

# The Innovative Medicines Initiative (IMI)

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## The Innovative Medicines Initiative: Public-Private Partnership for Drug Development

BioForum, June 21<sup>st</sup>, 2007

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efpia\*



# Agenda



- 
- What is IMI?
  - How will IMI operate?
  - Why is IMI important?

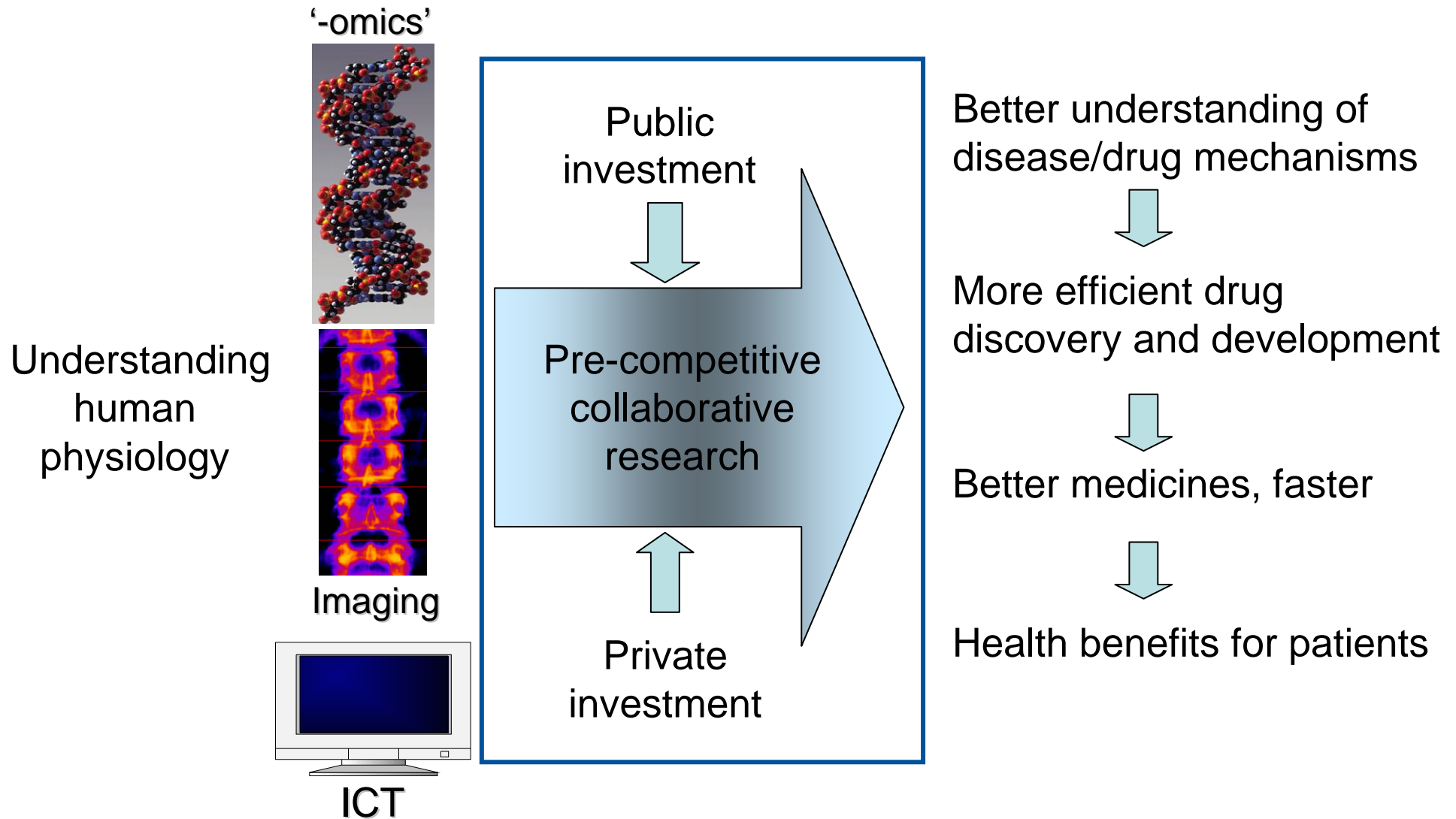
# The Drivers for a New R&D Model Based on Public-Private Partnership

