



Innovative Medicines Initiative (IMI): Focus, challenges and impact on drug discovery and development

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EUFEPS Conference: Effective Integration of Systems Biology, Biomarkers, Biosimulation and Modelling in Streamlining Drug Development
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The Innovative Medicines Initiative *What is it?*



- Clear, practical paths to accelerate the discovery and development of more effective innovative medicines with fewer side-effects.
- Innovative projects that address the causes of delay or bottlenecks in the R&D process.
- Unique pan-European public and private sector collaboration in biopharmaceutical research.
- First pre-competitive collaboration of this amplitude: €460 million per annum over 7 years (50% EU; 50% Industry)

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The Innovative Medicines Initiative History and Future

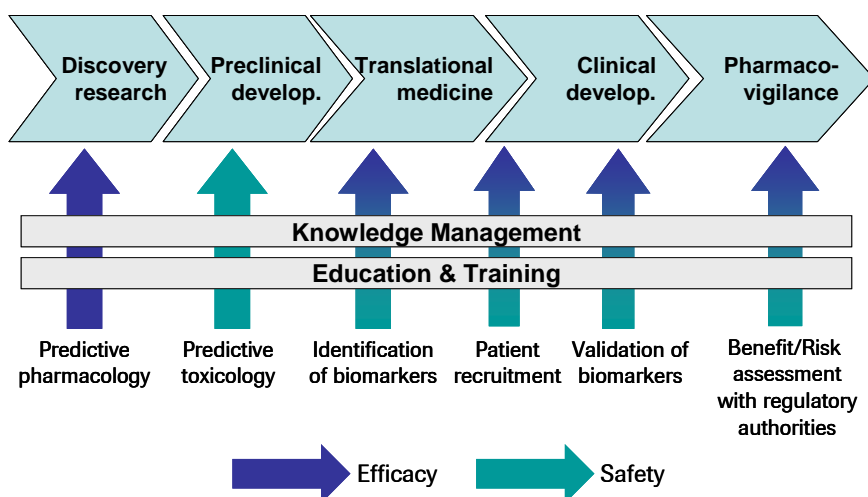


- Joint initiative between EFPIA and European Commission in 2004 – consultation with stakeholders throughout 04/05.
- Pilot proposal generated and now funded under Framework Programme 6, InnoMed
- Strategic Research Agenda:
www.efpia.org/4_pos/SRA.pdf
www.imi-europe.org
- IMI to be proposed as a Joint Technology Initiative under Framework Programme 7



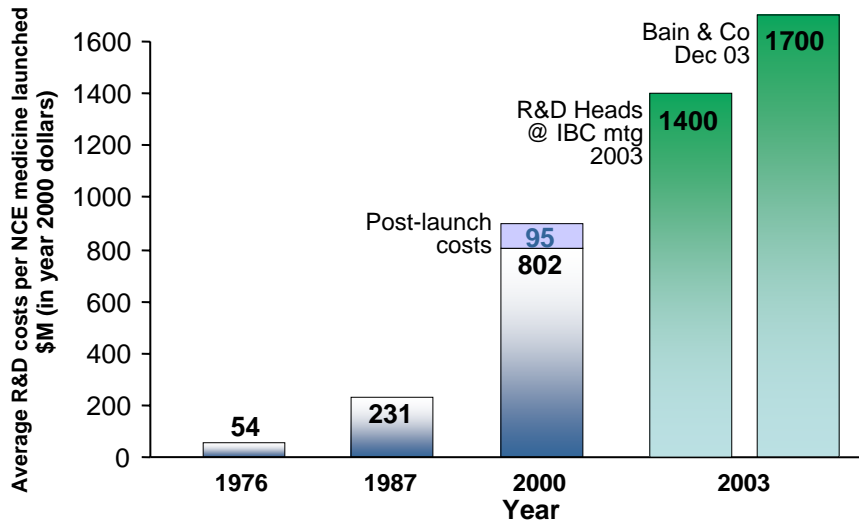
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The Innovative Medicines Initiative Strategic Research Agenda focus on the “pre-competitive” bottlenecks in the R&D Process



