Innovative Medicines Initiative
- the story so far

Ruxandra Draghia-Akli MD PhD
Director Health, Research & Innovation DG

Health Research at a Crossroads
Are Public-Private Partnerships the Way Forward?
European Parliament, Brussels, 13 November 2012

The early days

- Informal meeting at working level
- Idea to set up an European Technology Platform
- Vision document from EFPIA 2004
- Stakeholders consulted on Strategic Research Agenda
  - Convergence on most important issues to be considered
- Reflections on 'how'

Creating IMI

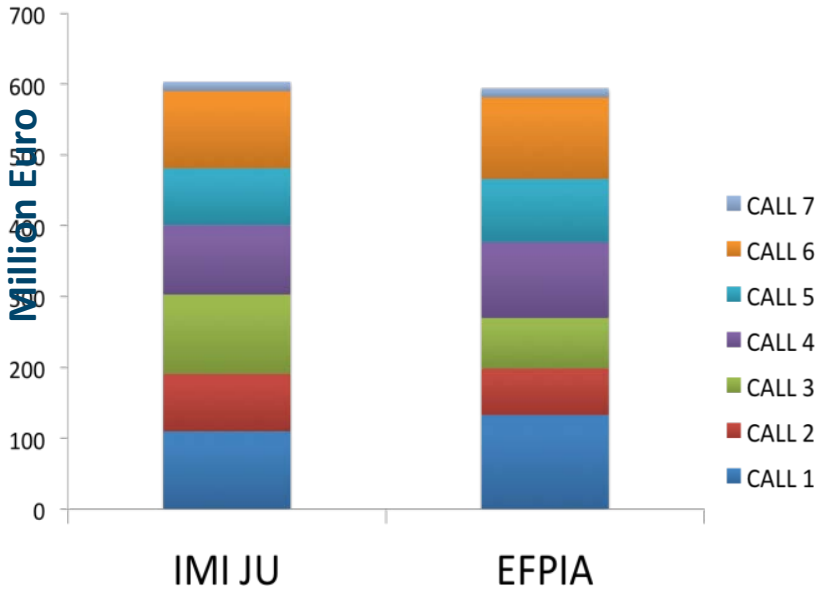
- New type of public/private partnership
- 1:1 funding, joint decision making
- All EU funding goes to SMEs, academia, patient organisations and regulatory agencies
- Large pharmaceutical industry, represented by EFPIA, contributes in-kind

Creating IMI

- Set up of a 'Joint Undertaking' between the EU and industry in the form of a 'community body'
- Council Regulation 2008/73 adopted in December 2007; strong support in EP
- Autonomy of Executive Office in September 2009 with Prof. Michel Goldman as Executive Director

