EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraCT database and EU Clinical Trials Register (EU-CTR)

Presented by: Laura Pioppo
Compliance and Inspection Sector
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Definitions information systems on clinical trials and medicinal products

EudraCT

- Is a confidential database of interventional clinical trials of medicinal products in the EU/EEA – initially accessible only to EU/EEA regulators;

EudraPharm

- Is the database of medicinal products authorised in the European Union, is a public source of information on medicinal products in the EU;

EU Clinical Trials Register EU-CTR

- Is, by law, part of EudraPharm, and it displays public information extracted from the EudraCT database.

EudraCT (current Version 8.0, launched on 10th March 2011) includes data related to Clinical Trials starting from 1st May 2004

Legal Framework: **Article 11 of Directive 2001/20/EC**

A European database accessible **only** to the Competent Authorities, European Commission and EMA containing:

- Extracts from the request for authorisation
- Any amendments made to the request
- Any amendments made to the protocol
- Opinion of the Ethics Committee
- Declaration of the end of the clinical trial
- Reference to inspections

Transparency: New Legal requirements have led to the development of EudraCT V 8.0 and EU-CTR

Two Regulations:

- Article 57(2) of Regulation (EC) No 726/2004
  - Relates to all clinical trials in EudraCT
- Article 41 of Regulation (EC) No 1901/2006
  - Relates to paediatric clinical trials

Article 57(2) of Regulation (EC) No 726/2004

" Where appropriate, the database **described under art. 1(l) (EudraPharm)** shall also include references to data on clinical trials currently being carried out or already completed, contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC **(EudraCT).** The Commission shall, in consultation with the Member States, issue guidelines on data fields which could be included and which may be accessible to the public."

Article 41 of Regulation (EC) No 1901/2006

1. "The European database created by ***Article 11 of Directive 2001/20/EC*** shall include clinical trials carried out in third countries which are contained in an agreed paediatric investigation plan ***(PIP),*** in addition to the clinical trials referred to in Articles 1 and 2 of that Directive (.... *omissis*) . ***By way of derogation from the provisions of Article 11 of Directive 2001/20/EC***, the Agency shall make public part of the information on paediatric clinical trials entered in the European database."

Implementing GLs:

Both Regulations require the EC to draw up guidances **on the nature of the information to be displayed to the general public.**

The two implementing guidelines (GLs) published by Commission are the following:

- Article 57(2) related guideline published - Final July 2008 is 2008/C 168/02

- Paediatric guideline published– Final February 2009 is 2009/C 28/01

New Legal requirements have lead to the development of future version of EudraCT (V 9.0)

To increase trasparency and also as required by Regulations in future there will be the publication of Results related data though the EU-CTR

Development EudraCT V 9.0 - Results related data

Technical Guidance on ***Results*** Information Publication- Draft for public consultation- deadline for comments was 30th September 2010.

Comments received have now been consolidated in a new version

New Legal requirements
General issues

Art. 57	Art. 41
• Phase II-IV adult trials conducted in the EEA	• Phase I-IV paediatric trials + third country trials in a PIP (including phase I trial in adults that are part of PIP)
This applies to:	This applies to:
• Trials of products with or without MAA	• The same

EU-CTR

Has been launched on 22nd March

It contains Protocol related data on:

- Clinical trials starting from 01.05.2004
- Phase II/III/IV Adult CTs with at least 1 site in the EEA;
- All phases paediatric CTs conducted in EEA;
- Paediatric clinical trials that are conducted completed outside of the EEA if they are part of an agreed PIP (including a small % of adult phase I trials if they are part of a PIP)

Criteria for publication of CTs in the EU-CTR

CTs conducted in adults: If they have a positive NCA decision and a positive IEC opinion and related dates;

CTs conducted in paediatric population: If they have a positive NCA decision. IEC opinion can be either positive or negative and the trial will be make public anyway.

Related dates will also appear.

Number of CTs published on the Register:

Number of clinical trials in EU Clinical Trials Register at 15.06.2010: **14739** of which

Number of clinical trials with subjects less than 18 years old: **1863**

This refers to the number of distinct CTs available in the EU-CTR (No. of protocols). It should be stressed that in EudraCT there at the moment around **29,500** distinct CTs of which around 9,000 are phase I trials conducted in adults that will not made public.

Publication of historical data (data from 01.05.2004 to 10.03.2011)

Few important things should be taken into account!

- The CTs that are missing do not full fill the criteria for publication as the NCA/IEC can be missing or they can be not authorized by the NCAs and IECs, we are closely in contact with the NCAs for improve the quality of the data.

- After search is perform the information appearing on the screen is related to the First Past the Post (FPP) record.

- Patch 1 has been released two weeks ago

Future enhancements in EU-CTR:

- Possibility to save the result of your search as a PDF and the ability to forward relevant links to other e-mail addresses (at the moment you can just save 1 record as PDF);

- Possibility to Export data as Excel;

- Improve the search functionality using Thesaurus;

- To add additional filters for search i.e. for rare disease;

- Clarify that the first search refer to the FPP;

- Interaction with the **WHO** to make the Register one the registries of the ICTRP and also ICMJE (International Committee of Medical Journal Editors)

Thank you for your attention!