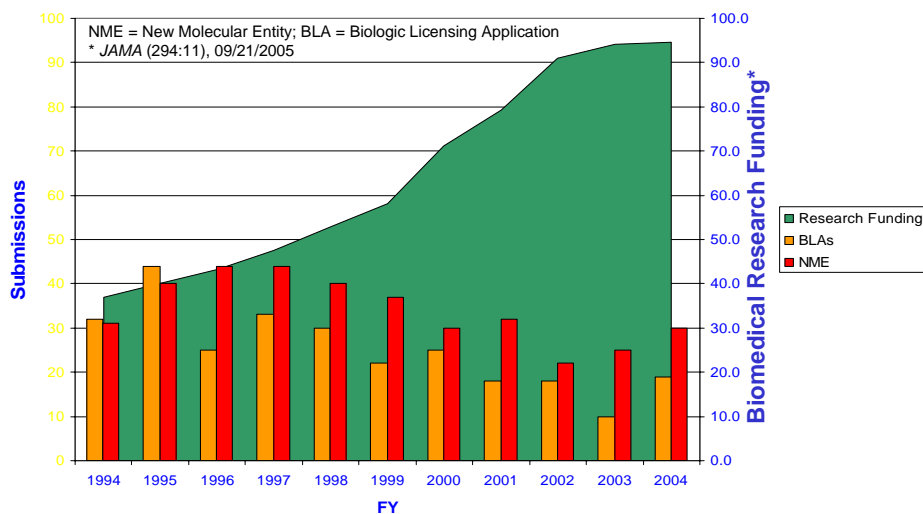
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The cost of innovation



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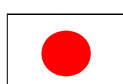
Trends in Biomedical Research Spending



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Global recognition of the problem



	Innovative Medicines Initiative (EU)
	Medicamentos Innovadores (Spain)
	Top Institute Pharma (Netherlands)
	ECRIN (France)
	Safety Biomakers (UK)
	FDA Critical Path Initiative (NIH)
	Safe and Innovative Medicines (PhRMA)
	Biomarker Initiative (PhRMA)
	Critical Path Institute (University of Arizona)
	Center for Biomedical Innovation (MIT)
	Toxicogenomics Project (JPMA)
	Proteome Factory Consortium (JPMA)
	Large-scale Clinical Trial Network

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The drivers for a new R&D model of public-private partnership



- Cost and timelines of drug development
 - Need a change the paradigm of drug discovery to decrease attrition and improve effectiveness
- Wealth of novel opportunities from genomics
 - How to pick the right molecules and bring them to the right patients
- The potential of increased cooperation with stakeholders
 - Greater academic collaboration, increased patient involvement and better dialogue with regulators
- The need for increased openness
 - Transparency of operation e.g. publication of Clinical Trial data, sharing toxicology data, etc.

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SAFETY: Making Medicines Safer



- Goal: improve the predictability of toxicological observations
- Main recommendations:
 - Create a European Centre for Drug Safety Research
 - Establish a framework for biomarker development to study human relevance and regulatory utility
 - Develop computational methods for predicting toxicity
 - Pharmacovigilance: Develop novel methods of risk prediction and benefit-risk assessment

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EFFICACY: Making Medicines More Effective



- Goal: improve clinical performance and early access to innovative medicine
- Main recommendations:
 - Focus on areas of high scientific challenge
 - cancer, inflammatory disease, brain disorders, metabolic disease, infectious disease
 - Stimulate translational medicine in an integrated fashion
 - Create disease-specific imaging networks
 - Develop partnership with regulators for innovative clinical trial design and acceptance of biomarkers

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KNOWLEDGE MANAGEMENT: Underpinning Infrastructure



- Goal: manage and organise data to create knowledge to predict benefit and risk of new therapies
- Main recommendations:
 - Develop enhanced knowledge representation models and data exchange standards for complex systems
 - Build a core reference database of validated experimental data extracted from the literature
 - Design standards for and build an expert tool to allow the federation of local databases in a secured environment

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EDUCATION & TRAINING: Underpinning Resource



- Goal: support the interdisciplinary education essential for the bioscience sector
- Main recommendations:
 - Create a European Medicines Research Academy for education and training for professionals involved in biomedical R&D and regulation
 - Map existing activities within E&T and develop programmes for the critical areas of need
 - Foster mobility between academia and industry

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Systems Biology, Biomarkers, Biosimulation and Modelling



Cancer theme

- Cancer Specific Community of Experts in Systems Biology
 - Improved understanding of disease and target
 - Prevention, invasion and metastasis, pulmonary disease
 - Cross-disease interests in cancer, respiratory physiology and inflammation
- Clinical Pharmacology Community of Experts
 - Modelling and simulation in clinical development
- Biomarker Community of Experts
 - Integrated research programme using SB for identification and prioritisation of biomarkers