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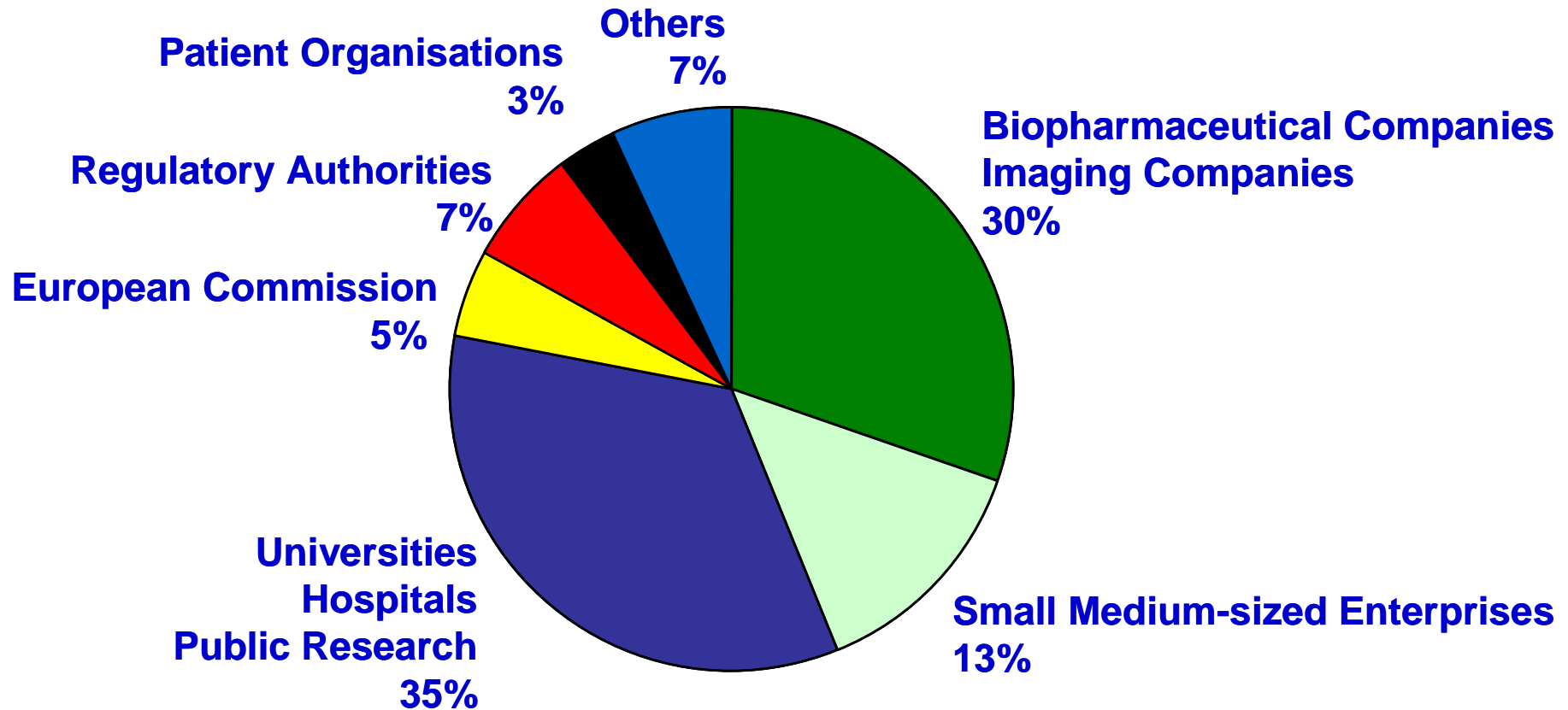


- The need to enhance European's competitiveness;
- Timelines and cost of drug development;
- The potential of increased cooperation between stakeholders;
- Wealth of novel opportunities from new science and technologies.

