actual Start date of Recruitment	2018-06-26
Long term follow up planned?	

No

Long term follow up rationale

Long term follow up duration

Independent data monitoring committee (IDMC) involvement? No

Protection of trial subjects

The study was conducted according to the protocol, ICH Good Clinical Practice (GCP), ICH guidelines, and the ethical principles that have their origin in the Declaration of Helsinki.

Background therapy

Evidence of comparator(s)

F. Population of Trial Subjects

Subject number per country

Country	Actual number of subjects enrolled
Bulgaria	43
Japan	49
Poland	11
Russian Federation	46
Serbia	63
Slovakia	19
Ukraine	67
United States	43
Total: worldwide	341
Total: EEA	73

Age group breakdown for Trial

Age Range	Actual number of subjects enrolled
In Utero	0
Pre-term newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Age Range	Actual number of subjects enrolled
Adolescents (12-17 years)	0
Adults (18-64 years)	339
From 65 years	
Elderly (From 65-84 years)	2
Elderly 85 years and over	0
Total	341

Subject Disposition

Subject Disposition

Recruitment Details

Pre-Assignment

Screening Details

A total 344 subjects were randomized in this study. Three subjects, who were randomized but never received any dose of study medication, were not included in the reporting.

Pre-Assignment Period

Periods

Overall Study (overall period)

Blinding Implementation Details:

Is this the baseline period? true

Mutually exclusive arms? true

Non-Mutual Exclusive Number of Subjects:

Allocation: Randomised-Controlled

Blinding Used: Double-blind

Roles Blinded: Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Started

SEP-4199 200 mg (Experimental) SEP-4199 200 mg/day (supplied in two 100mg tablets)	SEP-4199 400 mg (Experimental) SEP-4199 400 mg/day (supplied in two 200mg tablets)	Placebo (Placebo) Placebo (supplied in two tablets/day)	Total *(=sum per row)*

113	114	114	341 *(calculated)*

Completed

SEP-4199 200 mg (Experimental) SEP-4199 200 mg/day (supplied in two 100mg tablets)	SEP-4199 400 mg (Experimental) SEP-4199 400 mg/day (supplied in two 200mg tablets)	Placebo (Placebo) Placebo (supplied in two tablets/day)	Total *(=sum per row)*
92	101	99	292 *(calculated)*

Reasons Not Completed

Adverse event, non-fatal

SEP-4199 200 mg (Experimental) SEP-4199 200 mg/day (supplied in two 100mg tablets)	SEP-4199 400 mg (Experimental) SEP-4199 400 mg/day (supplied in two 200mg tablets)	Placebo (Placebo) Placebo (supplied in two tablets/day)	Total *(=sum per row)*
10	8	2	20 *(calculated)*

Lack of Efficacy

SEP-4199 200 mg (Experimental) SEP-4199 200 mg/day (supplied in two 100mg tablets)	SEP-4199 400 mg (Experimental) SEP-4199 400 mg/day (supplied in two 200mg tablets)	Placebo (Placebo) Placebo (supplied in two tablets/day)	Total *(=sum per row)*
0	1	0	1 *(calculated)*

Lost to Follow-up

SEP-4199 200 mg (Experimental) SEP-4199 200 mg/day (supplied in two 100mg tablets)	SEP-4199 400 mg (Experimental) SEP-4199 400 mg/day (supplied in two 200mg tablets)	Placebo (Placebo) Placebo (supplied in two tablets/day)	Total *(=sum per row)*
0	1	0	1 *(calculated)*

Consent withdrawn by subject

SEP-4199 200 mg (Experimental) SEP-4199 200 mg/day (supplied in two 100mg tablets)	SEP-4199 400 mg (Experimental) SEP-4199 400 mg/day (supplied in two 200mg tablets)	Placebo (Placebo) Placebo (supplied in two tablets/day)	Total *(=sum per row)*
5	2	8	15 *(calculated)*

Protocol Violation

SEP-4199 200 mg (Experimental) SEP-4199 200 mg/day (supplied in two 100mg tablets)	SEP-4199 400 mg (Experimental) SEP-4199 400 mg/day (supplied in two 200mg tablets)	Placebo (Placebo) Placebo (supplied in two tablets/day)	Total *(=sum per row)*
0	1	0	1 *(calculated)*