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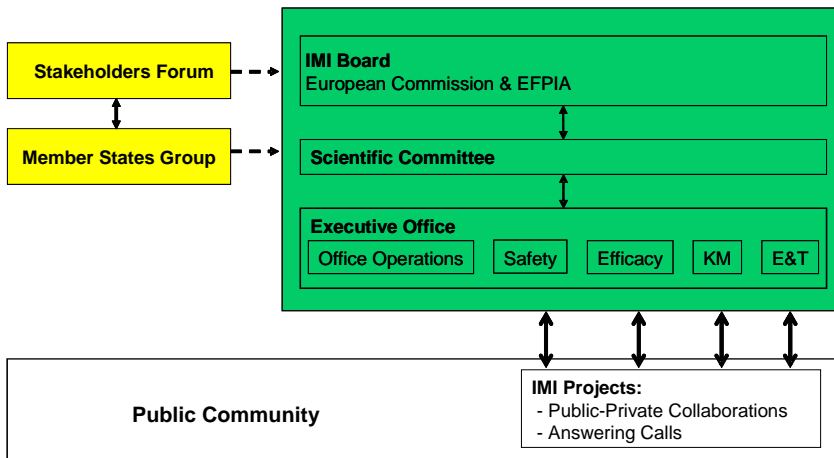
IMI structure and governance Guiding Principles



- A Joint Undertaking as defined by Article 171 of the Treaty of Rome
- IMI's governance structure reflects:
 - science driven approach
 - collaboration between stakeholders
 - rapid take up of research results
 - convergence and synergies with national and international efforts
 - transparency and openness
- IMI will be an open structure where the research will be done by:
 - industry, SMEs, academia, clinics, patient organisations, etc. following open calls and peer review.
- Rules for IPR will be fair and clear to all participants from the onset.

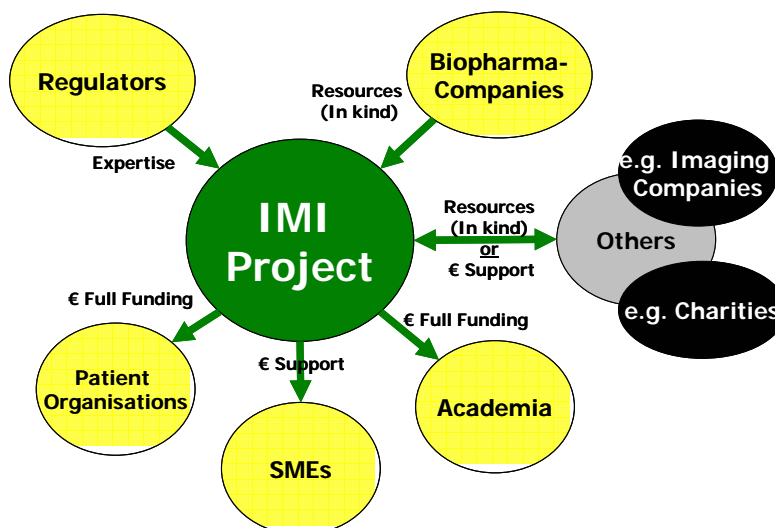
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IMI structure and governance



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Project Participants & their Contribution



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Benefits of IMI for Europe



- Synergy with national research funding through good EU co-ordination
- Stimulus for large and small companies
- More jobs in the EU and contributing to the Lisbon objective
- More education and training in the biomedical arena
- More effective healthcare with focus on translational science
- Decreasing the brain drain by strengthening the European science base

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Next Steps



- | | |
|-----------------|--|
| 1Q2007 | European Commission finalises package for submission to the Member States (European Competitiveness Council) |
| 1-2Q2007 | European Commission submits package to the European Competitiveness Council |
| 3-4Q2007 | Competitiveness Council approves IMI |
| 3-4Q2007 | Executive Office set up |
| 4Q2007 | IMI publishes first calls for proposals |

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It is Possible.... InnoMed

16 Companies – 14 Universities – 7 SMEs from across EU

- 18 mio euros including European Commission funding
- Biomarkers in Alzheimer's Disease:
 - Better and earlier diagnosis of onset of disease
- Predictive Toxicology:
 - New approaches to measure earlier potential medicine side effects



The Innovative Medicines Initiative IPR Policy “Research Use”



Research Use after Completion of the Project

The right to make and use products or processes which are protected by licensed IP for all purposes relating to research, discovery, development, approval and commercialisation of diagnostic or pharmaceutical products.

Licensee	Foreground IP	Background IP necessary to use Foreground IP
Project Participants	Made available for Research Use on a royalty free non-exclusive basis	Made available for Research Use on a non-exclusive basis on fair and reasonable terms or royalty free
Third Parties	Made available for Research Use on a non-exclusive basis on fair and reasonable terms, which may include free use.	Made available for Research Use on a non-exclusive basis on fair and reasonable terms

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The Innovative Medicines Initiative IPR Policy “Direct Exploitation”



Direct Exploitation after Completion of the Project:

- The right to develop, sell or otherwise commercialise products or processes which are the subject of the IPR itself.
- Participants may exploit their intellectual property rights as they see fit beyond the Research Use rights described in the IP Policy.
Participants may agree such use rights in the Project Agreement.

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