

*ECRAN meeting
Luxembourg, May 21th, 2014*

The importance to promote independent clinical trials: *where are the European researchers ?*



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Need for independent clinical trials

➤ *Clinical trials :*

1 - for registration

- development of innovative health products
- exploring new indications for existing drugs

2 - post-registration

- comparative assessment of efficacy and safety of approved healthcare strategies



➤ *evidence-based medical practice*

➤ *international cooperation required:*

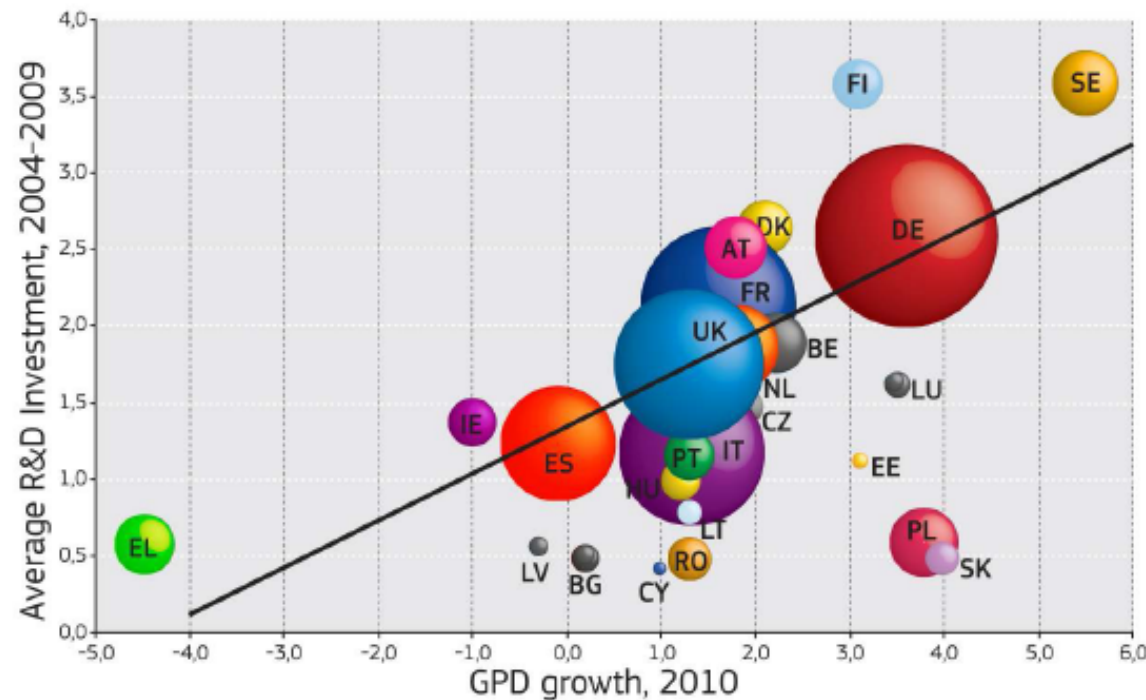
- cost
- expertise
- access to patients

Investing in research and innovation



Investment in R&D is part of the solution to exit from the economic crises

*In which
area ?
Priorities for
citizens ?
Impact on
citizens ?
Impact on
economy ?*



Funding multinational clinical trials ?



Funding mechanisms for post-registration multinational trials : comparative assessment of efficacy and safety of approved healthcare

- National funding
- ERA-nets - JPIs ?



- European Union



- IMI and industry



- International, charities



- Health & HTA authorities ?



Health impact and return on investment of medical research ?

- Estimated 40% per annum
 - ad perpetuum
- For medical research as a whole,
 - not restricted to **clinical** research
- Public funding to
 - projects
 - infrastructures
- Combined impact on
 - Innovation
 - Healthcare cost containment
 - Improved healthcare strategies
- > reduces burden of disease
 - Improved productivity of healthy population
 - Improved quality of life



Effect of a US National Institutes of Health programme of clinical trials on public health and costs

S Claiborne Johnston, John D Rootenberg, Shereen Katrak, Wade S Smith, Jacob S Elkins, Lancet 2006; 367: 1319-27

- Background

Few attempts have been made to estimate the public return on investment in medical research. The total **costs and benefits to society** of a clinical trial, the final step in testing an intervention, can be estimated by evaluating the **effect of trial results on medical care and health**.

- Methods

All phase III randomised trials funded by the US National Institute of Neurological Disorders and Stroke before Jan 1, 2000, were included. Pertinent publications on use, **cost to society**, and **health effects** for each studied intervention were identified by systematic review, supplemented with data from other public and proprietary sources. Regardless of whether a trial was positive or negative, information on use of tested therapies was integrated with published per-use data on costs and health effect (converted to 2004 US\$) to generate **10-year projections** for the US population.