Other Reason: Due to COVID-19

SEP-4199 200 mg (Experimental) SEP-4199 200 mg/day (supplied in two 100mg tablets)	SEP-4199 400 mg (Experimental) SEP-4199 400 mg/day (supplied in two 200mg tablets)	Placebo (Placebo) Placebo (supplied in two tablets/day)	Total *(=sum per row)*
4	0	2	6 *(calculated)*

Other Reason: NON-COMPLIANCE WITH STUDY DRUG

SEP-4199 200 mg (Experimental) SEP-4199 200 mg/day (supplied in two 100mg tablets)	SEP-4199 400 mg (Experimental) SEP-4199 400 mg/day (supplied in two 200mg tablets)	Placebo (Placebo) Placebo (supplied in two tablets/day)	Total *(=sum per row)*
0	0	2	2 *(calculated)*

Other Reason: Not Due to COVID-19

SEP-4199 200 mg (Experimental) SEP-4199 200 mg/day (supplied in two 100mg tablets)	SEP-4199 400 mg (Experimental) SEP-4199 400 mg/day (supplied in two 200mg tablets)	Placebo (Placebo) Placebo (supplied in two tablets/day)	Total *(=sum per row)*
2	0	1	3 *(calculated)*

Reasons Joined

Products

Arm	Product Name	Product Code	Product Other Name	Dosage and Administration Details	Pharmaceutical Forms	Routes of Administration
SEP-4199 200 mg	SEP-4199			200 mg/day (supplied in two 100mg tablets)	Tablet	Oral use
SEP-4199 400 mg	SEP-4199			400 mg /day (supplied in two tablets)	Tablet	Oral use
Placebo	Placebo			supplied in two tablets	Tablet	Oral use

Baseline Characteristics

Baseline Characteristics Information

The baseline Period is : Overall Study

How are baseline characteristics being reported?

Per Arm in the baseline period

Subject Analysis Sets

Reporting Groups

Reporting Group Title	Number of subjects	Description	Options
SEP-4199 200 mg	113	SEP-4199 200 mg/day (supplied in two 100mg tablets)	
SEP-4199 400 mg	114	SEP-4199 400 mg/day (supplied in two 200mg tablets)	
Placebo	114	Placebo (supplied in two tablets/day)	

Age Characteristics

Title: Age Categorical

Description:

Unit: Participants

Reporting Group Values	SEP-4199 200 mg	SEP-4199 400 mg	Placebo	Total
Overall number of baseline subjects	113	114	114	341 (calculated)
<=18 years	1	1	1	3
Between 18 and 65 years	112	111	113	336
>=65 years	0	2	0	2
Total	113 (calculated)	114 (calculated)	114 (calculated)	341 (calculated)

Title: Age Continuous

Description:

Unit: Years

Central Tendency Type: Arithmetic Mean

Dispersion Type: Standard Deviation

Reporting Group Values	SEP-4199 200 mg		SEP-4199 400 mg		Placebo	
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
Unit of measure (Years)	42	11.65	44.4	12.72	43.3	12.10

Gender Characteristics

Title: Gender, Male/Female

Description:

Unit: Participants

Reporting Group Values	SEP-4199 200 mg	SEP-4199 400 mg	Placebo	Total
Overall number of baseline subjects	113	114	114	341
Female	69	76	64	209
Male	44	38	50	132

Study Categorical Characteristics

Title: Age, Customized

Description:

Unit: Participants

Reporting Group Values	SEP-4199 200 mg	SEP-4199 400 mg	Placebo	Total
Overall number of baseline subjects	113	114	114	341 (calculated)
18-64 years	113	112	114	339
>=65 years	0	2	0	2

Title: Race (NIH/OMB)

Description:

Unit: Participants

Reporting Group Values	SEP-4199 200 mg	SEP-4199 400 mg	Placebo	Total
Overall number of baseline subjects	113	114	114	341 (calculated)
American Indian or Alaska Native	1	1	0	2
Asian	16	16	17	49
Black or African American	6	8	8	22
More than one race	0	0	0	0
Native Hawaiian or Other Pacific Islander	1	2	1	4
Unknown or Not Reported	0	0	0	0
White	89	87	88	264

Title: Ethnicity (NIH/OMB)

Description:

Unit: Participants

Reporting Group Values	SEP-4199 200 mg	SEP-4199 400 mg	Placebo	Total
Overall number of baseline subjects	113	114	114	341 (calculated)

