

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



IMI – Revolutionising Europe's Pharmaceutical Industry
IMI Matters!

6 October 2011

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Main Policy Drivers for IMI

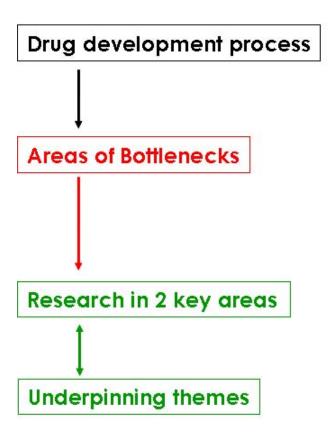
- IMI addresses the key societal challenge of health of European Citizens in a situation of an ageing population
- Increasing competitiveness of European health-related industries and businesses
- IMI addresses the goal of the Innovation Union to enhance the cooperation between the worlds of science and business

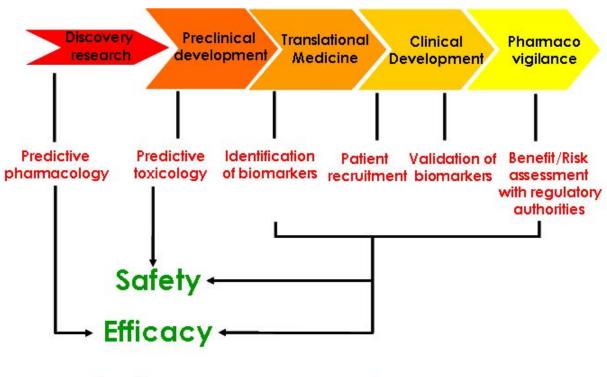




IMI OBJECTIVES

Helping to speed up the development of better and safer medicines for patients





Knowledge Management Education & Training





IMI Governance: the composition of IMI JU



COOPERATION



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

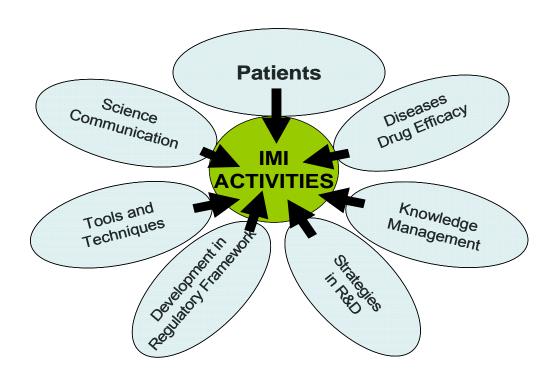






Research Performed in IMI is Based on a Scientific Research Agenda

- 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

COOPERATION



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 »





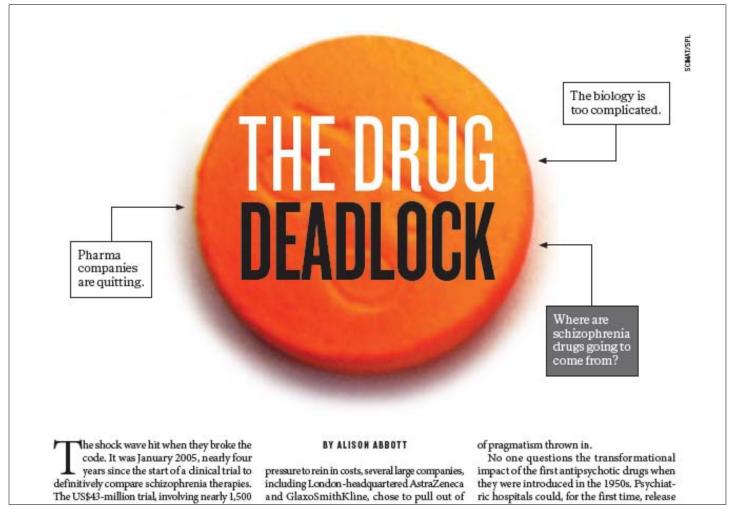
Establishing Common Databases: A Key Investment to Ensure Fast Knowledge Uptake

- New databases have been constructed allowing the <u>collation and</u> 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





NEWMEDS Consortium: at the Forefront of Research on Schizophrenia



COOPERATION





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

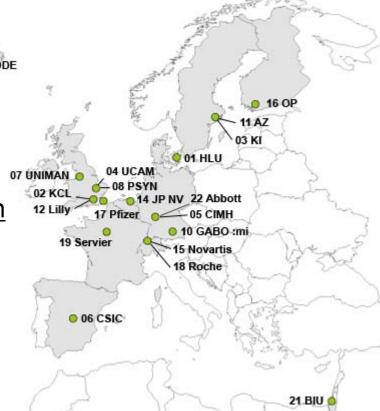
- Reliance on old clinical trial methodology

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

COOPERATION



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



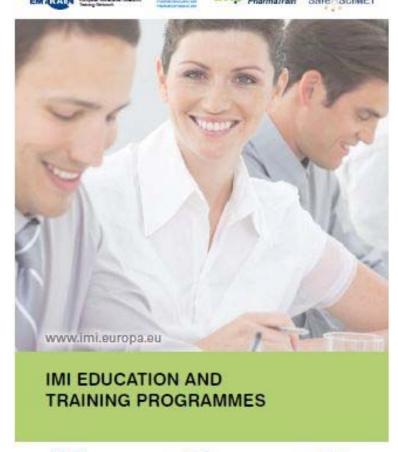
IMI Education & Training Projects

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

	Number of SME	SME funding	Total Funding	%
Call 1	25	14.602.472	109.593.433	13,32%
Call 2	22	15.455.411	80.740.072	19,14%
Call 1 and 2	47	30.057.883	190.333.505	15,79%

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





Topic for Large Project from 4th call: EMIF Patient Level Data - Knowledge Management -

Patient level health information has potential to significantly advance medical and pharmaceutical research; <u>particular need for such information for paediatric populations</u>



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





ABOUT IMI



The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.

IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.

IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA.



efpia

more (*)

IMI at the European Parliament

Join IMI and the other Joint Technology Initiatives in Brussels on 6 October to find out how they are successfully driving innovation. mo€

IMI at Eurobiotech

Join IMI on 12 October for an event in Krakow, Poland on 'IMI – New opportunities for drug research in Europe'. more ●

IMI NEWSFLASH



19/09/2011: IMI has opened the online submission tool for Expressions of Interest to IMI's 4th Call:

http://t.co/SLbGF8my Deadline = 18 October 2011.

01/09/2011 : New!

Questions and answers on the IMI 4th Call topics are now online at http://t.co/8rCq9Dz

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FINDING PARTNERS

IMI has updated its Partner Search e-tool which now provides direct links to potential partners for people interested in finding possible partners in

VISIT IMI'S ONGOING PROJECTS

IMI currently funds 23 projects with a combined budget of over €450 million and covering drug safety and efficacy, knowledge

IMI VIDEOS



WEB UPDATES

- IMI launches 4th Call f
- IMI Open Info Day videos are available now



Thank you for your attention!

