Why IMI matters to the EU’s health research goals?

IMI - Revolutionising Europe’s Pharmaceutical Industry
IMI Matters!
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Maria Vidal, MD PhD
Head of Unit - Medical Research, Directorate Health Research and Innovation DG - European Commission
Main Policy Drivers for IMI

- IMI addresses the key societal challenge of health of European Citizens in a situation of an ageing population

- Increasing competitiveness of European health-related industries and businesses

- IMI addresses the goal of the Innovation Union to enhance the cooperation between the worlds of science and business
IMI OBJECTIVES
Helping to speed up the development of better and safer medicines for patients

Drugs development process

Areas of bottlenecks

Research in 2 key areas

Underpinning themes

Discovery research
Preclinical development
Translational Medicine
Clinical Development
Pharmacovigilance

Prominent areas:
- Predictive pharmacology
- Predictive toxicology
- Identification of biomarkers
- Patient recruitment
- Validation of biomarkers
- Benefit/risk assessment with regulatory authorities

Knowledge Management

Education & Training

Safety

Efficacy
IMI Governance: the composition of IMI JU

IMI Joint Undertaking (IMI JU)

- Governing Board
- Executive Director (+ staff)
- Scientific Committee

2 Founding Members

- Overall responsibility for the operations of IMI

- Responsible for day-to-day management

- 15 members
  - Scientific advise to the Board
IMI Governance: External Advisory Bodies

Annual meeting open to all stakeholders
(e.g. academia, SMEs, patient organisations, Regulatory authorities, EFPIA and other industry)
Communication and Feedback

One representative per Member and Associated State
Interface with stakeholder in MS/AS and communication
Chair is observer in Governing Board
Research Performed in IMI is Based on a Scientific Research Agenda

- The Scientific Research Agenda prepared through consultation with all relevant stakeholders
- The Patient in the Focus of Pharmaceutical Research
IMI particular features

- Problem-solving approach and precompetitive research
- Potential to address unmet medical needs ("unlock" a specific area)
- Dialogue with the regulatory authorities
- Work beyond usual habits
  Participation to large and new types of partnerships.
  Data and knowledge sharing at larger scale.
- New research tools to be rapidly and broadly spread and taken up within the scientific and industrial community

A tailor-made IMI intellectual property policy provides the adequate provisions to support this challenge.
Expectations for IMI

- Address open innovation
- Tool to reinvigorate drug development for the benefit of patients
- Consolidate research networks and PP collaboration
IMI State-of-Art

● 2 calls implemented:
  ▶ 23 projects running in 2011 with ~190M€ from IMI JU and ~200 M€ from EFPIA companies

● 3rd call projects under negotiation

● 4th call launched in July, deadline 18 October 2011

● Solid reflection on remaining calls engaged

● 1st Interim evaluation of IMI JU
Key Achievements of Ongoing Projects

More examples in following session « IMI Breakthroughs »
New databases have been constructed allowing the collation and warehousing of data in projects such as **NEWMEDS**, **SUMMIT** and **U-BIOPRED**.

- **eTOX** is in the process of establishing the largest shared database of preclinical safety data
- The value of these databases in promoting pre-competitive collaboration and better knowledge management has already been shown
The shock wave hit when they broke the code. It was January 2005, nearly four years since the start of a clinical trial to definitively compare schizophrenia therapies. The US$43-million trial, involving nearly 1,500 patients, was so expensive and so time-consuming that it was never completed.

The drug deadlock was a result of the biology being too complicated. Pharma companies are quitting. The biology is too complicated.

Where are schizophrenia drugs going to come from?

BY ALISON ABBOTT

pressure to rein in costs, several large companies, including London-headquartered AstraZeneca and GlaxoSmithKline, chose to pull out of the trial. No one questions the transformational impact of the first antipsychotic drugs when they were introduced in the 1950s. Psychiatric hospitals could, for the first time, release patients from the long-term wards. But to make a drug that works for schizophrenia, companies have to find the balance between profit and philanthropy.