# Science and technology advances present significant opportunities



# Broad Consultation to develop the IMI Strategic Research Agenda



Total of 350 participants

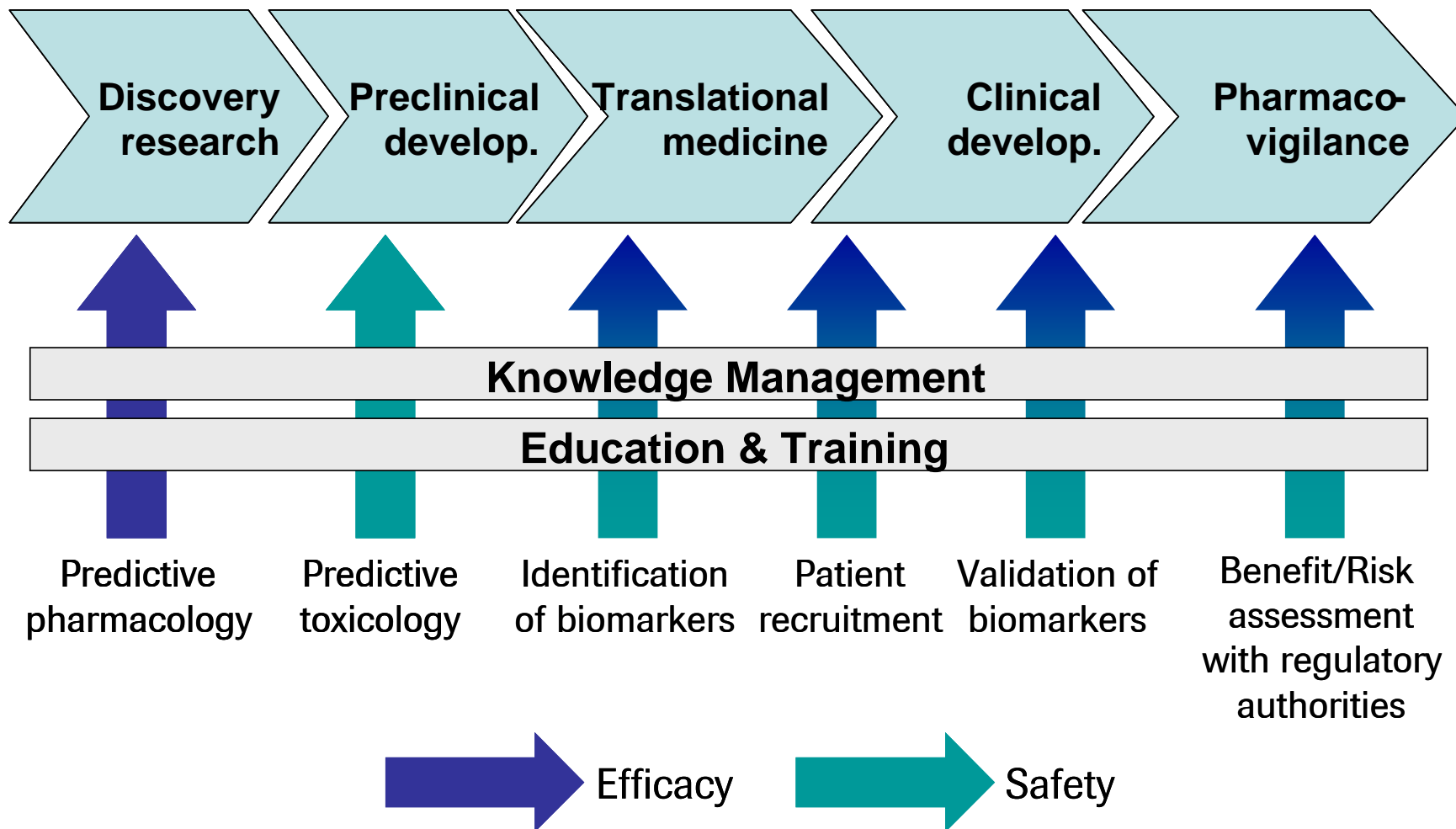
# The IMI Strategic Research Agenda

<http://www.imi-europe.org>

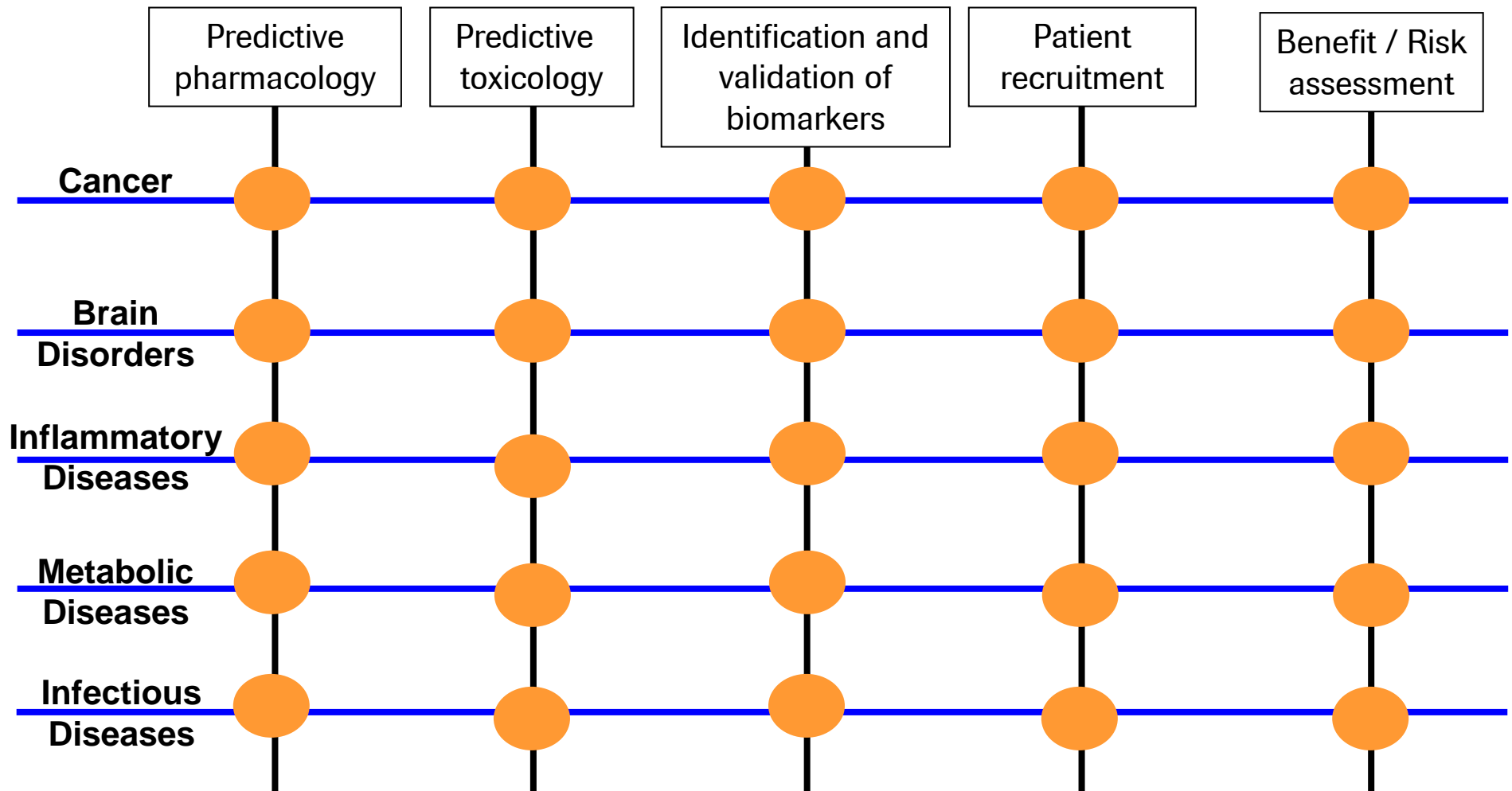


- Identifies pre-competitive bottlenecks in the R&D process;
- Proposes recommendations to address these bottlenecks;
- Proposes a new model of Public-Private collaborations to implement these recommendations;
- IMI will be the first pre-competitive collaboration of this amplitude: up to €2 billion (50% EU; 50% Industry).

