Unlocking the mysteries of access to clinical trials data in the EU

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Declaration of interests

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The opinions expressed herein are those of the author. The Executive Agency for Health and Consumers is not responsible for the use of the information presented here.
What is HAI Europe?

• Established as a consumer network in 1981
• Members include consumers, public interest organisations, health care providers, academics, media and individuals
• Independent of pharmaceutical industry funding
• Goals: promote access to essential medicines and their rational use
Overview

- Status quo of EU access rules & clinical trials data
  - Clinical Trials Directive
  - Access to Documents Regulation
- Challenges to access all trials data
- Future opportunities to open up access
Clinical Trials Directive

- EU Directive 2001/20/EC
- Registration of all trials in EU and certain paediatric trials

Trials in EU

Trials abroad

Market approved medicine

Trial data supporting market application
Eudra CT

- Exchange of info between sponsors & regulatory authorities
- Generates unique EudraCT reference number

Ref: https://eudract.ema.europa.eu/
EU Clinical Trials Register

- Public repository of information in EudraCT
- Includes design of trial, sponsor, investigational medicinal products and therapeutic areas, status of trial

Ref: https://www.clinicaltrialsregister.eu/
EU Clinical Trials Register

- No data disclosure
- Information dependent on EudraCT
- View of a trial entry:

<table>
<thead>
<tr>
<th>F. Population of Trial Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>F.1 Age Range</td>
</tr>
<tr>
<td>F.1.1 Trial has subjects under 18</td>
</tr>
<tr>
<td>F.1.1.1 In Utero</td>
</tr>
<tr>
<td>F.1.1.2 Preterm newborn infants (up to gestational age &lt; 37 weeks)</td>
</tr>
<tr>
<td>F.1.1.3 Newborns (0-27 days)</td>
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<tr>
<td>F.1.1.4 Infants and toddlers (28 days-23 months)</td>
</tr>
<tr>
<td>F.1.1.5 Children (2-11 years)</td>
</tr>
<tr>
<td>F.1.1.6 Adolescents (12-17 years)</td>
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</tbody>
</table>
Access to Documents

- EU Regulation 1049/2011
- Scope
  - All EU documents
    - When does trials data become an EU document?

- Trials in EU
- Trials abroad
- Market approved medicine
- Trial data supporting market application
Access to Documents

- Exceptions
  - Protection of personal data (i.e. name, ID number..)
  - Protection of commercial confidentiality
    - Inc. intellectual property, trade secrets, commercial confidences

→ Unless overriding public interest exception
EU access case studies

- La Revue Prescrire (2008)
- Nordic Cochrane Centre (2008 – 2011)
- Cochrane Collaboration & Tamiflu (2009)
Access to Doc’s: Reality Check

- La Revue Prescrire (2008)
- Received assessment report from EMA for rimonabant
Access advocate: EU Ombudsman

- European Ombudsman
  - Consumer and public protector
  - Investigates complaints of mal-administration

Photo credit: website, Office of the European Ombudsman
Appeal to EU Ombudsman

... for access to EMA documents:

- Nordic Cochrane Centre (2008 – 2011)
  - Two anti-obesity medications
  - Clinical study protocols and reports ...
  - ... are these commercially confidential?

Successful appeals to EU Ombudsman for access to EMA documents:

- Nordic Cochrane Centre (2008 – 2011)
  - Two anti-obesity medications
  - Clinical study protocols and reports ...

Ref: http://www.guardian.co.uk/society/2011/may/10/drug-regulators-accused-obesity-drug
Successful appeals to EU Ombudsman for access to EMA documents:

  - Anti-acne medication
  - Suspected serious adverse reaction reports ...

... are these documents?

Access to all data: Pipe dream?

• European Medicines Agency released 22,000+ pgs of Roche’s Tamiflu trial reports = **Incomplete picture**
• Challenge: Agency does not possess all the raw data

Photo credit: Tom Jefferson, 2012 presentation
Scope of EU access rules

- Trials in EU
- Trials abroad
- Trial data supporting market application
- Market approved medicine
Trials in developing countries

- Ethical issues?
- Safety issues?

Unethical trials are unscientific trials

EU Clinical Trials Proposal (2012)

- **Scope**
  - All trials in at least one EU Member State

- **Process**
  - Proposal from the European Commission (= EU executive branch)
  - Now being reviewed by the 27 Member States and the European Parliament
  - To be concluded in 2013
EU Clinical Trials Proposal (2012)

- Art 78: EU Portal to apply for approval & submit docs
  - To be made public

- Questions still remain…
- **Who** will monitor completeness and accuracy?
- **What** data and information will be included?
- **When** will the data be publicly disclosed?
- **How** will the information and data be retrievable? (Format)
EU Access Scorecard

(-) Retroactive data disclosure
(-) EU agencies must possess the data
(+ ) Includes databases and pharmacovigilance data
(+ ) Narrow definition of commercial confidentiality
(-) No current definition of public interest exception
(-) In most cases, trial must be in EU geographic territory

→ EU’s access regime: A piecework approach
Thank you!

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