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

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Health Action International (HAI) Europe

Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.

Declaration of interests

This presentation arises from the Developing Rational Use of Medicines in Europe project, which has received funding from the European Union in the framework of the Health programme.

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.

Executive Agency for Health and Consumers

What is HAI Europe?

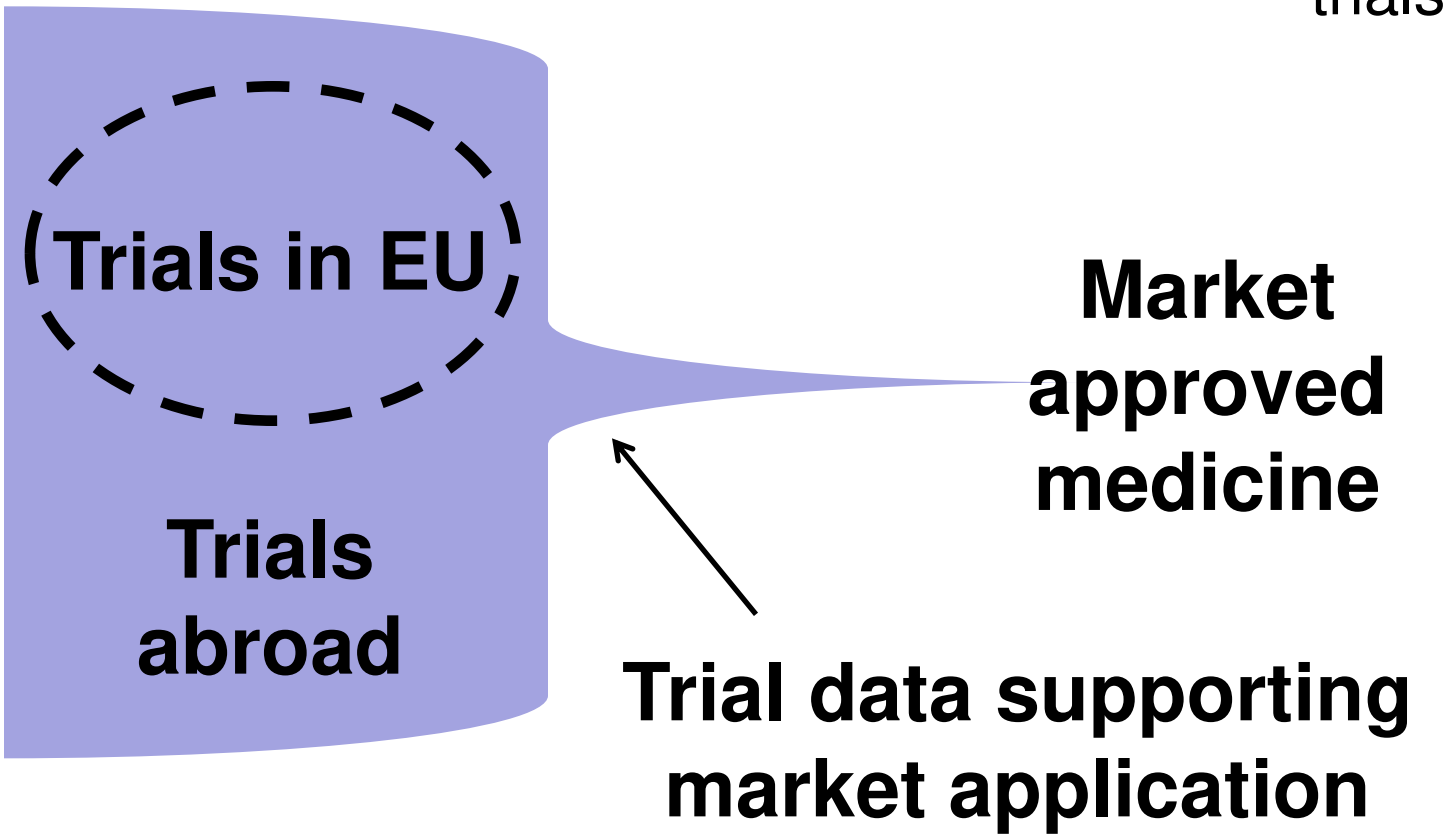
- Established as a consumer network in 1981
- Members include consumers, public interest organisations, health care providers, academics, media and individuals
- Independent of pharmaceutical industry funding
- Goals: promote access to essential medicines and their rational use