Hispanic or Latino	3	3	2	8
Not Hispanic or Latino	110	109	112	331
Unknown or Not Reported	0	2	0	2

Title: Country Name

Description:

Unit: Participants

Reporting Group Values	SEP-4199 200 mg	SEP-4199 400 mg	Placebo	Total
Overall number of baseline subjects	113	114	114	341 (calculated)
Bulgaria	11	10	22	43
Japan	16	16	17	49
Poland	5	1	5	11
Russia	18	20	8	46
Serbia	19	26	18	63
Slovakia	8	5	6	19
Ukraine	22	20	25	67
United States	14	16	13	43

Title: Region of Enrollment

Description:

Unit: Participants

Reporting Group Values	SEP-4199 200 mg	SEP-4199 400 mg	Placebo	Total
Overall number of baseline subjects	113	114	114	341 (calculated)
Europe	83	82	84	249
Japan	16	16	17	49
United States	14	16	13	43

Title: Baseline BMI Category

Description:

Unit: Participants

Reporting Group Values	SEP-4199 200 mg	SEP-4199 400 mg	Placebo	Total
Overall number of baseline subjects	113	114	114	341 (calculated)

< 18.5 kg/m2	0	3	0	3
18.5 - <25.0 kg/m2	51	50	45	146
25.0 - <30.0 kg/m2	42	33	40	115
>=30.0 kg/m2	20	28	29	77

Study Continuous Characteristics

Title: Baseline Weight (kg)

Description:

Unit: kg

Central Tendency Type: Arithmetic Mean

Dispersion Type: Standard Deviation

Reporting Group Values	SEP-4199 200 mg		SEP-4199 400 mg		Placebo	
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
Unit of measure (kg)	75.3	14.47	74.8	16.19	77.5	16.59

Title: Baseline BMI (kg/m^2)

Description:

Unit: kg/m^2

Central Tendency Type: Arithmetic Mean

Dispersion Type: Standard Deviation

Reporting Group Values	SEP-4199 200 mg		SEP-4199 400 mg		Placebo	
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
Unit of measure (kg/m^2)	26.2	4.53	26.6	4.91	27	4.94

Title: Baseline MADRS Total Score

Description: Measure Description: MADRS is a clinician-rated assessment of the subject's level of depression. The measure contains 10 items that measure apparent and reported sadness, inner tension, reduced sleep and appetite, difficulty concentrating, lassitude, inability to feel, and pessimistic and suicidal thoughts, each ranging from 0 to 6. The MADRS total score ranges from 0 to 60, with higher scores indicating increased depressive symptoms

Unit: units on a scale

Central Tendency Type: Arithmetic Mean

Dispersion Type: Standard Deviation

Reporting Group Values	SEP-4199 200 mg		SEP-4199 400 mg		Placebo	
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
Unit of measure (units on a scale)	33.5	5.77	33.8	5.63	34.1	5.35

Title: Baseline CGI-BP-S Depression Score

Description: Measure Description: Clinical Global Impressions - Severity: Bipolar Version (CGI-BP-S) score (depression) is a single value, clinician-rated assessment of illness severity, and 7-point scale with range from 1 = normal, not at all ill; 2 = borderline mentally ill; 3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill; 7 = among the most extremely ill subjects. A higher score is associated with greater illness severity.

Unit: units on a scale

Central Tendency Type: Arithmetic Mean

Dispersion Type: Standard Deviation

Reporting Group Values	SEP-4199 200 mg		SEP-4199 400 mg		Placebo	
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
Unit of measure (units on a scale)	4.8	0.66	4.8	0.65	4.9	0.70

End Points

Reporting Groups

Periods	Arms
Overall Study (overall period)	SEP-4199 200 mg
	SEP-4199 400 mg
	Placebo

End Points

Primary: Change from Baseline in Montgomery-Asberg Depression Rating Scale (MADRS) total score at Week 6

Countable or measurable?	Measurable
Description:	MADRS is a clinician-rated assessment of the subject's level of depression. The measure contains 10 items that measure apparent and reported sadness, inner tension, reduced sleep and appetite, difficulty concentrating, lassitude, inability to feel, and pessimistic and suicidal thoughts, each ranging from 0 to 6. The MADRS total score ranges from 0 to 60, with higher scores indicating increased depressive symptoms
Time Frame:	6 Weeks
Measure Type:	Least Squares Mean
Precision/Dispersion Type:	Standard Error
Units:	units on a scale
Percentage:	

