




Health NCP Net IMI Online Training, 02.08.2011

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Projekträger im DLR



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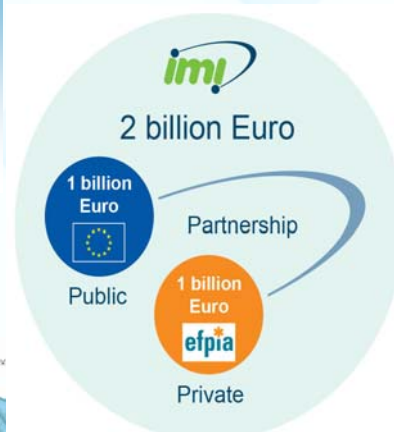
Introduction

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vB1

What is the Innovative Medicines Initiative (IMI)?



- Biggest public-private partnership in the area of medicine
- Innovative collaboration established between the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA) as a Joint Technology Initiative under FP7
- Aims at making the drug discovery and development process in Europe more efficient, to bring better medicines faster to patients
- Public funding goes exclusively to academia, SMEs, patient organisations and Regulatory Authorities

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vB1 see word document for reformulation
von Bethlenfalvy; 02.07.2009

How is IMI operating?



- IMI supports collaborative research projects following open and competitive calls with a peer review process by independent experts
- Project funding via combined contributions from
 - public funds for academia, public organizations, small and medium sized companies (SMEs), patients associations, ...
 - private - in form of 'in kind' contributions from the participating pharmaceutical companies
- Average project size 20 million EURO
- Average partnership 10-15 pharmaceutical companies and 10-15 academic, SME, regulatory, patient organizations

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Governance




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Why apply?



- Looking for additional **funding**
- Interested in **patient-centric** biomedical/pharmaceutical research
- Interested in **collaborating** with large pharmaceutical companies


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Key concepts



- **Non-competitive research** for EFPIA companies
- **Competitive calls** for IMI beneficiaries
- **Open collaboration** in final consortia