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

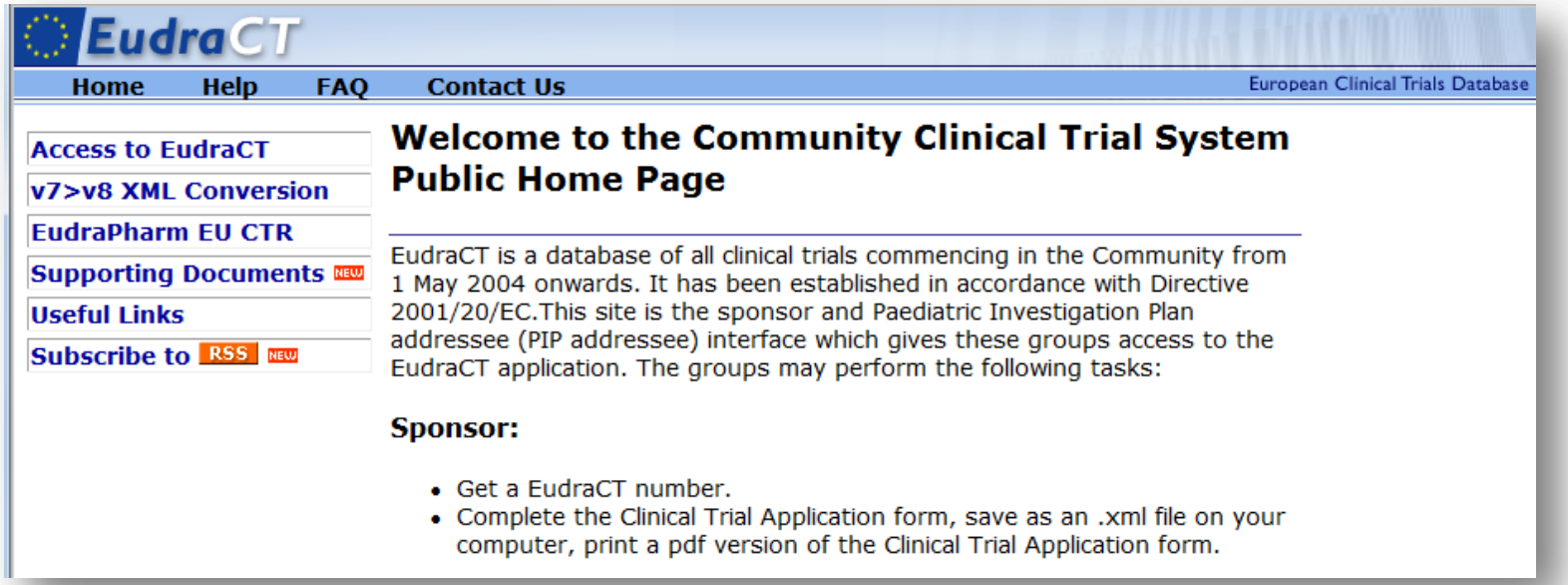
Clinical Trials Directive

- 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



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/

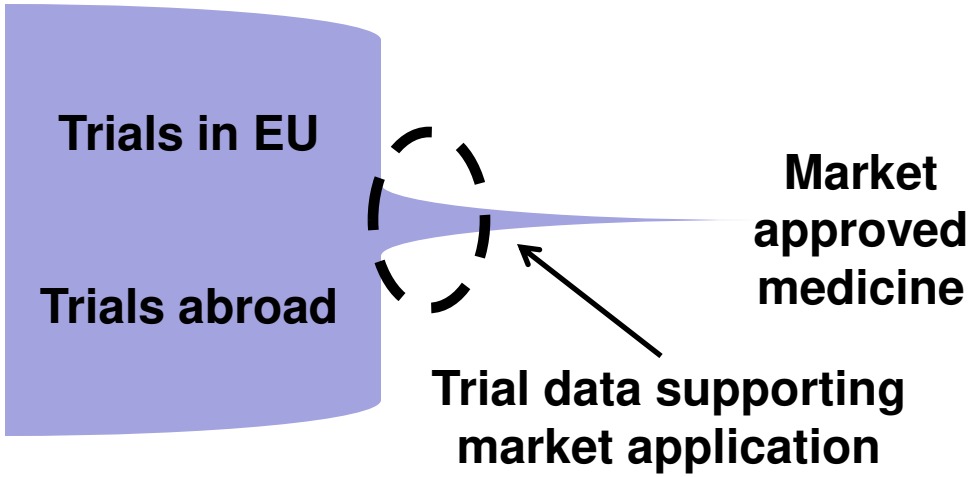
EU Clinical Trials Register