Arm Reporting Groups						
	Overall Study SEP-4199 200 mg		**Overall Study SEP-4199 400 mg**		**Overall Study Placebo**	
Number of subjects that started the Arm:	113		114		114	
Number of Subjects Analyzed:	96		97		96	
Comment: (The comment is mandatory when the number of subjects analysed is zero)	The analysis population was the ITT population, excluding subjects from Japan Region		The analysis population was the ITT population, excluding subjects from Japan Region		The analysis population was the ITT population, excluding subjects from Japan Region	
	Least Squares Mean	Standard Error	Least Squares Mean	Standard Error	Least Squares Mean	Standard Error
	-19.485	1.226	-19.324	1.182	-16.196	1.231

Statistical Analysis	
Reporting Groups	
Overall Study Arm: SEP-4199 200 mg	
Arm: Placebo	
Subject Analysis Groups	
Nothing selected	
Statistical Analysis Details	
Analysis Title	SEP-4199 200mg and Placebo

Analysis Description	
Analysis Comment	
Analysis Specification	Pre-specified
Analysis Type	
Subjects in this analysis	192
Statistical Test of Hypothesis	
P-Value Comparator	=
P-Value	0.044
P-Value Comment	nominal p-value
Method	Mixed Models Analysis
Parameter Estimate	
Parameter Type	Mean Difference (Final Values)
Point Estimate	-3.290
% Confidence Interval	95
Number of sides	2-Sided
Lower Limit	-6.489
Upper Limit	-0.090
Variability Estimate	Standard Error of the Mean
Dispersion Value	1.625

Statistical Analysis	
Reporting Groups	
Arm: SEP-4199 400 mg	
Arm: Placebo	
Subject Analysis Groups	
Nothing selected	
Statistical Analysis Details	
Analysis Title	SEP-4199 400mg and Placebo
Analysis Description	
Analysis Comment	
Analysis Specification	Pre-specified
Analysis Type	
Subjects in this analysis	193
Statistical Test of Hypothesis	
P-Value Comparator	=

P-Value	0.051
P-Value Comment	nominal p-value
Method	Mixed Models Analysis
Parameter Estimate	
Parameter Type	Mean Difference (Final Values)
Point Estimate	-3.128
% Confidence Interval	95
Number of sides	2-Sided
Lower Limit	-6.273
Upper Limit	0.017
Variability Estimate	Standard Error of the Mean
Dispersion Value	1.597

Secondary: Change from baseline in global severity assessed by the Clinical Global Impressions – Severity: Bipolar version (CGI-BP-S) score (depression) at Week 6

Countable or measurable? Measurable

Description: Clinical Global Impressions – Severity: Bipolar Version (CGI-BP-S) score (depression) is a single value, clinician-rated assessment of illness severity, and 7-point scale with range from 1 = normal, not at all ill; 2 = borderline mentally ill; 3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill; 7 = among the most extremely ill subjects. A higher score is associated with greater illness severity.

Time Frame: 6 Weeks

Measure Type: Least Squares Mean

Precision/Dispersion Type: Standard Error

Units: units on a scale

Percentage:

Arm Reporting Groups						
	Overall Study SEP-4199 200 mg		Overall Study SEP-4199 400 mg		Overall Study Placebo	
Number of subjects that started the Arm:	113		114		114	
Number of Subjects Analyzed:	96		97		96	
Comment: (The comment is mandatory when the number of subjects analysed is zero)	The analysis population was the ITT population, excluding subjects from Japan Region		The analysis population was the ITT population, excluding subjects from Japan Region		The analysis population was the ITT population, excluding subjects from Japan Region	
	Least Squares Mean	Standard Error	Least Squares Mean	Standard Error	Least Squares Mean	Standard Error

	-2.020	0.144	-1.958	0.138	-1.739	0.144

Statistical Analysis	
Reporting Groups	
Overall Study Arm: SEP-4199 200 mg	
Arm: Placebo	
Subject Analysis Groups	
Nothing selected	
Statistical Analysis Details	
Analysis Title	SEP-4199 200mg and Placebo
Analysis Description	
Analysis Comment	
Analysis Specification	Pre-specified
Analysis Type	
Subjects in this analysis	192
Statistical Test of Hypothesis	
P-Value Comparator	=
P-Value	0.143
P-Value Comment	nominal p-value
Method	Mixed Models Analysis
Parameter Estimate	
Parameter Type	Mean Difference (Final Values)
Point Estimate	-0.281
% Confidence Interval	95
Number of sides	2-Sided
Lower Limit	-0.658
Upper Limit	0.095
Variability Estimate	Standard Error of the Mean
Dispersion Value	0.191