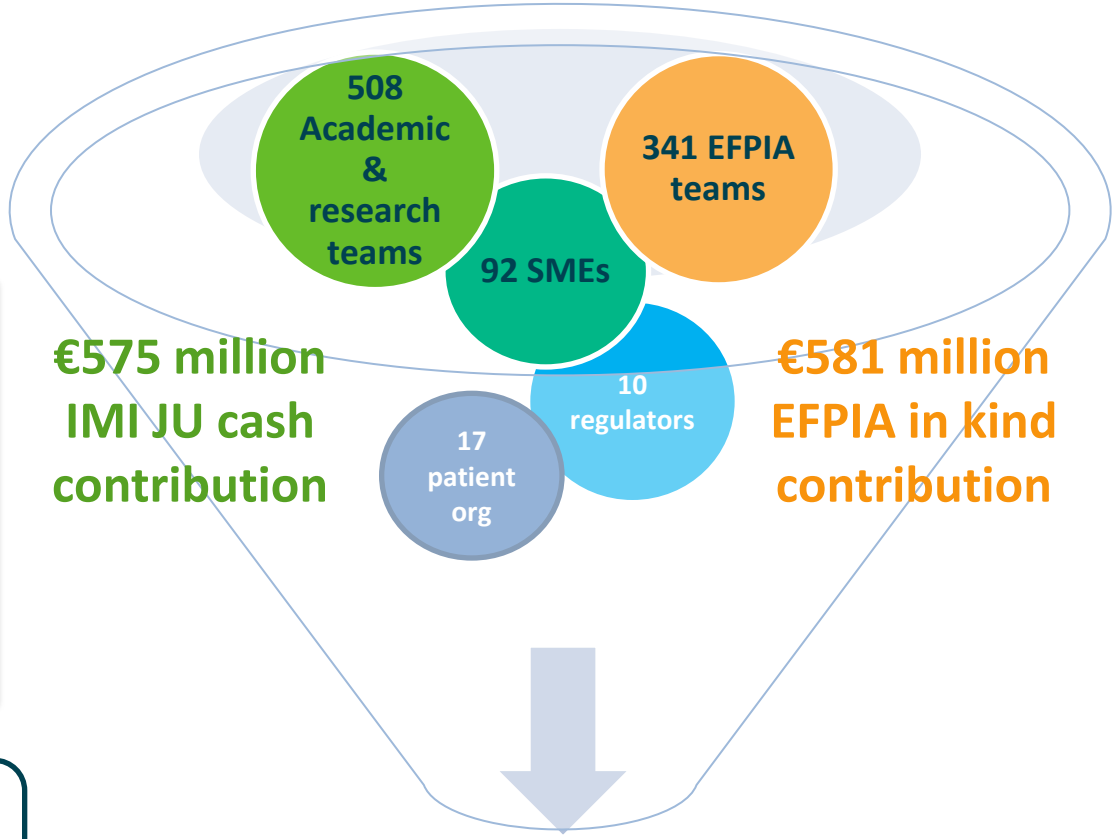
Implementing IMI

- 7 calls so far
- First projects run for ~3 years but generate already exciting results, way beyond state of the art



- 8th call to be launched shortly, will bring contributions from IMI Joint Undertaking and EFPIA to ~€750 million each