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

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

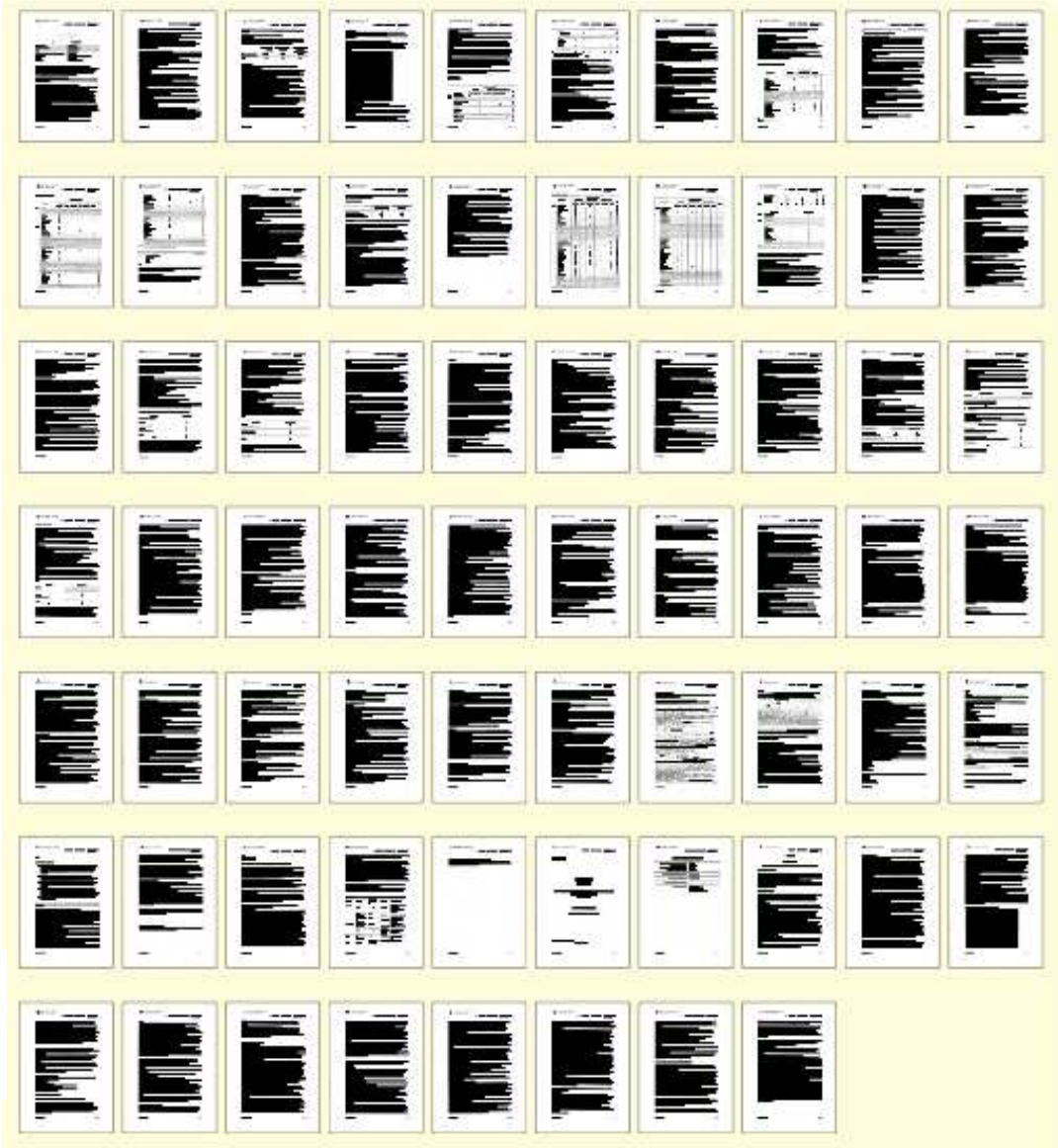


Image credit: La revue Prescrire

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?

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

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?