Effect of a US National Institutes of Health programme of clinical trials on public health and costs

S Claiborne Johnston, John D Rootenberg, Shereen Katrak, Wade S Smith, Jacob S Elkins, Lancet 2006; 367: 1319-27

- Findings

28 trials with a total cost of **\$335 million** were included. **Six** trials (21%) resulted in measurable **improvements in health**, and **four** (14%) resulted in **cost savings to society**. At 10 years, the programme of trials resulted in an estimated additional **470 000 quality-adjusted life years** at a total cost of **\$3.6 billion** (including costs of all trials and additional health-care and other expenditures). Valuing a quality-adjusted life year at per-head gross domestic product, the projected net benefit to society at 10-years was **\$15.2 billion**. 95% CIs did not include a net loss at 10 years.

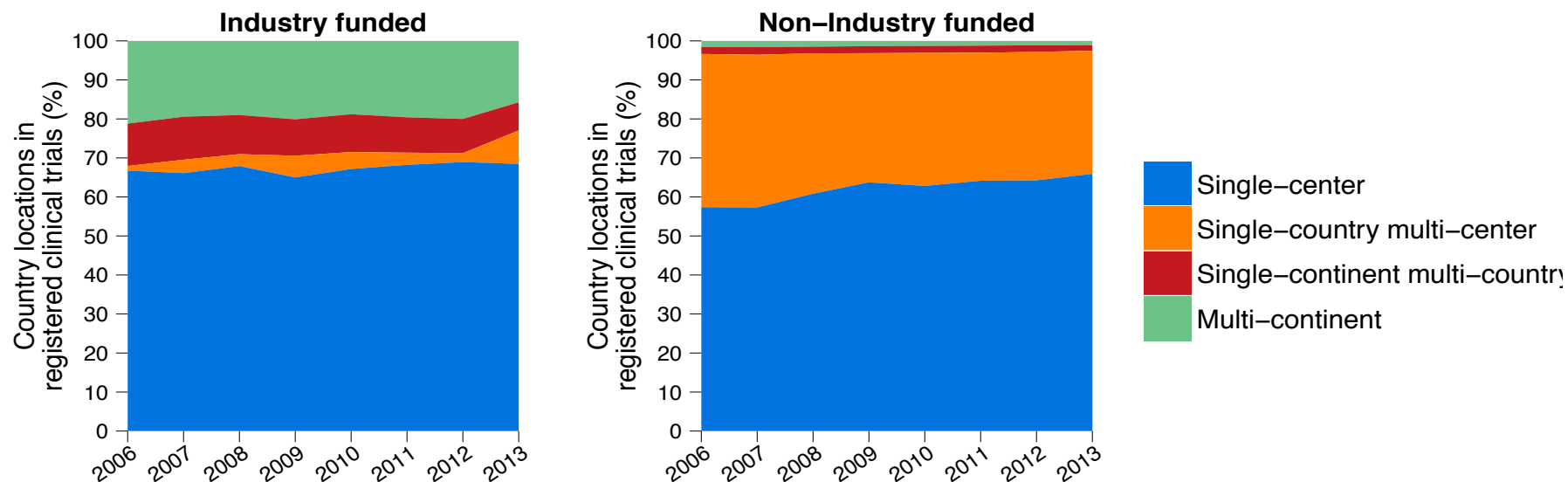
- Implications

For this institute, the public return on investment in clinical trials has been substantial. Although results led to increases in health-care expenditures, health gains were large and valuable

