





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?

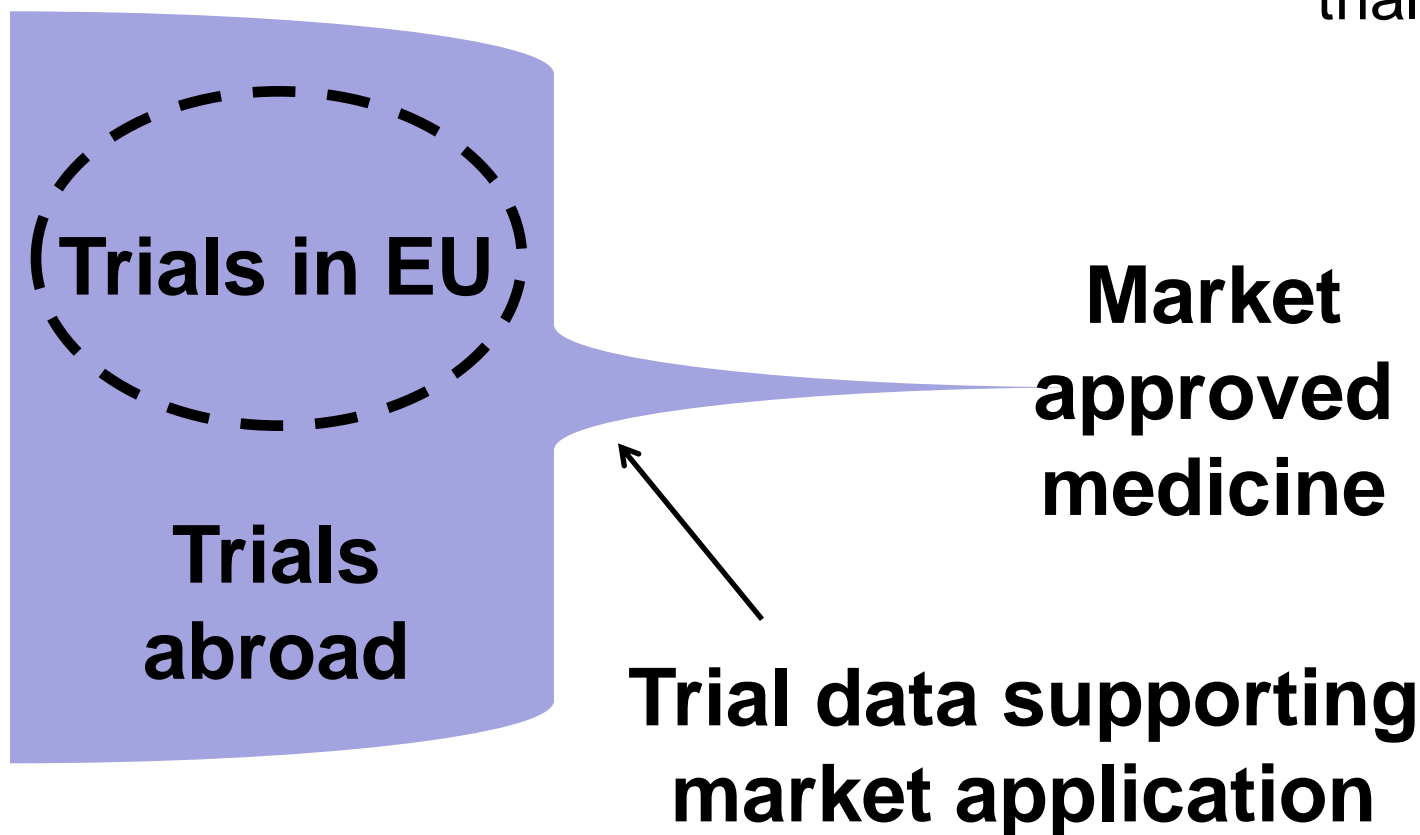
- Established as a consumer network in 1981
- Members include consumers, public interest organisations, health care providers, academics, media and individuals
- Independent of pharmaceutical industry funding
- Goals: promote access to essential medicines and their rational use