Ref: http://www.ombudsman.europa.eu/cases/summary.faces/en/11740/html.bookmark

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

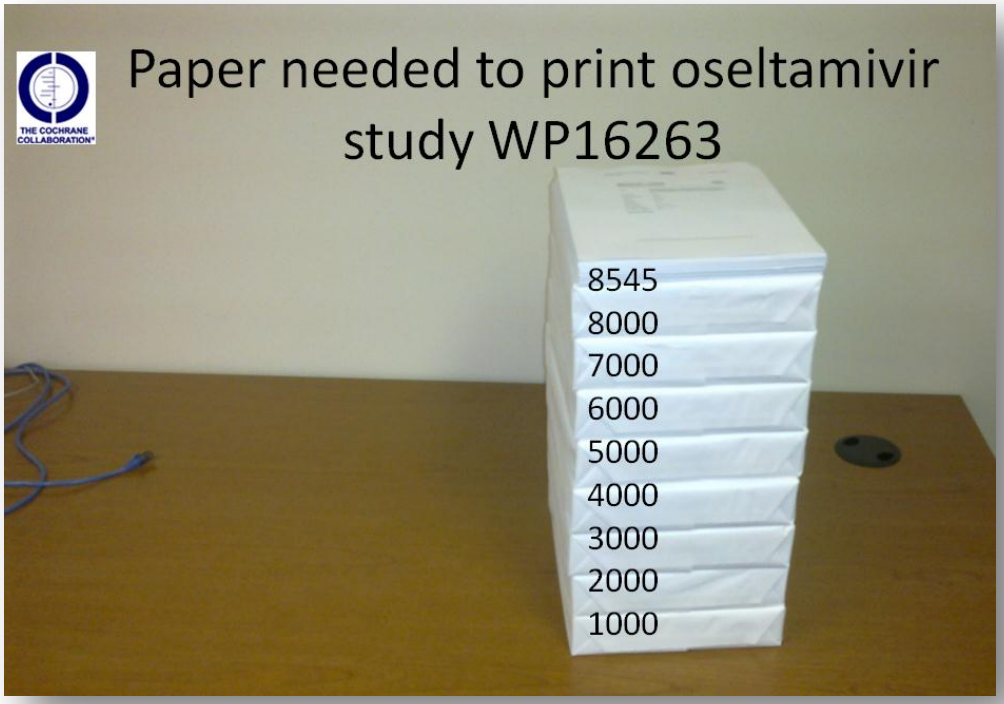
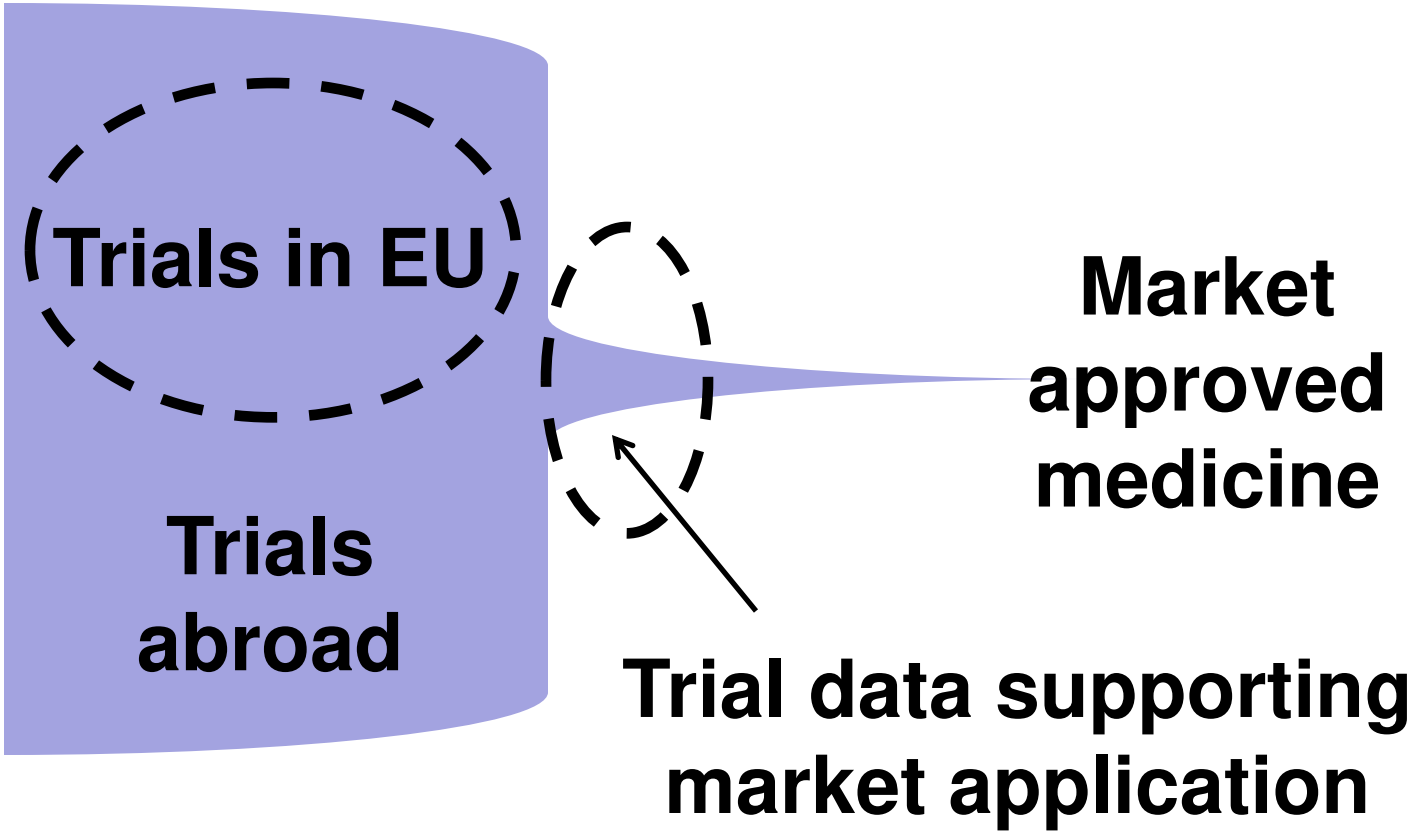


Photo credit: Tom Jefferson, 2012 presentation
Ref: http://www.nytimes.com/2012/04/11/opinion/drug-data-shouldnt-be-secret.html?_r=0

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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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 piecework approach

Thank you!

Contact me: Katrina@HAIEurope.org

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