The European Clinical Trials Register (EU-CTR V1.1)

Noémie Manent
Compliance and Inspection Sector
Agenda

- EU Clinical Trial Register (EU CTR)
- WHO International Clinical Trials Registry Platform (ICTRP)
- Demo
EU Clinical Trial Register (EU CTR)
EU Clinical Trials Register

Launched on 22nd March 2011

It contains Protocol related data on:

- Clinical trials starting from 01.05.2004

- Phase II/III/IV Adult Clinical Trials with at least 1 site in the EU/EEA

- All phases paediatric Clinical Trials conducted in EEA

- Paediatric clinical trials that are conducted completed outside of the EEA if they are part of an agreed Paediatric Investigational Plan (PIP) (including a small % of adult phase I trials if they are part of a PIP)
What is not currently included in the register?

- Results of the clinical trials
- Non-interventional clinical trials
- Information on clinical trials for surgical procedures, medical devices or psychotherapeutic procedures
- Process of joining a clinical trial
- Provide navigation in languages other than English (translation of the webpage in all EU languages will be available in April 2012)
Transparency: legal requirements

For the protocol related information and for the results related information

Two Regulations

- Article 57(2) of Regulation (EC) No 726/2004
  - Complements the directive on clinical trial 2001/20/EC that establishes the database from which the data can be published into the register (data fields)

- Articles 41 & 53 of Regulation (EC) No 1901/2006 “paediatric regulation”
  - Relates to CT carried out in 3rd country and contained in an agreed paediatric investigation plan (PIP)
  - Make public part of the information on paediatric clinical trials
Criteria for publication of Clinical Trials:

<table>
<thead>
<tr>
<th>CTs in adults</th>
<th>CTs in paediatric population</th>
</tr>
</thead>
<tbody>
<tr>
<td>• positive NCA decision</td>
<td>• positive NCA decision</td>
</tr>
<tr>
<td>• positive IEC opinion and related dates appearing in EudraCT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• IEC opinion can be either positive or negative and related dates will also appear</td>
</tr>
<tr>
<td>EudraCT Number</td>
<td>Resubmission Letter</td>
</tr>
<tr>
<td>----------------</td>
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</tr>
<tr>
<td>2008-002340-42</td>
<td>First Submission</td>
</tr>
<tr>
<td>2008-005120-86</td>
<td>First Submission</td>
</tr>
<tr>
<td>2008-002283-34</td>
<td>First Submission</td>
</tr>
</tbody>
</table>

RA awareness session on Clinical Trial related activities
EU CTR Release v1.1

- Additional search filters (rare diseases)
- Ability to multi-select in search filters
- Download of published data (plain text)
- User interface improvements
  - Ability to “Bookmark” URLs, including searches
  - Ability to send URL links in emails
  - Fix to allow use of browser “Back” button
  - Better support for other browsers
- Introduction of Really Simple Syndication (RSS) Feed e.g. Subscribe to EU CTR searches
- Internal pilot of improved searching using synonyms from thesaurus database
As of 2\textsuperscript{nd} Feb 2012 \textbf{16450 public CTs} of which

- Number of clinical trials with subjects less than 18 years old: \textbf{2095}
- more than \textbf{32,068} distinct CTs of which around 10,127 are phase I trials conducted in adults and therefore they will not be made public.

This refers to the number of distinct CTs available in the EU-CTR (No. of protocols).
1. Public Enquiry

2. IT SERVICE DESK
euctr@ema.europa.eu

3. Is IT Service Desk query?
   - yes
     - 4. IT Service Desk will reply to the query
   - no
     - not sure

5. IT Service Desk will follow up with the relevant department

Press Office
press@ema.europa.eu

Medical Information
Answers forwarded by V-PD-DIS to the external query address
(external.queries@ema.europa.eu)

Documents & Information Services (DIS)
info@ema.europa.eu

Business Team

END
Ongoing Results related activities

- Limited standardisation of data elements, often in development (ISO, CDISC, HL7 Clinical Trial Registry and Results, ICH E3)

- Development of data structure and standards for Results information requires:
  - Data standard
  - XML standard – single sponsor source to multiple registry destinations

- The structure of the data to be collected is mapped to those of ClinicalTrials.gov
WHO International Clinical Trials Registry Platform (ICTRP)
WHO - ICTRP

- The EU-CTR has been recognised as a primary registry of WHO ICTRP (International Clinical Trials Registry Platform)

- Information from the EU CTR will be available via the ICTRP next week

- It is an endorsement of the EU-CTR as a source of information for potential study subject as well as for sponsors, ethics Committees and policy makers

- It will help authors submitting trial papers to the leading medical journals since the ICMJE (International Committee of Medical Journal Editors) requires trials to be registered prospectively in a Primary Registry prior accepting an article for publication

- As a primary registry of ICTRP, EU CTR is therefore recognised by ICMJE

http://www.who.int/ictrp/en/
Demo

https://www.clinicaltrialsregister.eu/index.html
Thank you for your attention!
# New Legal requirements

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>• Phase II-IV adult trials conducted in the EEA</td>
<td>• Phase I-IV paediatric trials + third country trials in a PIP (including phase I trial in adults that are part of PIP)</td>
</tr>
</tbody>
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This applies to:
- Trials of products with or without MAA

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<th><strong>Art. 41 (R 1901/2006)</strong></th>
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<tr>
<td>Submitted by sponsor, at time of CTA submission and entered by NCAs at the time of a valid application</td>
<td>The same or by PIP addressee via EMA for non-EU trials and submitted no later than 1 month after EMA PIP decision or trial approval by third country, whichever is the later</td>
</tr>
<tr>
<td>Made public at the time of the clinical trial authorisation (NCA and Ethics Committee)</td>
<td>Made public at the time of clinical trial authorisation/refusal by Ethics Committee</td>
</tr>
</tbody>
</table>
### Results-related information

<table>
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<th><strong>Art. 41 (R 1901/2006)</strong></th>
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<tr>
<td>• Submission by sponsors within one year of the end of the trial, via European Medicines Agency</td>
<td>• Submission by sponsors, PIP addressee or MAH via EMA within 6 months of completion of trials</td>
</tr>
<tr>
<td>• XML file via the web interface provided by EMA or using a gateway technology</td>
<td>• The same for the rest</td>
</tr>
<tr>
<td>• No review prior to publication- clear disclaimers re content and context</td>
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<tr>
<td>• Available within 5 working days</td>
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