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

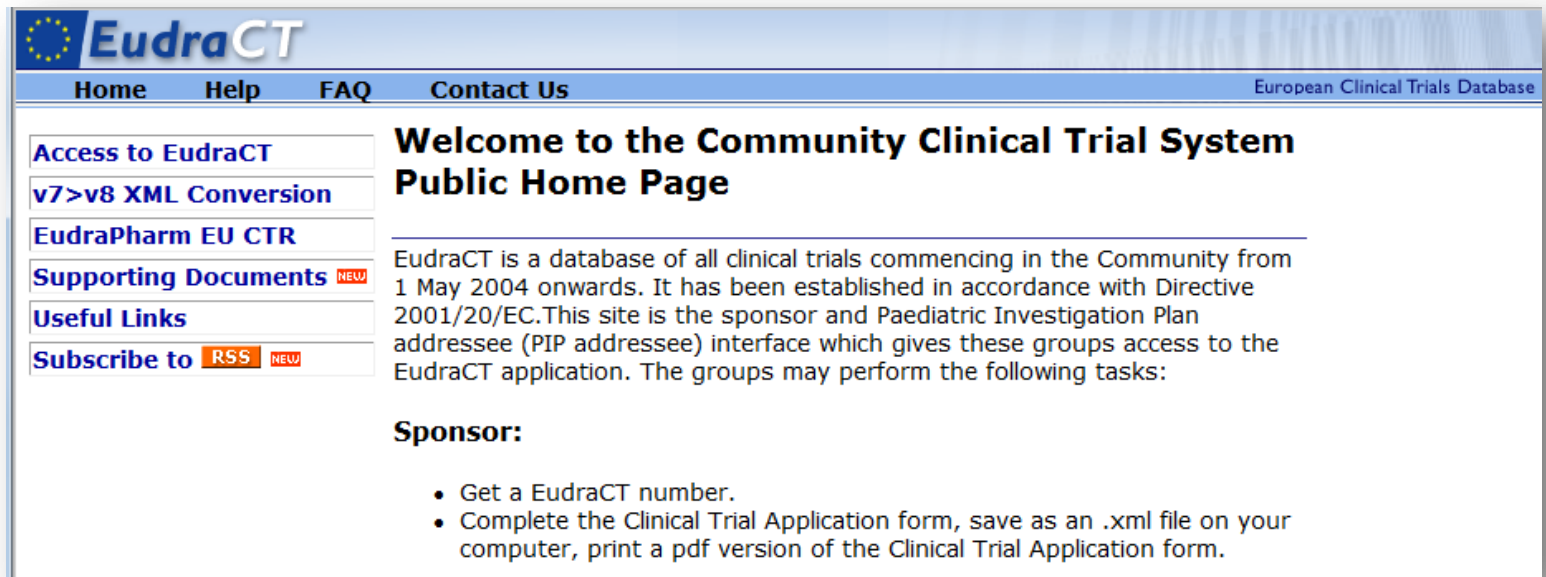
Clinical Trials Directive

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



Eudra CT

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

A screenshot of the EudraCT website's public home page. The page has a blue header with the EudraCT logo and navigation links: Home, Help, FAQ, and Contact Us. On the right side of the header, it says 'European Clinical Trials Database'. The main content area is white and features a sidebar on the left with links to 'Access to EudraCT', 'v7>v8 XML Conversion', 'EudraPharm EU CTR', 'Supporting Documents' (with a 'NEW' tag), 'Useful Links', and 'Subscribe to' (with 'RSS' and 'NEW' tags). The main text area has a heading 'Welcome to the Community Clinical Trial System Public Home Page' followed by a paragraph explaining that EudraCT is a database of clinical trials starting from May 2004, established under Directive 2001/20/EC. It also mentions a sponsor interface for Paediatric Investigation Plan (PIP) addressees. Below this, there is a 'Sponsor:' section with a bulleted list of tasks: 'Get a EudraCT number.' and 'Complete the Clinical Trial Application form, save as an .xml file on your computer, print a pdf version of the Clinical Trial Application form.'

EU Clinical Trials Register

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

A screenshot of the EU Clinical Trials Register website. At the top, a dark blue navigation bar contains the following links: Home | Search | About | Glossary | Data Quality | Joining a trial | Contacts | EudraPharm. Below this, a light blue header bar displays 'EU Clinical Trials Register' on the left and 'Clinicaltrialsregister.eu' on the right. The main content area is enclosed in a white box with a thin black border. It features the title 'Introduction to EU Clinical Trials Register' in bold blue text. Below the title is a bulleted list of two items. The first item states that the website allows searching for clinical trials in EU member states, the EEA, and outside the EU/EEA if they are part of a paediatric investigation plan (PIP), with a 'More...' link. The second item explains that the information is collected and entered by national medicine regulatory authorities or the addressee of a PIP decision for trials conducted outside the European Union, and that this information is now publicly available through the new website, with a 'More...' link.

