EUROPEAN COMMISSION / European Research Area / 7th Framework Programme

Innovation, Investment, Infrastructures: the view from DG RTD

European Commission

Directorate-General for Research

Directorate F – Health

Ruxandra Draghia-Akli, MD, PhD – Director

Health related research infrastructures and their contribution to the EU's grand challenges

26 October 2010 Brussels

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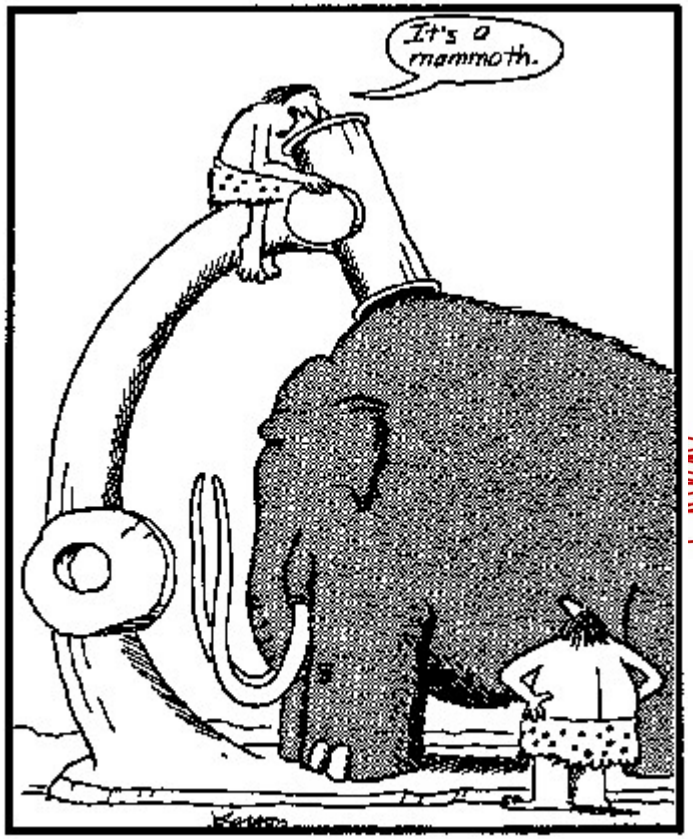
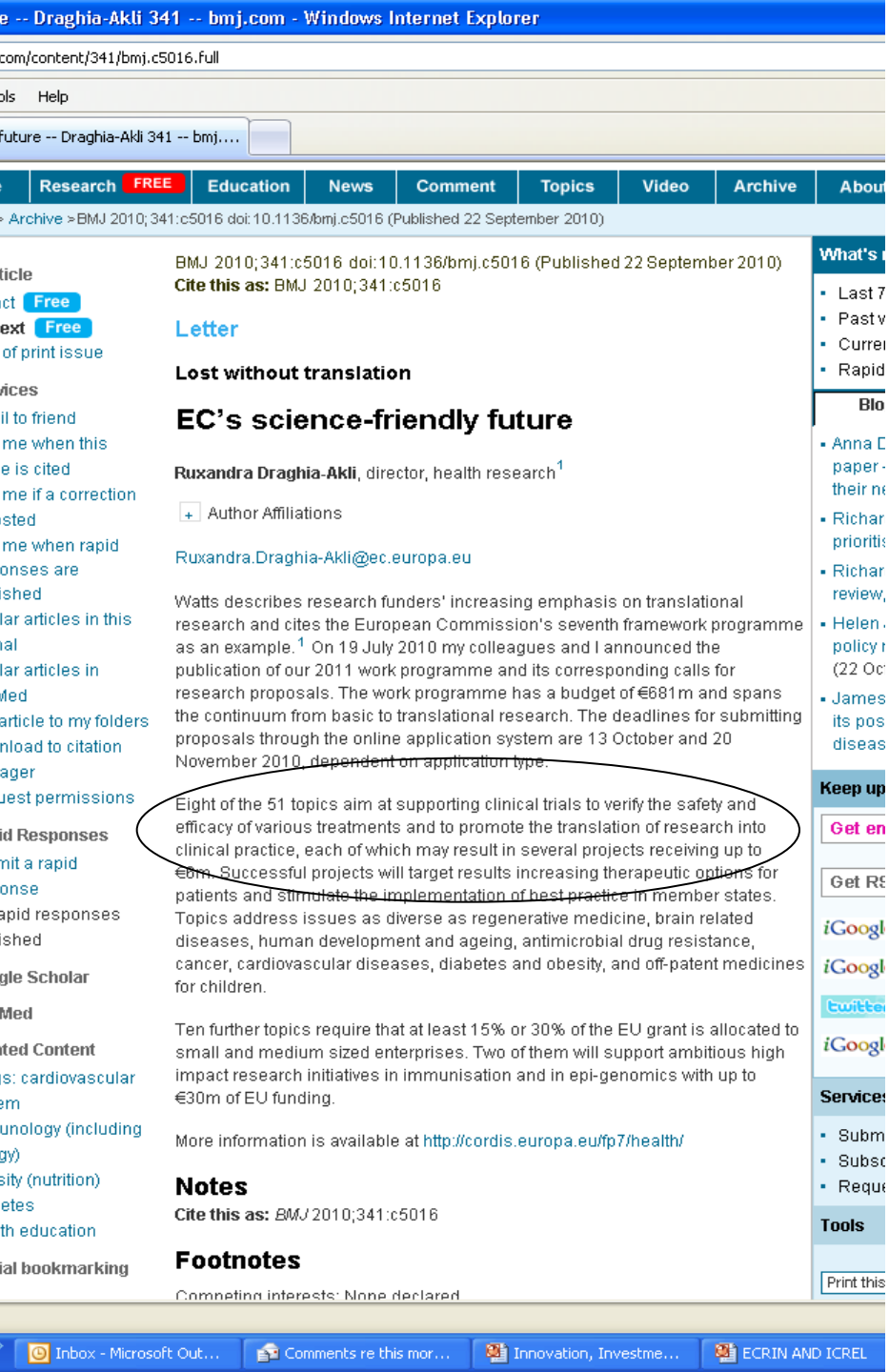
Early infrastructures and the benefits of collaboration…