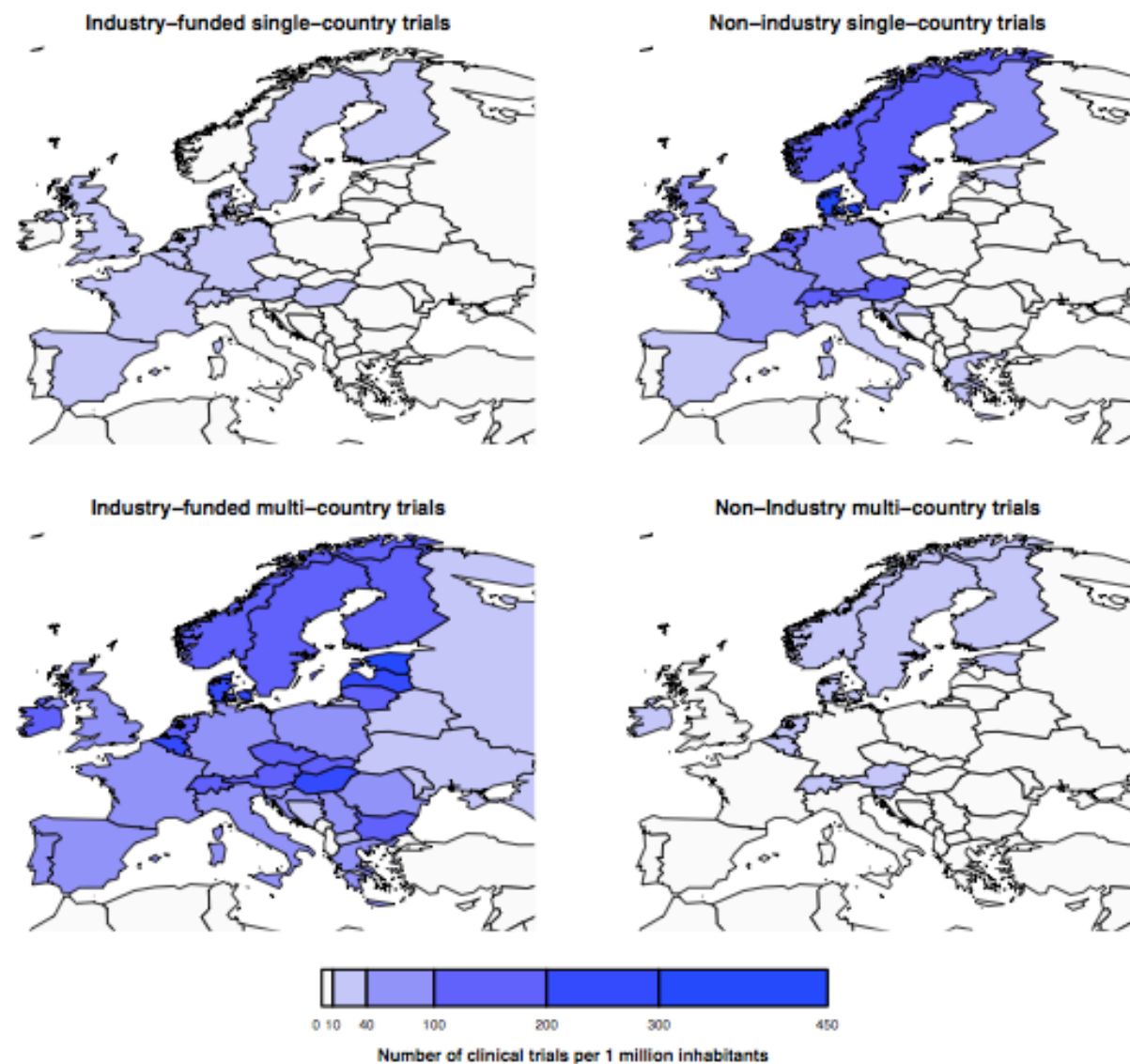
Rol = 5 times initial investment (trials plus healthcare expenditures) over 10 years.