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How to build an IMI project

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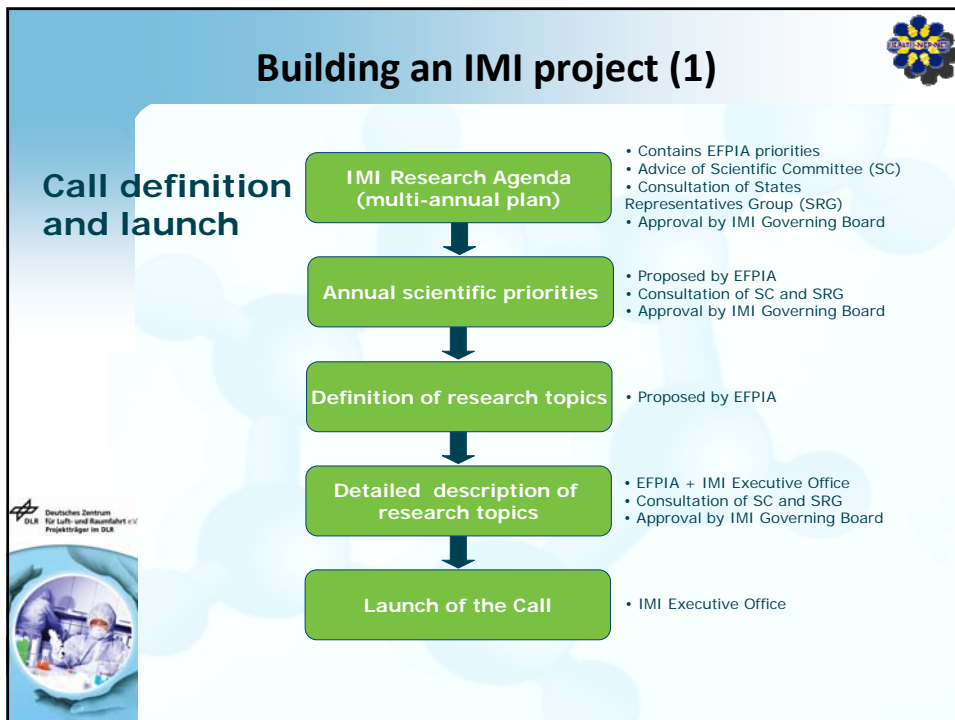
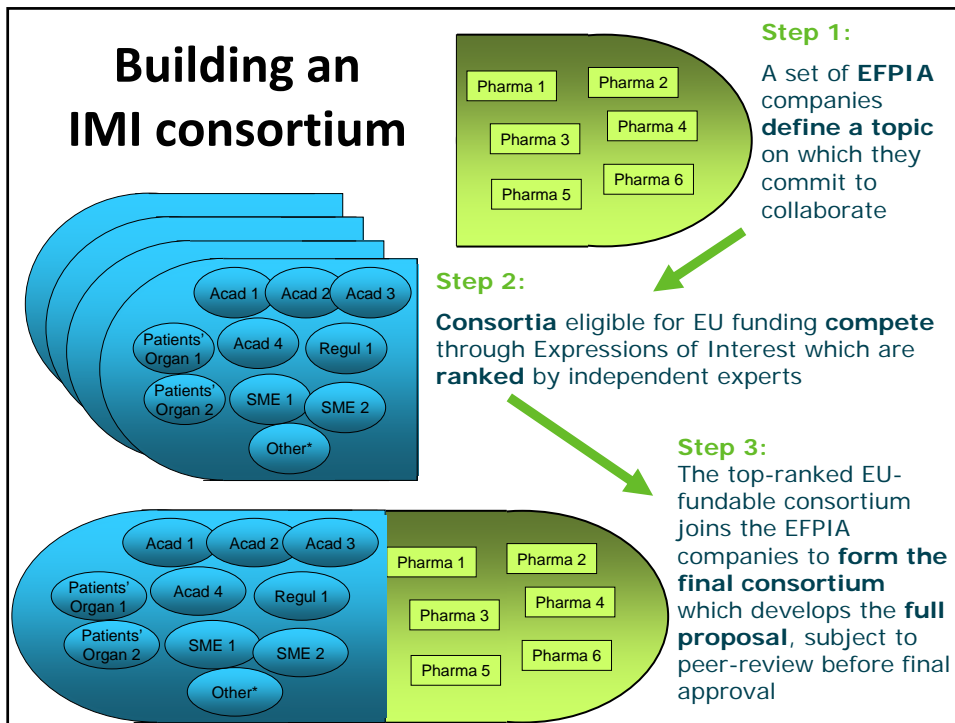
Eligibility for IMI JU funding



- **Eligible for funding**
 - Academia
 - SMEs (EU definition)
 - Patients' Organisations
 - Non-profit research organisations
 - Intergovernmental organisations
- **Not eligible for funding**
 - EFPIA companies (*in kind contribution*)
 - Companies that fall outside the EU definition of SMEs
 - Others
- IMI funds activities in the EU + FP7 associated countries

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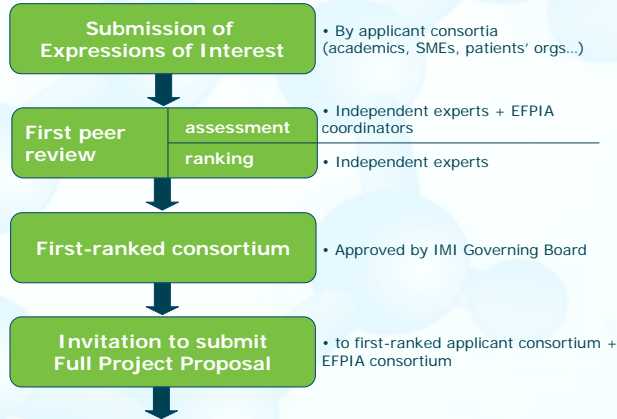


Building an IMI project (2)