# Pre-competitive bottlenecks in the R&D Process



# Safety and Efficacy Challenges are Often Disease Specific



# Potential outcome of IMI



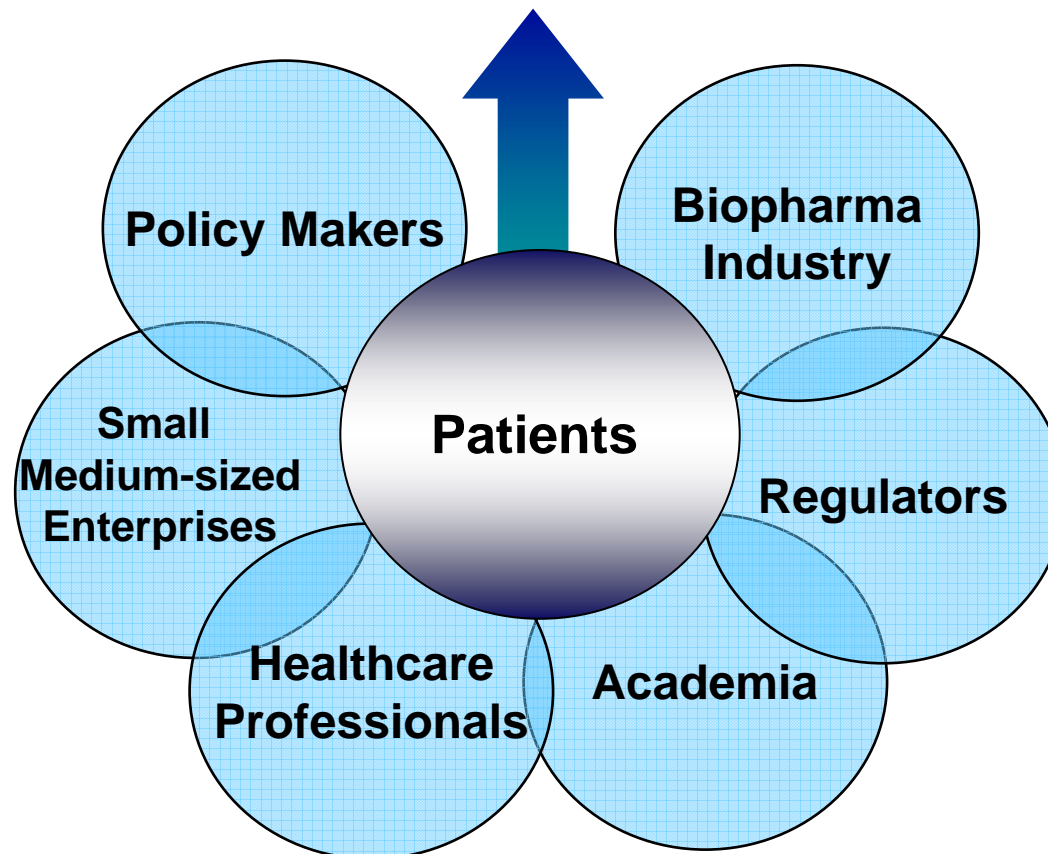
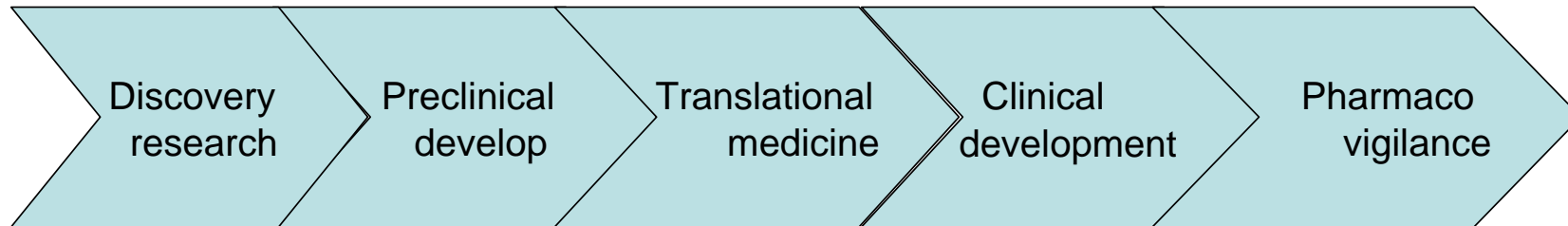
- Identification and validation with regulatory authorities of a new biological biomarker of kidney toxicity
- Acceptance by regulatory authorities of a new MRI protocol to follow the progression of Alzheimer's disease
- Better understanding of beta-cells function
- Improved access to biobanks in the EU
- Allow industry to share pre-competitive knowledge
- Improved pharmacovigilance tools
- ....

# Agenda



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# The 'Patient Centred Project' is a Research Collaboration Addressing Bottlenecks in the R&D Process