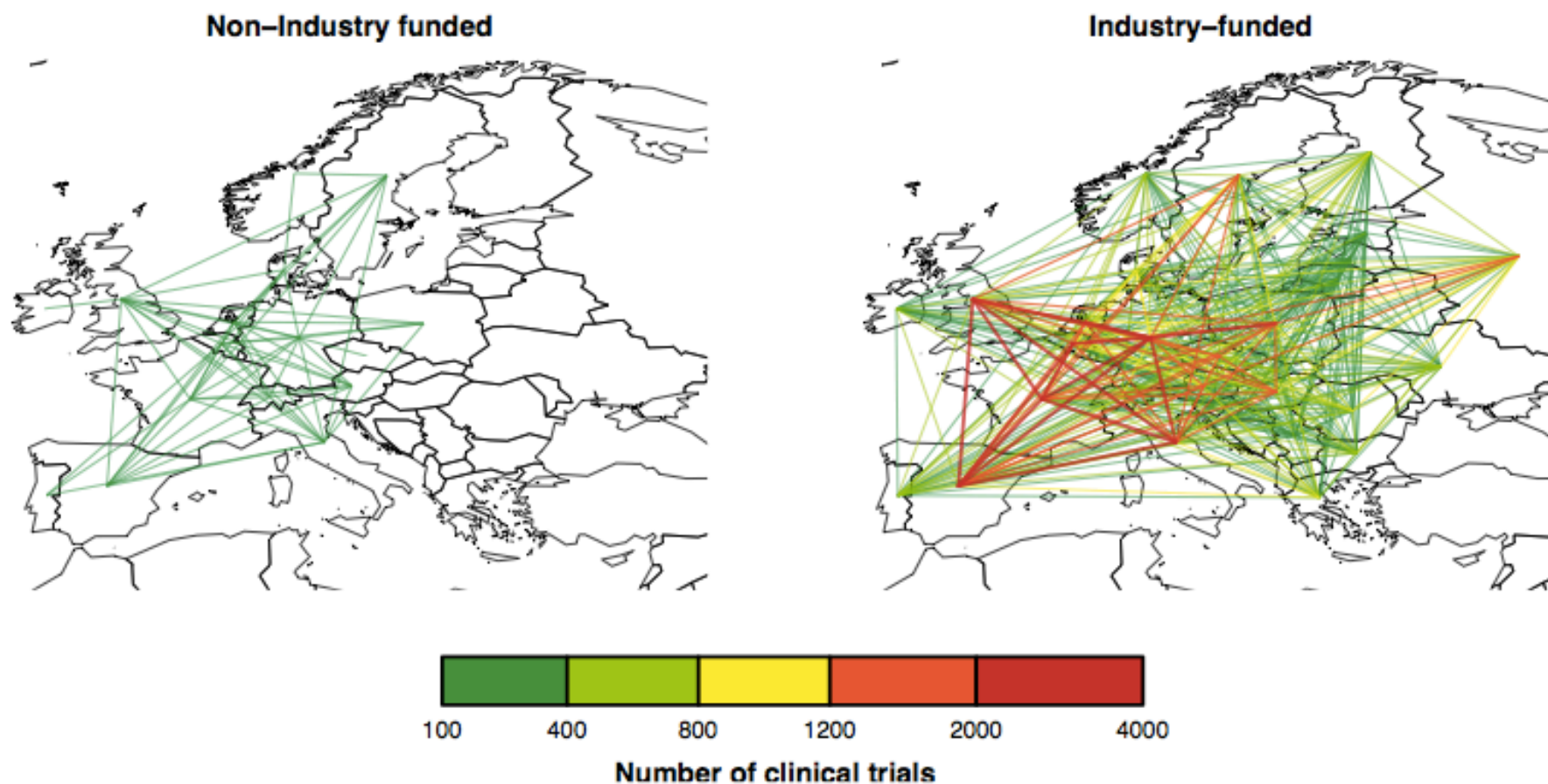
Collaboration trend



European collaborative distribution



European collaboration network



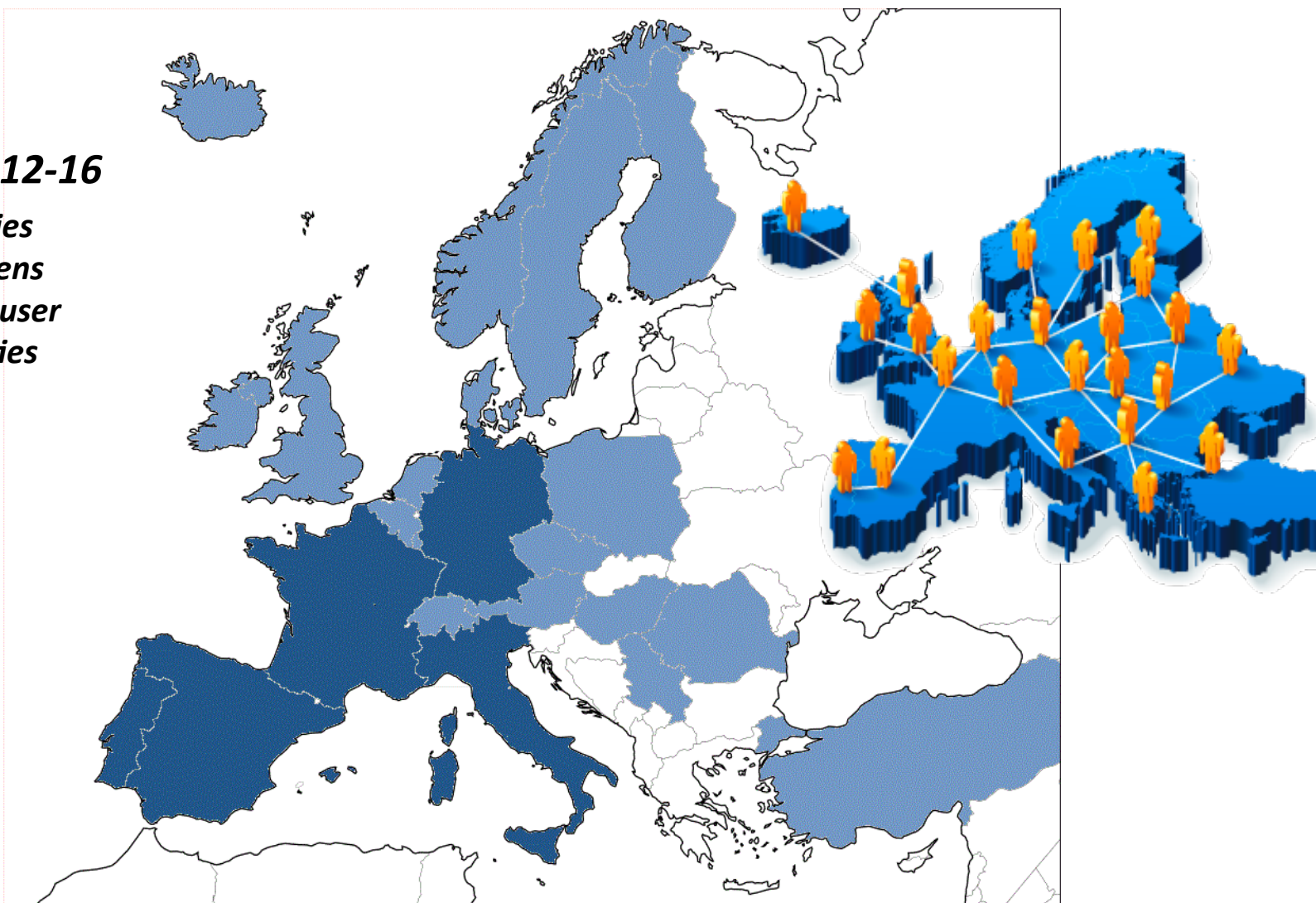


ECRIN IA 2012-16

*23 countries
567M citizens
Structuring user
communities*

*ECRIN-ERIC
5 countries
266M citizens
Sustainable
infrastructure*

*4 countries
about to join*



Economic impact : need for a structured research programme addressing:

- **Direct impact of clinical research infrastructures**
 - On innovation
 - On healthcare optimisation and evidence-based medicine
- **Indirect impact of clinical research infrastructures**
 - Capacity building
 - Also impacts attractiveness for industry trials
- **Impact of clinical research**
 - Innovation
 - Generates wealth (exporter countries)
 - Generates costs