Nature, 11 November 2010
To overcome major bottlenecks in developing models and methods in drug discovery for schizophrenia and depression
- Lack of accurate animal models
- Lack of tools and tests to provide early indication of efficacy
- Reliance on old clinical trial methodology

NEWMEDS project pools data of 23,401 anonymized schizophrenia patients from 67 trials on 11 compounds in over 25 countries

The single largest database of clinical trial data ever amassed in psychiatric research

For depression, bringing together
Data from public projects and 3 companies on the genetics and clinical response in 1800 well characterized patients

€8.2 M from IMI; €13.2 M EFPIA in-kind
U-BIOPRED consortium: at the Forefront of Research on Severe Asthma

U-BIOPRED Consortium

*Development and validation of a biomarker ‘handprint’ in asthma to predict disease severity and allow more personalised therapies*

12 Partners

- 5 EFPIA Pharma Companies
- 6 Academic Institutions
- 1 SME

The U-BIOPRED team has recruited the first of over 1000 people into a major new study of severe asthma

A new stepwise algorithm for the better diagnosis of severe asthma required for the successful planning and execution of clinical trials, has been agreed by consortium
U-BIOPRED consortium: at the Forefront of Research on Severe Asthma

Diagnosis and definition of severe refractory asthma: an international consensus statement from the Innovative Medicine Initiative (IMI)

Elisabeth H Bel,¹ Ana Sousa,² Louise Fleming,³ Andrew Bush,⁴ K Fan Chung,⁵ Jennifer Versnel,⁶ Ariane H Wagener,¹ Scott S Wagers,⁷ Peter J Sterk,¹ Chris H Compton,⁸ on behalf of the members of the Unbiased Biomarkers for the Prediction of Respiratory Disease Outcome (U-BIOPRED) Consortium, Consensus Generation⁹

ABSTRACT
Patients with severe refractory asthma pose a major healthcare problem. Over the last decade it has become increasingly clear that, for the development of new targeted therapies, there is an urgent need for further characterisation and classification of these patients. The

DIAGNOSIS AND DEFINITION OF SEVERE ASThma OVER THE LAST 15 YEARS
Various documents proposing different clinical definitions of ‘severe asthma’ in adults and children have been published over the last 15 years by international task forces, workshops, networks and

Thorax, 23 November 2010
IMI Education & Training Projects

European Medicines Research Training Network (EMTRAIN)

European Programme in Pharmacovigilance and Pharmacoepidemiology (Eu2P)

Pharmaceutical Medicines Training Programme (PharmaTrain)

European Modular Education and Training Programme in Safety Sciences for Medicines (SafeSciMET)

Contribute to building of ERA
### SME Involvement in IMI Projects

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SMEs involved in all projects except the education and training projects from the first call.
What is in the pipeline?

Update of the IMI Scientific Research Agenda

- Extensive consultations with stakeholders
- Decision June 2011

Forms the basis for Future Calls of IMI

IMI JU 4th Call (2011) closing date 18 October 2011, particular effort on Knowledge Management

The remaining calls will bring:

- Larger projects for some topics
- Special focus on knowledge management to harness the wealth of data generated by IMI projects
Patient level health information has potential to significantly advance medical and pharmaceutical research; particular need for such information for paediatric populations. 

Potential so far not used because of hurdles.

By submitting a proposal to this topic, researchers can contribute to fulfilling the vision for EMIF to create a lasting and comprehensive framework to use patient level data:
- Broad network for access to existing data
- Governance model for ethics and privacy
- Data management and analysis

**Three topics under EMIF**
- Information framework / knowledge management service layer
- Metabolic complications of obesity in adults and children
- Protective and precipitating markers for the development of AD and other dementias
More about IMI on the IMI Website imi.europa.eu
Thank you for your attention!