Home | Search | About | Glossary | Data Quality | Joining a trial | Contacts | EudraPharm

EU Clinical Trials Register Clinicaltrialsregister.eu

Introduction to EU Clinical Trials Register

- The **EU Clinical Trials Register website** allows you to search for information on clinical trials in European Union (EU) member states and the European Economic Area (EEA) and clinical trials which are conducted outside the EU/EEA if they form part of a paediatric investigation plan (PIP). [More...](#)
- The information on the website is collected and entered **by national medicine regulatory authorities** or by the addressee of a PIP decision for trials conducted outside the European Union. They are required by European Union law to enter details of clinical trials into a database called EudraCT. The information stored in this database is now being made publicly available through **a new website, the EU Clinical Trials Register**. Information on the website dates from May 2004. [More...](#)

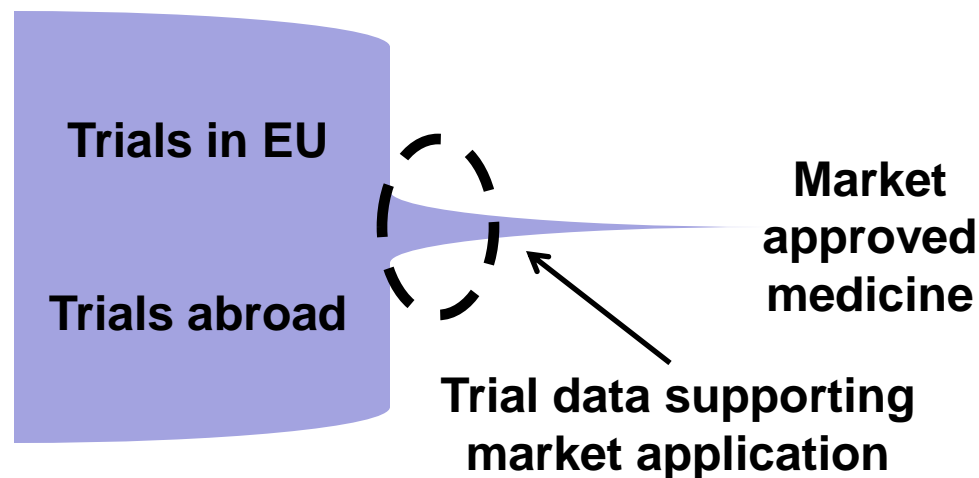
EU Clinical Trials Register

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

F. Population of Trial Subjects		
F.1 Age Range		
F.1.1	Trial has subjects under 18	No
F.1.1.1	In Utero	Information not present in EudraCT
F.1.1.2	Preterm newborn infants (up to gestational age < 37 weeks)	Information not present in EudraCT
F.1.1.3	Newborns (0-27 days)	Information not present in EudraCT
F.1.1.4	Infants and toddlers (28 days-23 months)	Information not present in EudraCT
F.1.1.5	Children (2-11years)	Information not present in EudraCT
F.1.1.6	Adolescents (12-17 years)	Information not present in EudraCT