 - Care optimisation, evidence-based medicine, cost containment
 - Productivity, quality of life

OECD Global Science Forum

Facilitating International Cooperation in Non-Commercial Clinical Trials

OCTOBER 2011



[www.oecd.org/sti/sci-tech/
49344626.pdf](http://www.oecd.org/sti/sci-tech/49344626.pdf)



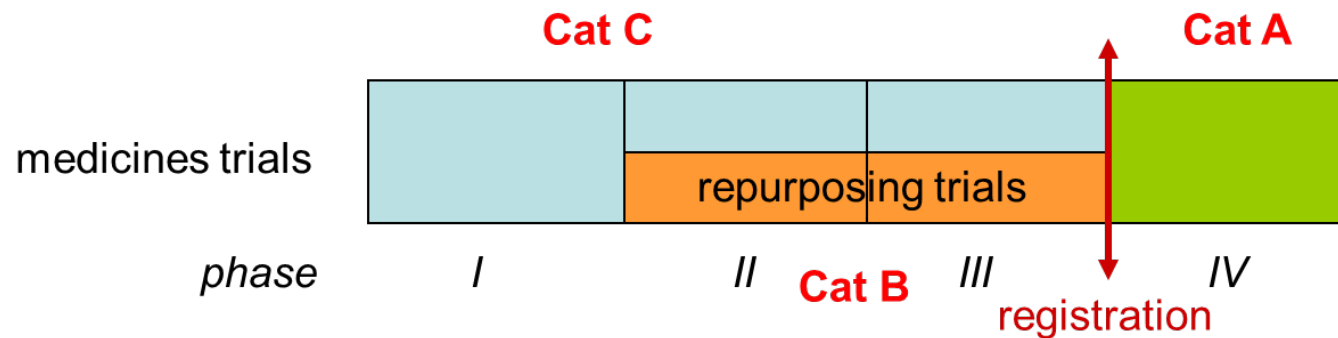
Follow-up / implementation

- WG on infrastructure and funding
- WG on investigator training and certification
- WG on accreditation of ethics committees
- WG on patient involvement
- WG on comparative effectiveness research
- WG on regulation



Towards an independent assessment of innovative health products ?

- New products
- Repurposing trials



- Need for independent, multinational organisation ensuring quality and credibility of results