Innovative Medicines Initiative - the story so far

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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

- 508 Academic & research teams
- 341 EFPIA teams
- 92 SMEs
- 17 patient org
- 10 regulators

EU-AIMS contribution to autism

€575 million IMI JU cash contribution

€581 million EFPIA in kind contribution

~ 3500 researchers

> 200 publications

eTOX contribution to cardiotoxicity
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

Knowledge fragmentation / Data pooling
Insufficient understanding of disease
Lack of predictive biomarkers for drug efficacy/safety
Late involvement of regulators in R&D
Inappropriate clinical trial design
Insufficient pharmacovigilance tools
Scientists insufficiently trained
Insufficient incentive for industry
Insufficient patient involvement in R&D
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

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<th>NEuMEDS</th>
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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
Thank you!

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