Statistical Analysis
Reporting Groups
Arm: SEP-4199 400 mg

Arm: Placebo	
Subject Analysis Groups	
Nothing selected	
Statistical Analysis Details	
Analysis Title	SEP-4199 400mg and Placebo
Analysis Description	
Analysis Comment	
Analysis Specification	Pre-specified
Analysis Type	
Subjects in this analysis	193
Statistical Test of Hypothesis	
P-Value Comparator	=
P-Value	0.243
P-Value Comment	nominal p-value
Method	Mixed Models Analysis
Parameter Estimate	
Parameter Type	Mean Difference (Final Values)
Point Estimate	-0.219
% Confidence Interval	95
Number of sides	2-Sided
Lower Limit	-0.588
Upper Limit	0.150
Variability Estimate	Standard Error of the Mean
Dispersion Value	0.187

Adverse Events

Adverse Events

Adverse Events Information

Timeframe for adverse event reporting

Adverse events were untoward medical occurrences that occurred on or after the first dose of study medication.

Up to 7 weeks

Adverse events reporting additional description

Adverse events were untoward medical occurrences that occurred on or after the first dose of study medication.

Assessment Type	Systematic
Frequency threshold for reporting non-serious adverse events:	5
Dictionary name	MedDRA
Dictionary name - if other	
Dictionary version	19.1

Adverse Events Reporting Groups

Reporting Group Totals	**SEP-4199 200 mg** SEP-4199 200 mg/day (supplied in two 100mg tablets)	**SEP-4199 400 mg** SEP-4199 400 mg/day (supplied in two 200mg tablets)	**Placebo** Placebo (supplied in two tablets/day)
Total # Subjects Exposed	113	114	114
Total # Subjects Affected by Serious Adverse Events	1	0	1
Total # Subjects Affected by Non Serious Adverse Events	21	23	29
Total # of Deaths (all causes)	0	0	0
Total # of Deaths Resulting From Adverse Events			

Serious Adverse Events

Reporting Groups:	**SEP-4199 200 mg**	**SEP-4199 400 mg**	**Placebo**
Injury, poisoning and procedural complications			
Foot fracture *Systematic*			
# of subjects affected	0	0	1
# of subjects exposed	113	114	114
# of occurrences (all)	0	0	1
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Nervous system disorders
Ischaemic stroke *Systematic*

# of subjects affected	1	0	0
# of subjects exposed	113	114	114
# of occurrences (all)	1	0	0
# of occurrences causally related to treatment	1	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Non Serious Adverse Events

Threshold for non-serious adverse event reporting is: 5%

Reporting Groups:	**SEP-4199 200 mg**	**SEP-4199 400 mg**	**Placebo**
Infections and infestations			
Nasopharyngitis *Systematic*			
# of subjects affected	4	4	6
# of subjects exposed	113	114	114
# of occurrences (all)	4	4	6

Investigations			
Electrocardiogram QT prolonged *Systematic*			
# of subjects affected	0	9	0
# of subjects exposed	113	114	114
# of occurrences (all)	0	9	0

Nervous system disorders			
Headache *Systematic*			
# of subjects affected	11	3	13
# of subjects exposed	113	114	114
# of occurrences (all)	12	3	16

Psychiatric disorders			
Anxiety *Systematic*			
# of subjects affected	1	2	7

# of subjects exposed	113	114	114
# of occurrences (all)	2	5	7

Insomnia *Systematic*			
# of subjects affected	5	5	7
# of subjects exposed	113	114	114
# of occurrences (all)	6	6	9

More Information

More Information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Amendment Date	Description

Interruptions (globally)

For any interruption, the restart date must not be before the interruption date.

Were there any global interruptions to the trial? No

Interruption Date	Description	Restart Date

Limitations and caveats

Limitations and caveats applicable to this summary of the results

Online References

Provide identifiers to retrieve publications of interest in regards to the results of this clinical trial. **Enter PubMed Identifier (PMID)**

CTIS

Data fields displayed on this tab are specific to CTIS and are not included in EudraCT Results Submissions.

CTIS

Additional Results Analysis Information

Additional Information about the clinical trial