Competition between applicant consortia

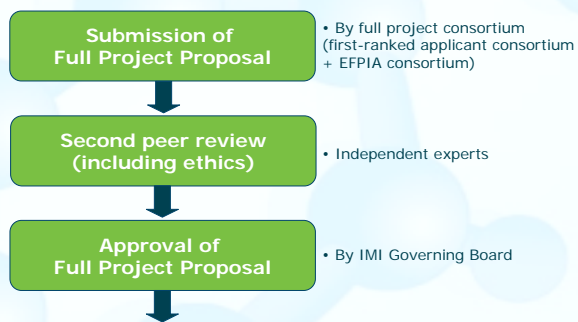
(potential IMI beneficiaries)



Building an IMI project (3)



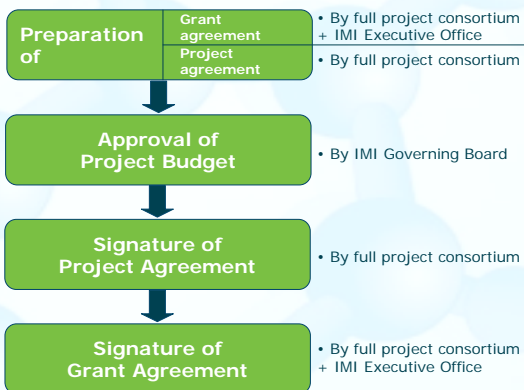
Joint preparation of Full Project Proposal



Building an IMI project (4)



Contract negotiation



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Funding rules



- | | |
|---|--|
| <ul style="list-style-type: none"> R&D-Activities <p>max. 75% of</p> | <ul style="list-style-type: none"> Management and Training Activities <p>max. 100% of</p> |
|---|--|
- direct + indirect costs
(indirect costs max. 20% of direct costs or actual indirect costs) **! NEW !**

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Funding rules



- R&D-Activities
max. 75% of
direct + indirect costs
(indirect costs max. **20%** of direct costs or **actual indirect costs**)
- Management and Training Activities
max. 100% of

Deviation from FP7 - Example:

Project with direct projekt costs for R&D-Activities of 100.000 Euro.

In IMI:

100.000 Euro + 20% Overhead (20.000 Euro) = 120.000 Euro total costs


IMI JU funding: (75%): **90.000 Euro**

in FP7 (Special Transition Flat Rate):

100.000 Euro + 60% Overhead (60.000 Euro) = 160.000 Euro total costs

EC funding (75%): **120.000 Euro**

Difference IMI - FP7: 30.000 Euro


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Ongoing IMI projects



Figures and examples

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Calls 1 & 2: consolidated figures



	Call 1	Call 2	Total
Projects	15	8	23
EFPIA Companies	21	21	23
Academic teams	195	103	298
SME teams	24	23	47
Patients' organisat.	9	2	11
Total Budget (M€)	281	172	453



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Country of Origin of IMI Beneficiaries

Austria	11	Israël	4
Belgium	18	Italy	19
Czech Republic	1	Luxembourg	2
Denmark	10	Netherlands	29
Estonia	1	Norway	2
Finland	10	Poland	2
France	44	Portugal	2
Germany	55	Serbia	1
Greece	4	Spain	22
Hungary	3	Sweden	24
Iceland	1	Switzerland	18
Ireland	4	United Kingdom	75



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SME/Academic Viewpoint

OPPORTUNITIES

- Networking - deal opportunities
- Access to multicentric studies on large cohorts
- International visibility
- Private funding opportunities

THREATS

- Transfer or sharing of the IP and know-how
- Financing
- Diffusion of sensitive information
- Administrative burden



Aspects to be considered before preparing an application in IMI



- IMI IP Policy deviates from FP7 rules for participation
 - broader definition of „affiliated entities“
 - access rights for „affiliated entities“ and third parties
 - time limit for access rights
 - „research use“
- Financial rules deviate from FP7 (Overhead)
- Application and Evaluation deviates significantly from FP7
 - e.g. participation of EFPIA coordinator & deputy in evaluation of EoI, pre-ranking of EoI by EFPIA consortium
 - Change of coordinator from 1st to 2nd stage