# Guiding Principles for the IMI organisation

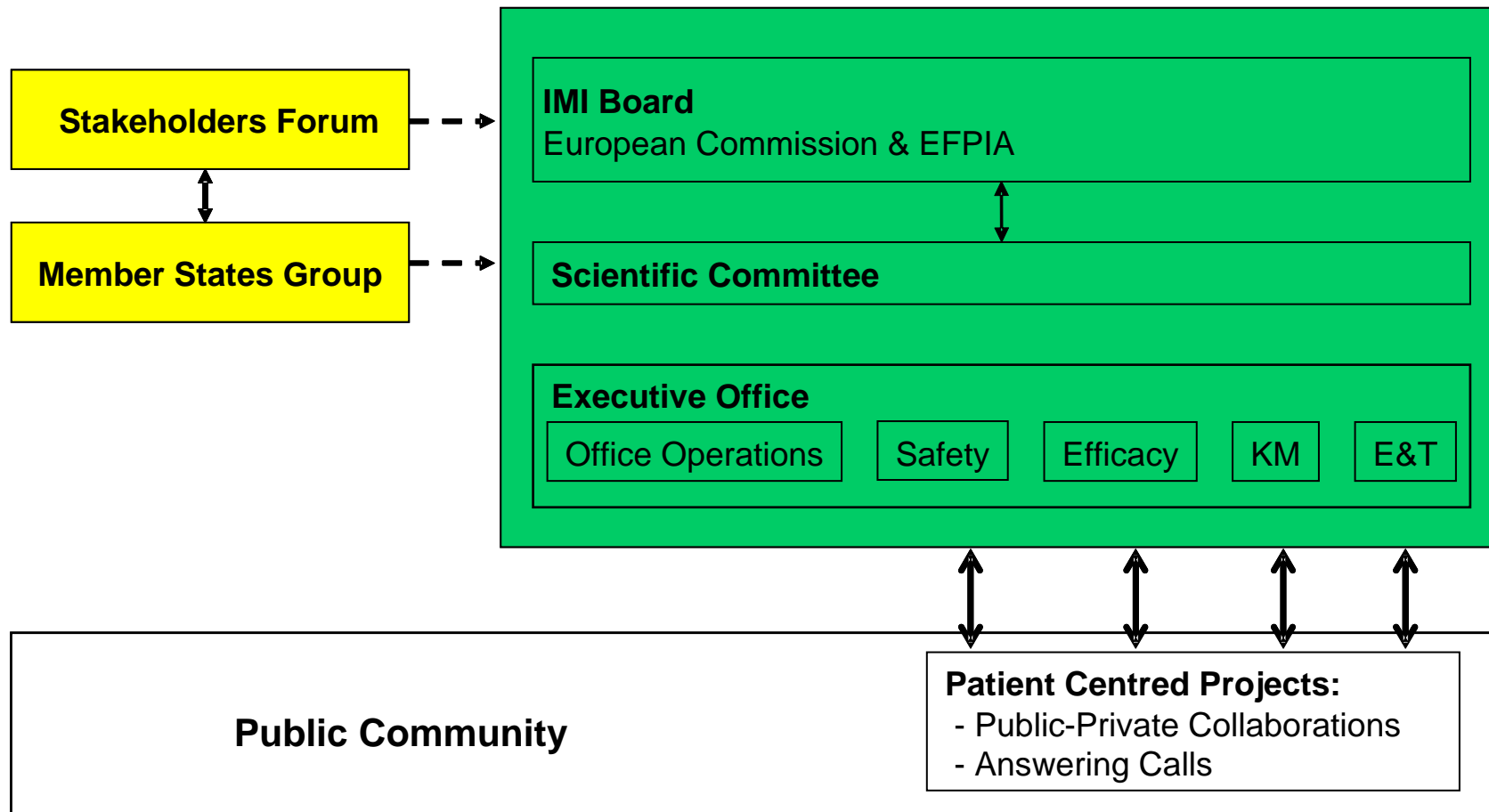