Early microscope



Insofar as scientific discoveries have been finding their way into clinical practice for two centuries, and will continue to do so, it's self evident that translation (by whatever name) happens, and will go on happening.

The point now at issue is how far the biomedical research community can take firmer control of the process. How far it can be speeded up and given direction.

How far it will be possible, years from now, to be certain that without all the current effort, this drug or that diagnostic would still be a mere speculation in *Nature* or *Science*—lost without translation.

BMJ 2010;341:c4363

It is clear that infrastructures are crucial to facilitating the process of translation….

…and that the EU can ‘take control of the process’ by providing funding for research infrastructures, and funding for scientists to exploit the opportunities they present

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Clinical trials coordination/ policy analysis

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK

ICREL
Impact on Clinical Research of European Legislation

European Clinical Research Infrastructures Network

Designed to integrate clinical research in Europe through the interconnection of national networks of clinical research centres and clinical trial units and to develop services to provide support for **multicentre clinical studies in Europe** (13 countries: Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Spain, Sweden, Switzerland, United Kingdom).

Impact on Clinical Research of European legislation

One-year FP7 project (2008)

Aim was to measure and analyse the direct and indirect impact of the CTD 2001/20/EC and related legislations in the EU on all categories of clinical research and on the different stakeholders: commercial and non-commercial sponsors, ethics committees and competent authorities.

Delivered input to the discussions about the regulatory framework for the conduct of clinical trials in Europe.

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Project Acronym	Project Title	Project EC Contribution
ICREL	Impact on Clinical Research of European Legislation	348.600,00
EUROSTEMCELL	European Consortium for Communicating Stem Cell Research	830.238,00
TRANSEURO	Neural Transplantation In The Treatment Of Patients With Parkinson's Disease	11.994.095,00
IMPACTT	Immunoglobulin IgY pseudomonas A clinical trial for cystic fibrosis treatment	5.876.724,00

FP7 Health Programme objectives:

- Improving health of European citizens
- Increasing competitiveness of European health-related industries and businesses
- Addressing global health issues

Funding for translational and clinical research reinforced in recent years

- Largest part of the FP7 Health Theme is dedicated to translational research in major diseases
- 2011 call published on 19 July 2010 has a major focus on Investigator-Driven Clinical Trials (IDCT)
- Clarifications on financing in an explanatory memorandum also published
- Focus on IDCT will continue in the remaining calls of FP7

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Research priorities: highlights for the immediate future Work Programme 2011

- SME-dedicated topics
  - 15% contribution by end of FP7 i.e. €900M
- Supporting clinical trials to verify safety and efficacy
- High impact topics in epi-genomics and vaccinology/immunology

- *2012-13: brain, diabetes, lifestyle induced conditions, medical technologies, personalised medicines, health care systems, promotion & prevention …*

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Topics in the Health 2011 work programme

Focus on investigator-driven clinical trials (IDCT)

2.2.1-1 IDCT for childhood-onset neurodegenerative diseases
2.2.2-1 IDCT for therapeutic interventions in elderly populations
2.3.1-1 IDCT of off-patent antibiotics
2.4.1-1 Investigator-driven treatment trials for rare cancers
2.4.2-1 IDCT for the management of cardiovascular diseases
2.4.3-1 IDCT to reduce diabetes complications
4.2-1 IDCT on off-Patent medicines for children

Also
1.4-1 Regenerative medicine clinical trials
4.2-2 Adverse drug reaction research

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Other activities…

Commission workshop: "Can We Facilitate IDCT?"