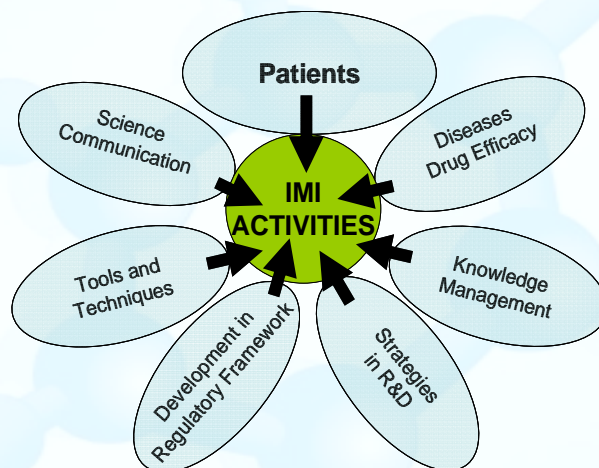


4th Call for Proposals

- Scientific agenda
- Topics
- Timeline




The revised Strategic Research Agenda: overall architecture



The revised Strategic Research Agenda: new research areas



- New taxonomy of human diseases - pharmacogenetics
- Rare diseases and stratified therapies
- Systems approaches in drug research
- 'Beyond high-throughput screening'- pharmacological interactions at the molecular level
- Active pharmaceutical ingredients development
- Advanced formulations
- Stem cells for drug development and toxicity screening
- Integration of imaging techniques into drug research

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The 4th Call for Proposals: key features



- First **'Think Big' topics** (\pm €50 million total budget per topic)
 - European Medical Information Framework (\pm €50 million)
 - Induced pluripotent stem cells (\pm €50 million)
- In addition, **new research areas** in pharmaceutical chemistry, oral drug delivery, binding kinetics, optimising delivery of biological macromolecules will be addressed
- The topics will continue to bring together **data, resources** and **expertise** from the **public and private sectors** to improve pharmaceutical research

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Call 4 topics



Medical Information System

1. A European Medical Information Framework (EMIF) of patient-level data to support a wide range of medical research
2. eTRIKS: European translational information and knowledge management services

Chemistry, Manufacturing and Control

3. Delivery and targeting mechanisms for biological macromolecules
4. *In vivo* predictive biopharmaceutics tools for oral drug delivery
5. Sustainable chemistry – delivering medicines for the 21st century

Technology and Molecular Disease Understanding

6. Human induced pluripotent stem (hiPS) cells for drug discovery and safety assessment
7. Understanding and optimising binding kinetics in drug discovery



EMIF: European Medical Information Framework




- **Patient level health information** is critically needed to advance medical and pharmaceutical research in adult and paediatric populations
- **EMIF** will provide:
 - Broad network for access to existing data
 - Governance model for ethics and privacy
 - Data management and analysis
- **Three topics** under EMIF:
 1. Information framework / **knowledge management** service layer
 2. Metabolic complications of **obesity** in adults and children
 3. Markers for the development of **Alzheimer's disease**



eTRIKS: European translational information and knowledge management services



- Translational research needs **management** and **sharing** of a large number of clinical and pre-clinical **data** between clinical and pre-clinical activities
- Proprietary **solutions exist** in companies:
 - **TRANSMART** in J&J, ready to move to the public domain
- Will make accessible a **wealth of data from translational research** projects (both IMI projects and other) available for the global translational research community
- Should seed a **stable, sustainable platform** and service to support academic and commercial translational research across Europe


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Delivery and targeting mechanisms for biological macromolecules



- Biological macromolecules have **high potential** as therapeutics but their **efficient delivery** at the right target is often **limited** (anti-sense oligonucleotides)
- Chemical **stabilisation** and **delivery** of macromolecules requires **collaborative efforts**:
 - Drug **development**
 - Molecular and cellular biology of **cellular uptake mechanisms**
 - Protein and nucleic acid **chemistry**
 - **Manufacturing** and **characterisation** of biological macromolecules
 - **Nanotechnologies**


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In vivo predictive biopharmaceutics tools for oral drug delivery