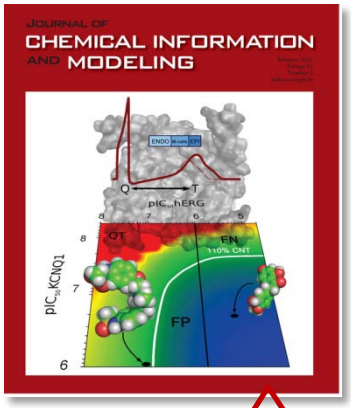
37 ongoing projects - key figures



€575 million IMI JU cash contribution

€581 million EFPIA in kind contribution

EU-AIMS contribution to autism



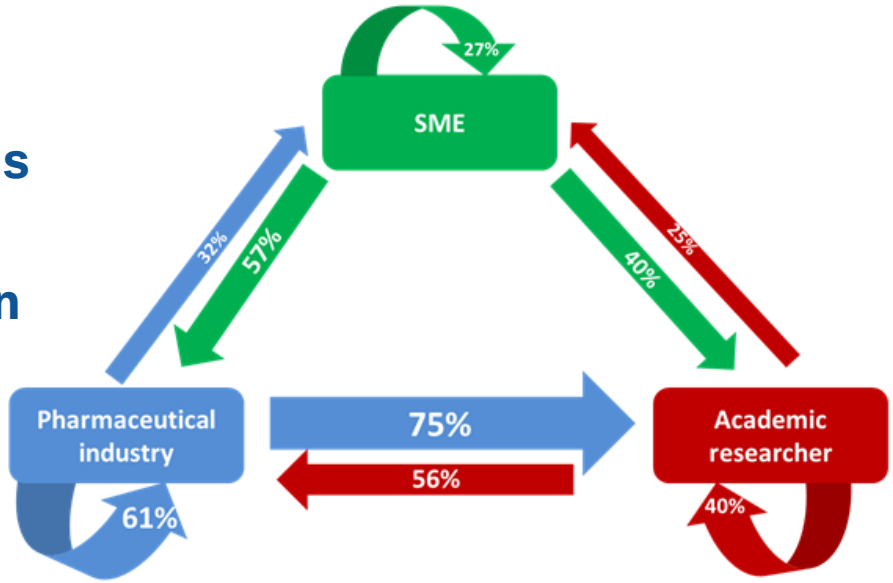
eTOX contribution to cardiotoxicity

~ 3500 researchers

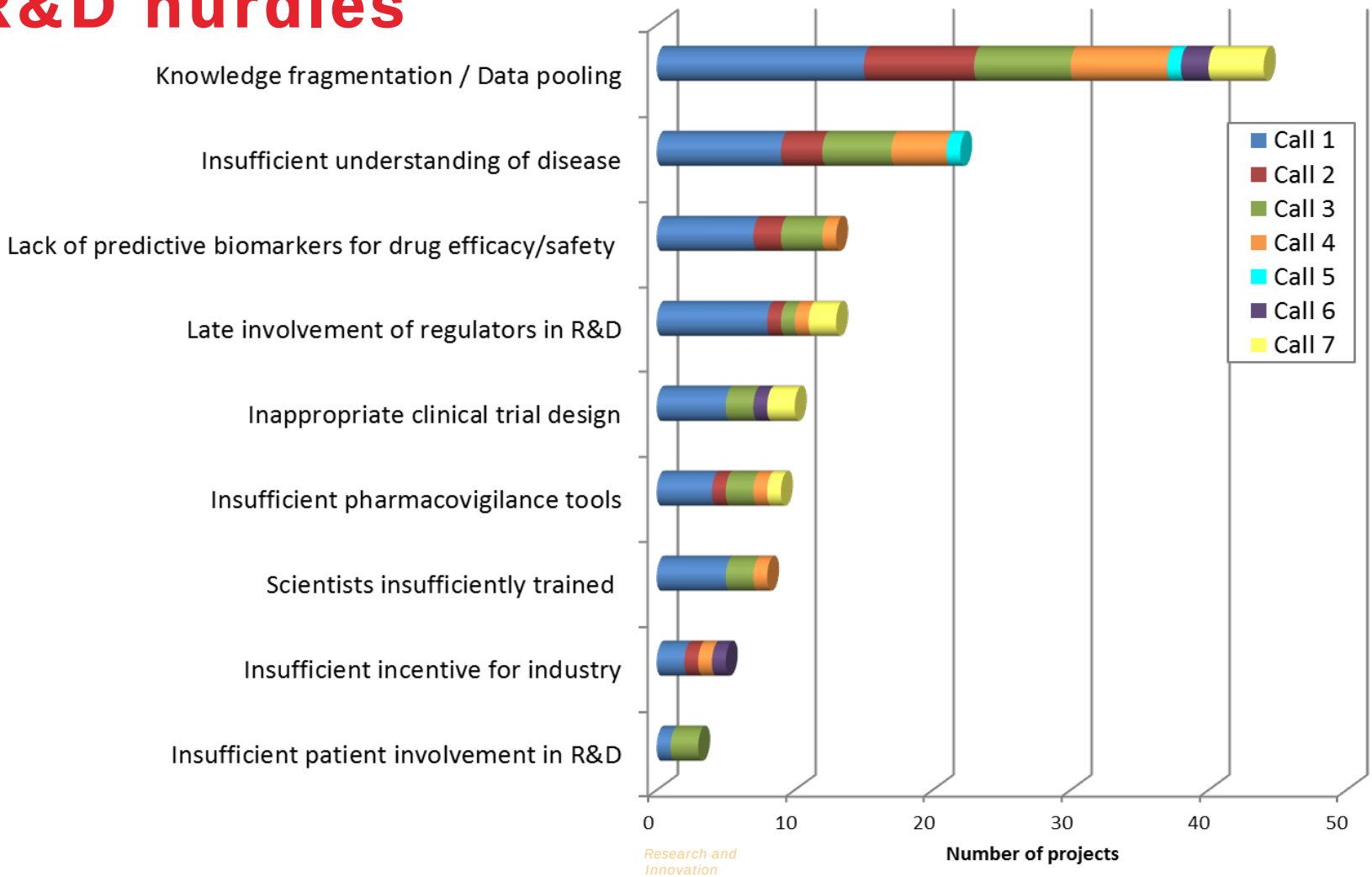
> 200 publications

Creating a real partnership

- The world largest PPP in pharmaceutical research
- Has succeeded in developing trust and dialog at many levels:
  - Between EU and pharmaceutical industry
  - Brought on board patients and regulators
  - True partnership between different research stakeholders: academia, SMEs, large industry, patients