Access to Documents

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



Access to Documents

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

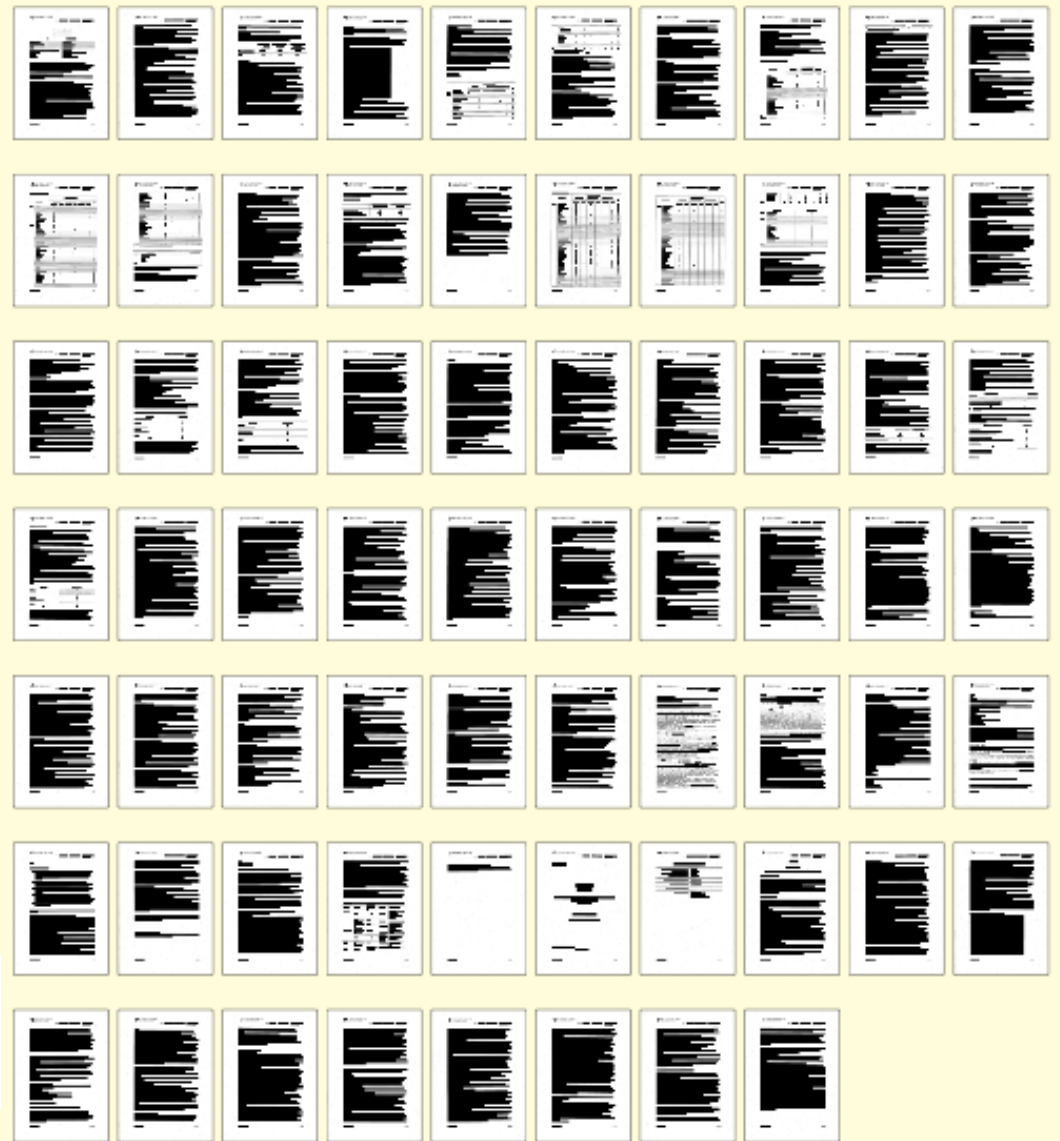
- Unless overriding public interest exception

EU access case studies

- La Revue Prescrire (2008)
- Nordic Cochrane Centre (2008 – 2011)
- Irish citizen (2008 – 2010, 2012)
- 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

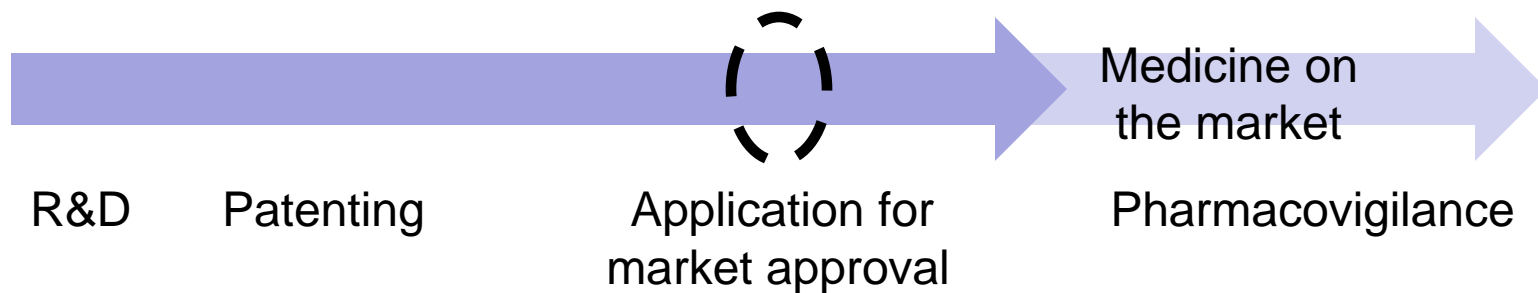
- Consumer and public protector
- Investigates complaints of mal-administration

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?