- Testing of oral drug delivery still mostly depends on **animal models**
- Predictive **in vitro tools**, integrated with **in silico models** are urgently needed
- Major opportunities for **combining expertise** between 'big pharma', SMEs and academic teams


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Sustainable chemistry



- Addresses the need for innovative methods for the **synthesis of chemical drugs**:
 - Novel organic and organo-metallic **catalysts**
 - Process intensification / **flow chemistry**
 - **Bio-catalysis**
 - **Synthetic biology**


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Human induced pluripotent stem cells in drug development



- hiPS are **promising tools** for the development of innovative medicines:
 - Drug **discovery**
 - Drug **safety**
- Need for public/private collaborative research to:
 - Establish **biobanks**
 - Access hiPS cell lines from different **ethnicities** and patients with defined **phenotypes/genotypes**
 - Establish standardised biological **assays**
 - Establish **collaborations** with other consortia

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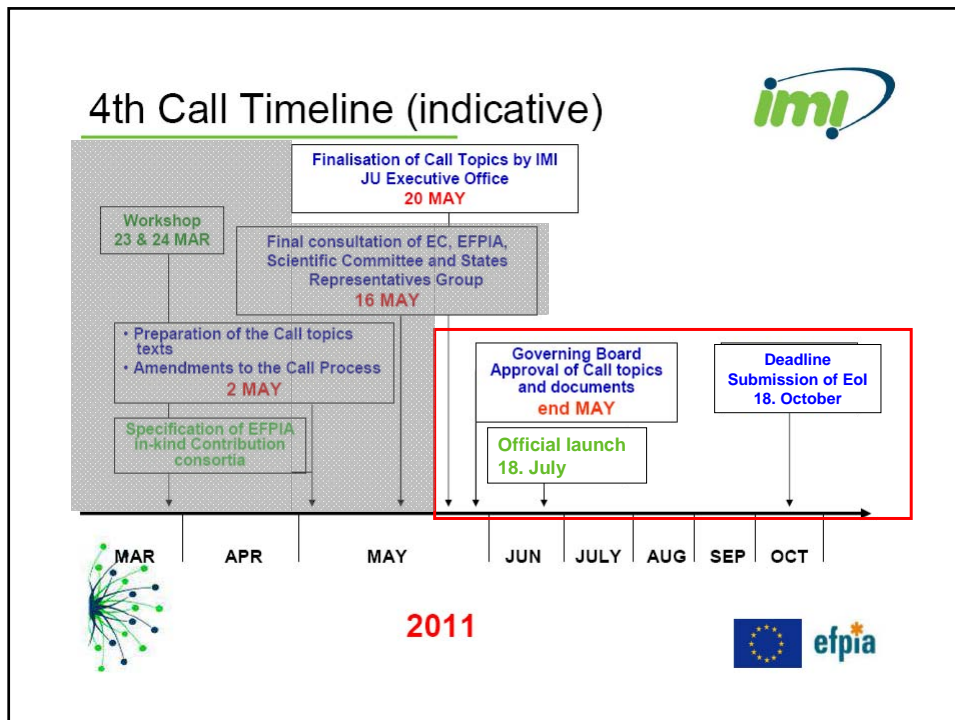
Understanding and optimising binding kinetics in drug discovery



- Need for improved understanding of **interactions** of small molecules with **protein targets**
- Pharma companies committed to provide **compounds**, assay **reagents** and **in vivo models** across many different drug targets (both soluble proteins and membrane-bound proteins)

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Call 4 timeline (indicative)

- Open Info Day: **17 June 2011**
- Official launch: **18. July 2011**
- Submissions start date (for submitting EoIs): **19 September 2011**
- Deadline for submission of Expression of Interests: **18. October 2011**
- Peer review evaluation: **November 2011**
- Deadline for submission of Full Project Proposals: **28. March 2012**
- Approval of Full Project Proposals: **May 2012**

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Partner Search tool



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IMI Partnering Platform

<http://www.imi-partnering.eu>



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- Questions? **E-mail**: infodesk@imi.europa.eu



Thank you!

