



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU Clinical Trial Register and EudraCT

PCWP-HCPWG Joint Meeting

Presented by: Ana Rodriguez
Head of Section, Clinical and Non-Clinical Compliance

An agency of the European Union





Agenda

EU-CTR and EudraCT

- General update
- EudraCT V9 Results Simple forms



General Update: EU Clinical Trials Register

- Launched & available to the public since March 2011
- Contains trials that include at least one clinical site in the EEA and trials conducted outside of the EEA when part of a Paediatric Investigative Plan (PIP)
- Possibility to search for information on any paediatric clinical trial, any adult clinical trial (except Phase 1) and any trial listed in a Paediatric Investigation Plan (PIP)
- The register, available on the WHO ICTRP platform, is a **primary** registry in the WHO network: wider access and benefit to EU researchers



General Update: EU Clinical Trials Register

The following lists are to be updated twice a year if an update is necessary:

- Patient/consumer organisations
- Healthcare professionals' organisations

The Agency is currently gathering feedback from sponsor organisations to update the Sponsor Contact Information Document.



Statistics in EudraCT and in the Public Register

Number of clinical trials in EudraCT: around 36,485

Number of clinical trials in the Public Register:
19,891

Of which 2,614 trials in subjects less than 18 years

Not published (*as per EU guidance*):

- trials in early phase of development (Phase 1)
- trials not approved by member states



Clinical Trials & Results in EudraCT

- The commission guideline on the posting and publication of results-related information was published in Oct 2012
- The database, that will allow the sponsors to provide the trial results directly in EudraCT, will be launched in Q4 this year
- In the register, the results are to be available within 6 months of the end of the trial for paediatric trials and 12 months for all other trials
- Strong collaboration with the US National Institute of Health (NIH) on the database data model



EudraCT V9 Results Simple forms: What is it?

- The document has been published by the European Commission in January 2013. It provides the list of the fields that can be viewed when reviewing the results of a clinical trial.
- It allows sponsors to provide a summary of the results in a structured data format (regardless the phase of development, the therapeutic area or the population studied)
- Note that this list is subject to minor changes and will be amended in a nearer future
- Results may be displayed in EU Clinical Trials register in a different visual representation



Format of the data fields of result-related information on clinical trial

http://ec.europa.eu/health/files/eudralex/vol-10/2013_01_22_tg_en.pdf



Screenshots



Clinical Trial Results - contents:

Trial information:

- Study identification
- Identifiers
- Sponsor details
- Paediatric regulatory details
- Result analysis stage
- General Information about the trial
- Population of trial subjects with actual number of subjects included in the trial

Subject disposition:

- Recruitment
- Pre-assignment Period
- Post Assignment Periods

Baseline Characteristics:

- Baseline Characteristics (Required) Age
- Baseline Characteristics (Required) Gender
- Baseline Characteristics (Optional) Study Specific Characteristic

End Points:

- Endpoint definitions
- End Point #1
 - Statistical Analyses
- End Point #2,
 - Statistical Analyses
- etc

Adverse Events:

- Adverse events information
- Adverse event reporting group
- Serious Adverse Events
- Non-serious adverse event

More Information:

- Global Substantial Amendments
- Global Interruptions and re-starts
- Limitations & Caveats

***Trial information form******EMA******Title of trial***

Full Title of the trial	
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Trial Identifiers

EudraCT Number 		Sponsor Protocol Code	
Other Trial Identifiers			
Other Identifier name	ISRCTN Number	NCT Number	WHO Universal Trial Reference Number (UTRN)
Other Identifier			

Sponsor

Organisation Name			
Street Address		Town/City	
Post code		Country	

Contact Points - Scientific Contact Point



Functional name of contact point		Name of organisation	
Telephone number			
Email address			

Contact Points - Public contact point ③

Functional name of contact point		Name of organisation	
Telephone number			
Email address			

Paediatric regulatory details

Is trial part of a Paediatric Investigation Plan?	[Circle one] Yes/No				
EMA Paediatric Investigation Plans					
Does article 45 REGULATION (EC) No 1901/2006 apply to this trial?	[Circle one] Yes/No		Does article 46 REGULATION (EC) No 1901/2006 apply to this trial?	[Circle one] Yes/No	

**Result analysis stage**

Primary completion date reached?	<i>[Circle one]</i> Yes/No	Primary completion date	
Analysis stage	<i>[Circle one]</i> Interim; Final	Date of interim/final analysis	
Global end of trial reached?	<i>[Circle one]</i> Yes/No	Date of global end of trial	

General information about trial

Main objective of the trial			
Actual date of start of recruitment to the protocol (in any country)			
Long term follow up planned	<i>[Circle one]</i> Yes/No	Follow up planning rationale	
Long term follow up duration	Value: _____ Unit: <i>[Select one]</i> Months; Years		

Independent Data-Monitoring Committee (IDMC) involvement	<i>[Circle one]</i> Yes/No
Protection of subjects ③	

Background therapy ④	
Evidence for comparator(s)	

Actual number of subjects included in the trial



Actual number of subjects included in each Country concerned

Country										
Number of subjects										

For multinational trials

Actual number of subjects included in the EEA	[Derived from table above]
Actual number of subjects included worldwide	[Derived from table above]

Age Group Breakdown for the whole trial

Age of subjects	Number of Subjects
In Utero	
Preterm newborn- gestational age < 37 wk	
Newborns (0-27 days)	
Infants and toddlers (28 days – 23 months)	
Children (2-11 years)	
Adolescents (12-17 year)	
Between 18 and 65 years	
From 65 years to 84 years	

85 years and over	
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**More Information****EMA****Global Substantial Protocol Amendments**

Amendment Date	Description

Global Interruptions and Restarts

Interruption Date	Description	Restart Date

Limitations and Caveats

Limitations and Caveats that apply to the results