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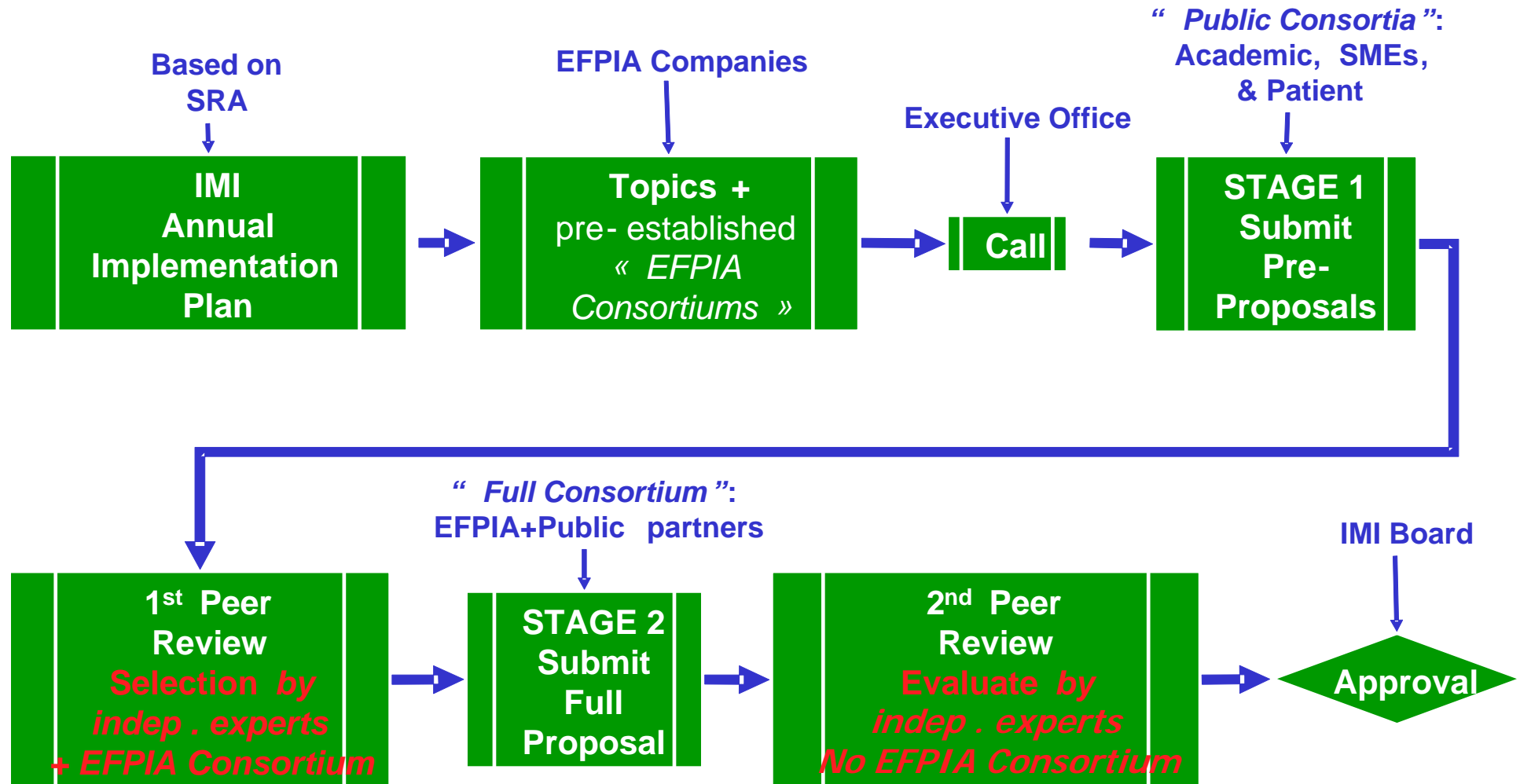
IMI governance has been designed to foster:

- Scientific Excellence
- Collaborative Environment
- Lean and efficient processes
- Transparency

# Structure and Governance



# Call & Evaluation process

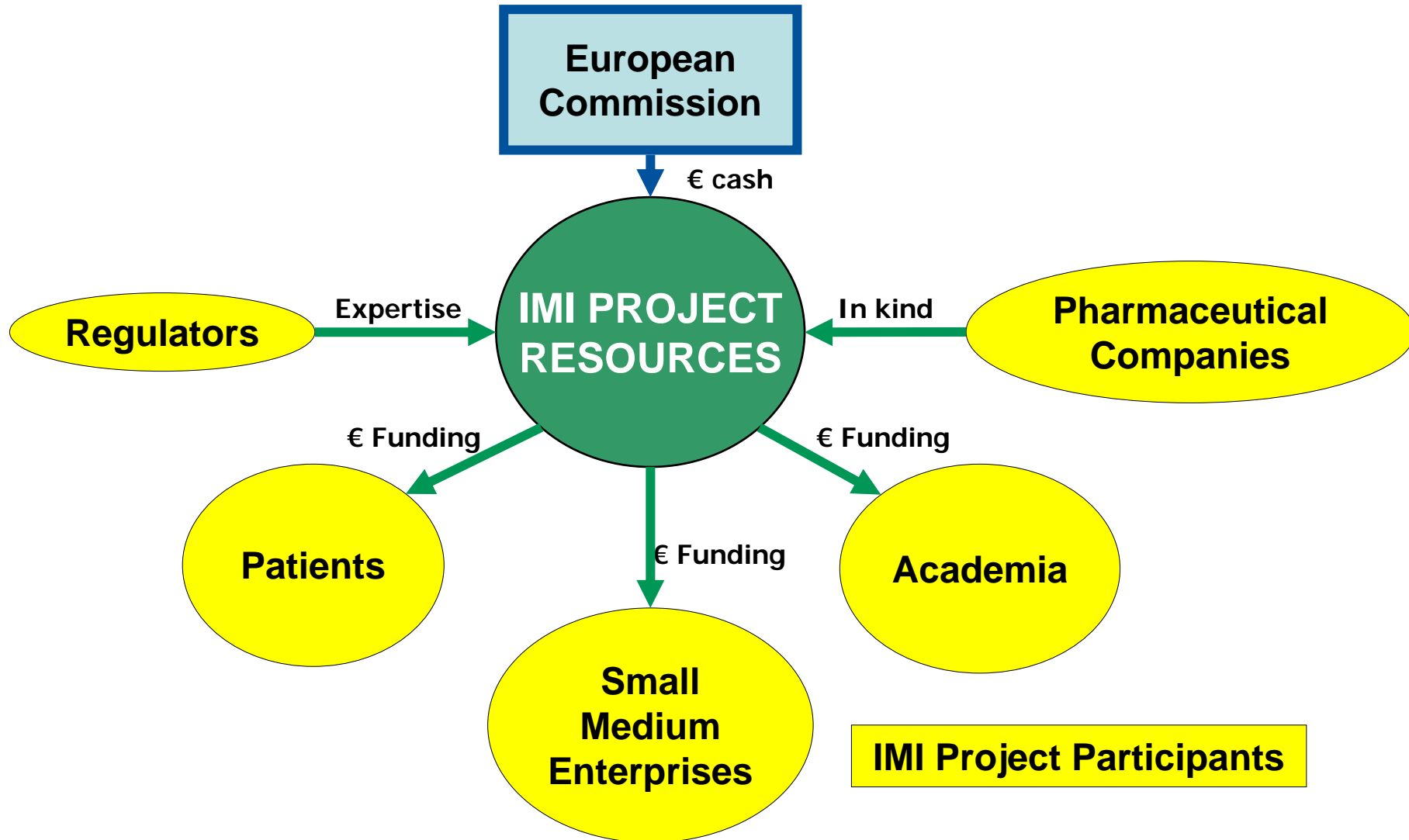


# IMI Budget



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- The European Union will contribute €1 billion in cash to IMI
  - The industry will match in kind on a project by project for €1 billion

# Project Participants & their Contribution



# Intellectual Property Rights Policy



- Promote knowledge creation and dissemination
- Promote knowledge exploitation
- Promote participation in IMI Projects of:
  - Academic institutions
  - Small biopharmaceutical companies
  - Large biopharmaceutical companies



# Licensing of IP for Research Use after Completion of Projects



<b>Licensee</b>	<b>Foreground IP</b>	<b>Background IP necessary to use Foreground IP</b>
<b>Project Participants</b>	Made available on a non exclusive royalty-free basis	Made available on a non exclusive basis on fair and reasonable terms or royalty free
<b>Third Parties</b>	Made available on a non exclusive basis on fair and reasonable terms which may include free use	Made available on a non-exclusive basis on fair and reasonable terms

# Complementarities and synergies must be exploited



EU National & Regional Initiatives

European Commission Collaborative Projects

US Initiatives

European Commission Infrastructure Projects

Japan Initiatives



Regulatory Authorities Initiatives: EMEA, FDA, MHW

Global Standardisation Initiatives: ICH, CDISC

European Brain Council

European Society Study Diabetes

NIH

Other academic institutions...

## Example of possible collaborations worldwide



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2003	Japan Pharmacogenomics Consortium (JPG)	Japan
2004	Innovative Medicines Initiative (IMI)	EU
2005	The Biomarkers Consortium (TBC)	US
2005	The Critical Path Institute (C-path)	US
2005	International Cancer Biomarker Consortium (ICBC)	Global
2006	The Center for Biomedical Innovation (CBI)	US
2006	Genetic Association Information Network (GAIN)	US
2007	7th Framework Programme	EU

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# IMI is the Top Priority R&D Project for the European Pharmaceutical Industry



- Increased collaboration with all relevant stakeholders;
- Faster interpretation of safety findings through sharing pre-competitive toxicology data;
- Reduction of animal use in safety evaluation;
- Validation of new assessment methods e.g. biomarkers;
- Fewer patients needed in pivotal trials;
- Faster approvals through better collaboration with EMEA;
- Fewer post-marketing withdrawals;
- More skilled professionals.

# Benefits of Increased Collaboration for All Stakeholders



- Access to pre-competitive knowledge that was previously out of reach
- Stimulation of creativity
- Achievement of critical mass
- Shared risk of failure
- Enhanced learning experience
  - ➔ **Generation of More Innovation**

# IMI is going to help supporting European competitiveness



- Increase knowledge about diseases and biomedical tools,
- Increase education and training in the biomedical arena,
- Foster small and medium sized enterprises in Europe,
- Create more R&D jobs in the EU in the public and private sectors,
- Retain talents in the EU

# How to Provide More Effective, Safer Medicines Faster?



- IMI is about R&D processes from target identification to pharmacovigilance;
- IMI is about tools and understanding of diseases, not about medicinal products;
- IMI is a unique public and private sector collaboration based on science and transparency;
- Member States have a critical role to play to make IMI a success for all citizens.

# IMI Status & Plan 2007-08



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- ✓ Adoption by the European Commission      May
  - ✓ Submission to the Competitiveness Council      May
  - ✓ Submission to the European Parliament      May
  - Opinion from the European Parliament      November-December
  - Approval by the Competitiveness Council      December-January
  - First Calls for Proposals      January-February
  - Start of First Patients Centred Projects      July

*The Ultimate Beneficiaries ...*



... All patients



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