Overcoming R&D hurdles



Improving R&D productivity

- **Eliminating poorly predictive pre-clinical models and establishing robust validated models for drug development**

  e.g. first human β cell line - diabetes, Tg models - AD, translatable challenge models – AD, chronic pain

- **More effective prediction of adverse drug effects and late attrition, discussed at early stages with regulators**

  e.g. in silico model to predict cardiac toxicity, translational biomarkers - cardio, renal and hepatotoxicity

- **Exploiting existing data and biobanks through meta-analysis**

  e.g. faster and cheaper trials for drug efficacy in schizophrenia, preclinical tox database, linking biobanks - autism research

Improving R&D productivity

Agreeing development and regulatory submission of key standards for drug development

e.g. diagnostic criteria - severe asthma, virtual carotid histology - diabetic macroangiopathy, biomarker qualification strategy

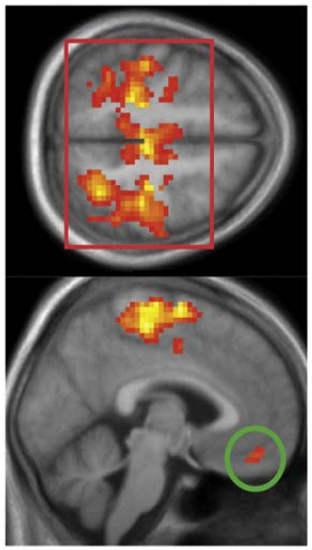
More efficient patient enrolment in clinical trials (localisation of patients for targeted clinical trials)

e.g. clinical investigator network - antibiotic development and autism, patient involvement, EHR

A closer look at neurosciences

Expected output	newmeds	PharmaCog	EU-AIMS Autism Research in Europe	EuroPain
Mechanistic knowledge	✓	✓	✓	✓
Patient stratification	✓	✓	✓	✓
Standardized model - in vitro -			✓	
Standardized model - in vivo -	✓	✓	✓	✓
Predictive biomarkers - genetic -	✓	✓	✓	
Predictive biomarkers - "omics" -	✓	✓	✓	✓
Predictive biomarkers - "imaging" -	✓	✓	✓	✓
Early involvement of regulators		✓	✓	

Understanding chronic pain and improving its treatment



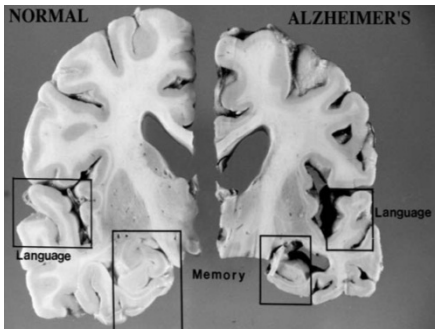
Objective

- Increase the understanding of chronic pain mechanisms to improve pharmacological treatment

Progress

- Novel pain target: CXCL5
- Better understanding of pain medication mechanism of action
- New translatable experimental models on pains, neuronal activity, quality of life
- New imaging biomarkers of brain activation related to chronic pain – currently tested on two sites in Denmark

Advancing science and treatment of Alzheimer's Disease



Objective

- To develop and validate the models required to increase the effectiveness of the drug discovery process in Alzheimer's disease

Progress

- Challenge model validated in 3 different species
- Translatable cognition touchscreen methodology for rodents
- Novel biomarkers to follow disease progression in transgenic mice
- Optimised 4 clinical study designs

Horizon 2020 and partnering

Public-private partnerships:

- **Through Joint Technology Initiatives or other formal structures (Art. 187)**
- **Through contractual agreements, which provide inputs for work programmes**
- **Only when criteria met e.g. clear commitments from private partners**
- **Also: public-public partnerships (e.g. ERA-Nets, Joint Programming Initiatives)**

Moving Forward with a PPP in Innovative Health Research – IMI²

→ Will be based on experience from IMI

European Commission

Thank you!

ruxandra.draghia-akli@ec.europa.eu
http://ec.europa.eu/research/health