- 10 November 2009 in Brussels
- Small group of high-level representatives from academia, industry, EU Commission (DGs Research, Health and Consumers, and Enterprise and Industry), national regulators, European Medicines Agency, insurance industry

Presentations and report available at:

http://ec.europa.eu/research/health/medical-research/clinical-trials/idct-workshop_en.html

Has demonstrated the need to adapt rules to promote international clinical trials.

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Involvement of patients in clinical trials

Patient Partner

Patient Partner project
Funded under FP7

Patient Partner final workshop will be held on December 7th and 8th 2010 in Brussels
http://patientpartner-europe.eu/

Value+ project coordinated by the European Patient Forum;
Funded under the Public Health Programme of the Health and Consumers DG
http://www.eu-patient.eu/Initatives-Policy/Projects/ValuePlus/

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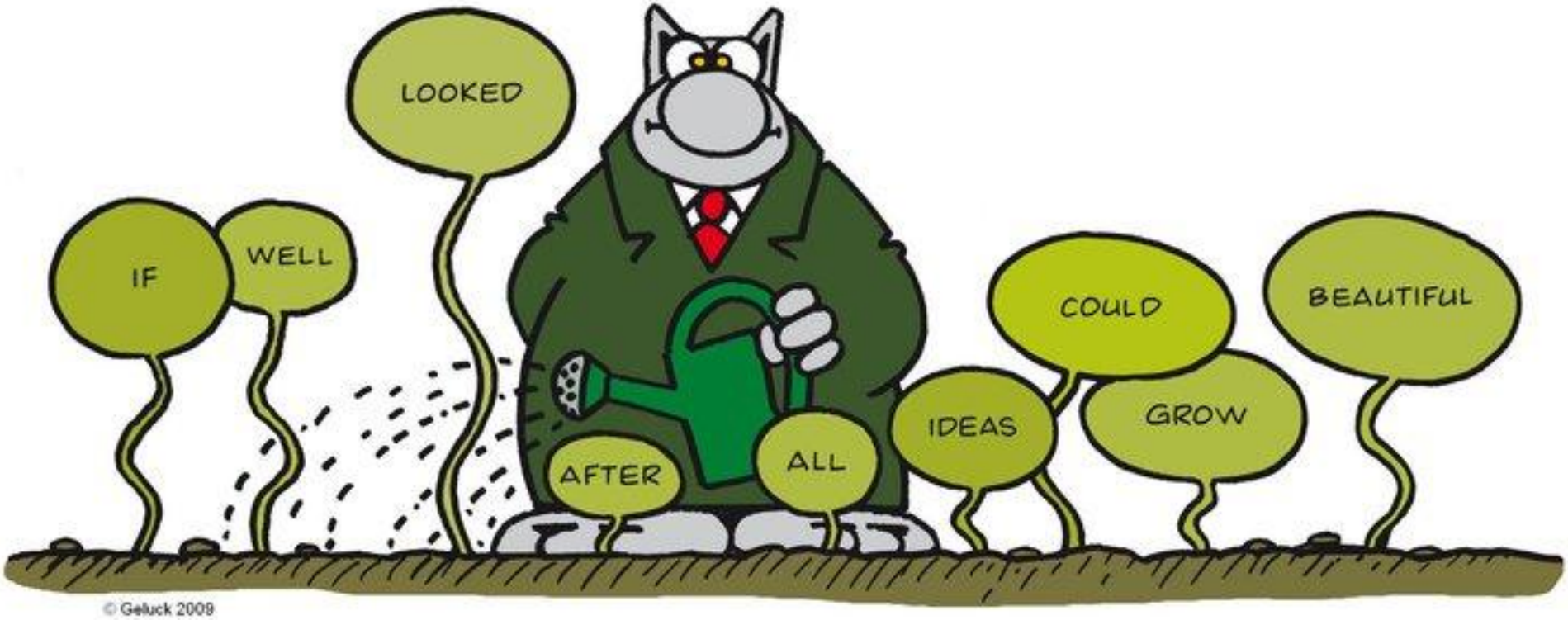
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