Access to Doc's: Success Stories

Successful appeals to EU Ombudsman for access to EMA documents:

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

Drug regulators accused of risking patient safety

Doctors make complaint after long battle with European Medicines Agency to see results of anti-obesity pill trials

theguardian

BMJ

ANALYSIS

Opening up data at the European Medicines Agency

BMJ 2011; 342 doi: <http://dx.doi.org/10.1136/bmj.d2686> (Published 10 May 2011)
Cite this as: BMJ 2011;342:d2686

Ref: <http://www.ombudsman.europa.eu/cases/summary.faces/en/5646/html.bookmark>

Ref: <http://www.guardian.co.uk/society/2011/may/10/drug-regulators-accused-obesity-drug>

Access to Doc's: Success Stories

Successful appeals to EU Ombudsman for access to EMA documents:

- Irish citizen (2008 – 2010, 2012)
 - 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

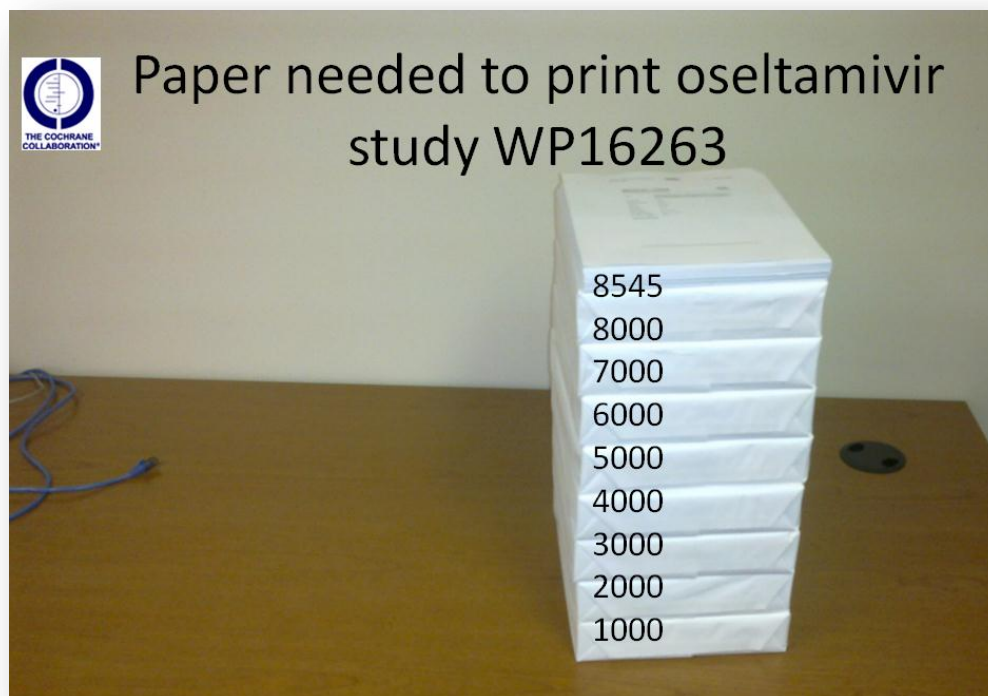
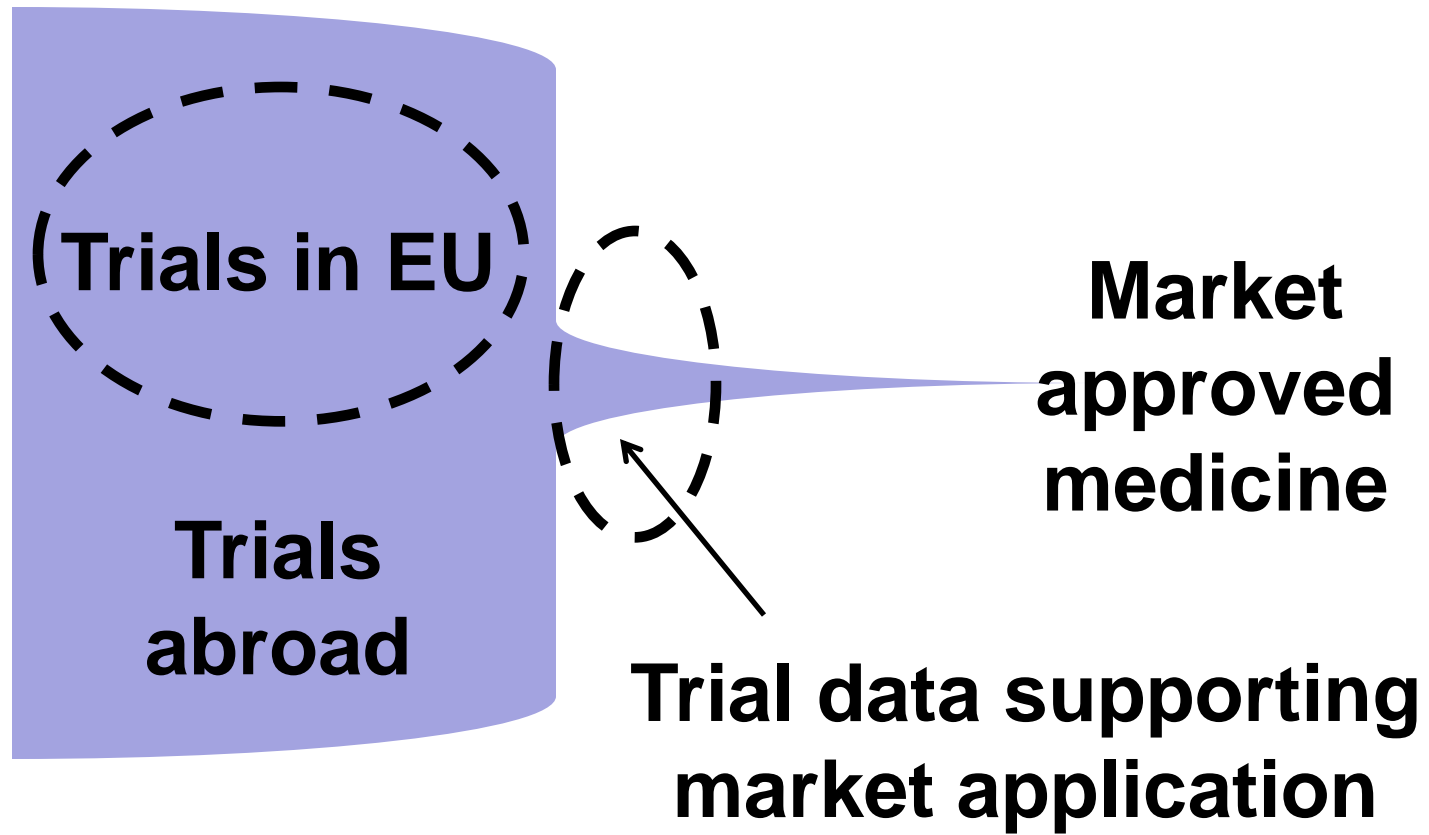


Photo credit: Tom Jefferson, 2012 presentation

Ref: http://www.nytimes.com/2012/04/11/opinion/drug-data-shouldnt-be-secret.html?_r=0

Scope of EU access rules



Trials in developing countries

- Report in The Independent (2011)
- Ethical issues?
- Safety issues?

Unethical trials are unscientific trials

From tragedy to travesty: Drugs tested on survivors of Bhopal

In the second part of a special report, Nina Lakhani exposes how survivors of the 1984 Bhopal gas disaster became unwitting guinea pigs in studies funded by Western drug companies

NINA LAKHANI | TUESDAY 15 NOVEMBER 2011

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Harry in, Hughes out: Redknapp back in the game as he lands QPR manager's job

Can you crack the World War II code - found on the leg of a dead pigeon?

Section of Whitehall closed off as naked man straddles statue



Ref: <http://www.independent.co.uk/news/world/asia/from-tragedy-to-travesty-drugs-tested-on-survivors-of-bhopal-6262412.html>

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 piecemeal approach**



Thank you!

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Videos: Ben Goldacre, Deborah Cohen
Peter Gotzsche, Tom Jefferson