

*History, State of play & Organisation*  
*Objectives & Research topics*  
*Call process*

**imi**

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European Commission

efpia



**imi**

# History



2000

## **Lisbon Strategy**

Europe most competitive & dynamic  
knowledge-based economy by 2010

2004

## **European Technology Platforms**

stakeholders under the lead of industry  
develop Strategic Research Agenda  
addressing bottlenecks to competitiveness

2007

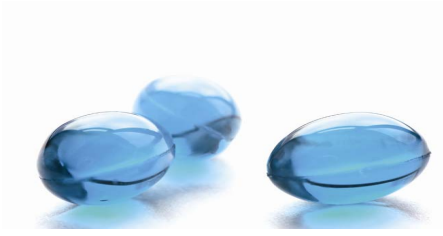
## **7th Framework Programme for Research**

2008

**Establishment of the Joint Undertakings**  
to implement the Joint Technology  
Initiatives

efpia\*



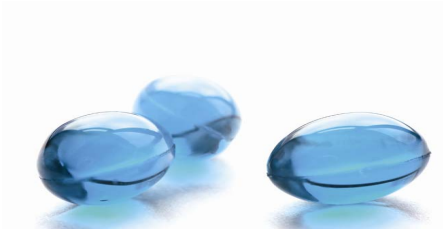


## Joint Technology Initiatives

Long term *public-private partnerships* in research at European level

Coordinated research efforts responding to industry needs in fields of high industrial & policy relevance

To be implemented through new legal entities -  
**Joint Undertakings**



**COUNCIL REGULATION (EC) No 73/2008  
of 20 December 2007**

**setting up the Joint Undertaking for  
the implementation of the Joint  
Technology Initiative on  
Innovative Medicines**

**Official Journal 04.02.2008**



2 Billion €

1 Billion €



1 Billion €

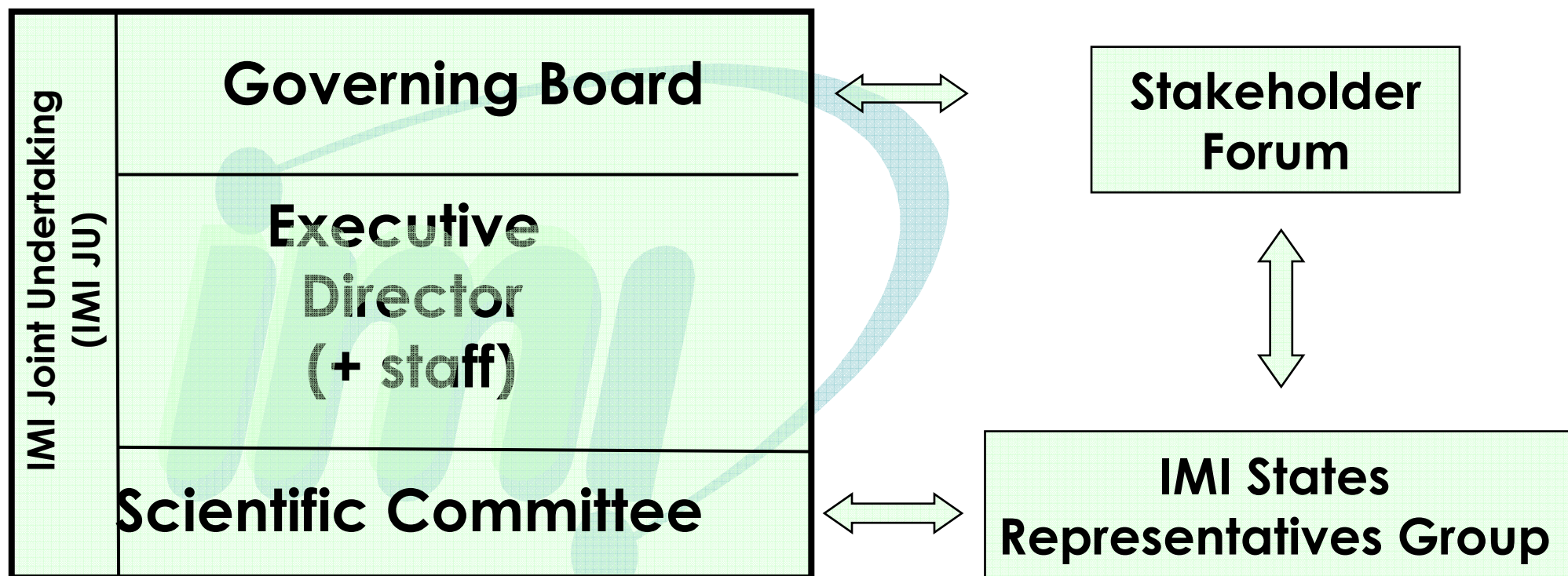


Public - Private  
Partnership





## IMI Governance





## Objectives

- IMI aims at removing major bottlenecks in drug development, where **research** is the key
- IMI aims at accelerating the development of safer and more effective medicines
- No new medicines will be developed as such as the focus shall be on the delivery of new tools, methods, technologies, improve knowledge management, and support the training of professionals.



## Why is IMI important



- High attrition rate in the development of drugs
  - 1 of 10.000 compounds make it to the market
  - Success rate from pre-clinic to market still below 10%
  - Even in Phase III every second compound fails
- Huge development costs for new medicines
  - more than 1 billion Euro
- Unmet medical needs in many disease areas



IMI will support 'pre-competitive pharmaceutical research', following **open and competitive calls** for project proposals, **peer review evaluation** and the conclusion of Grant Agreements and Project Agreements.



## Expected outcomes

Modernisation of the development process of medicines

Increased investments in biopharmaceutical R&D in Europe

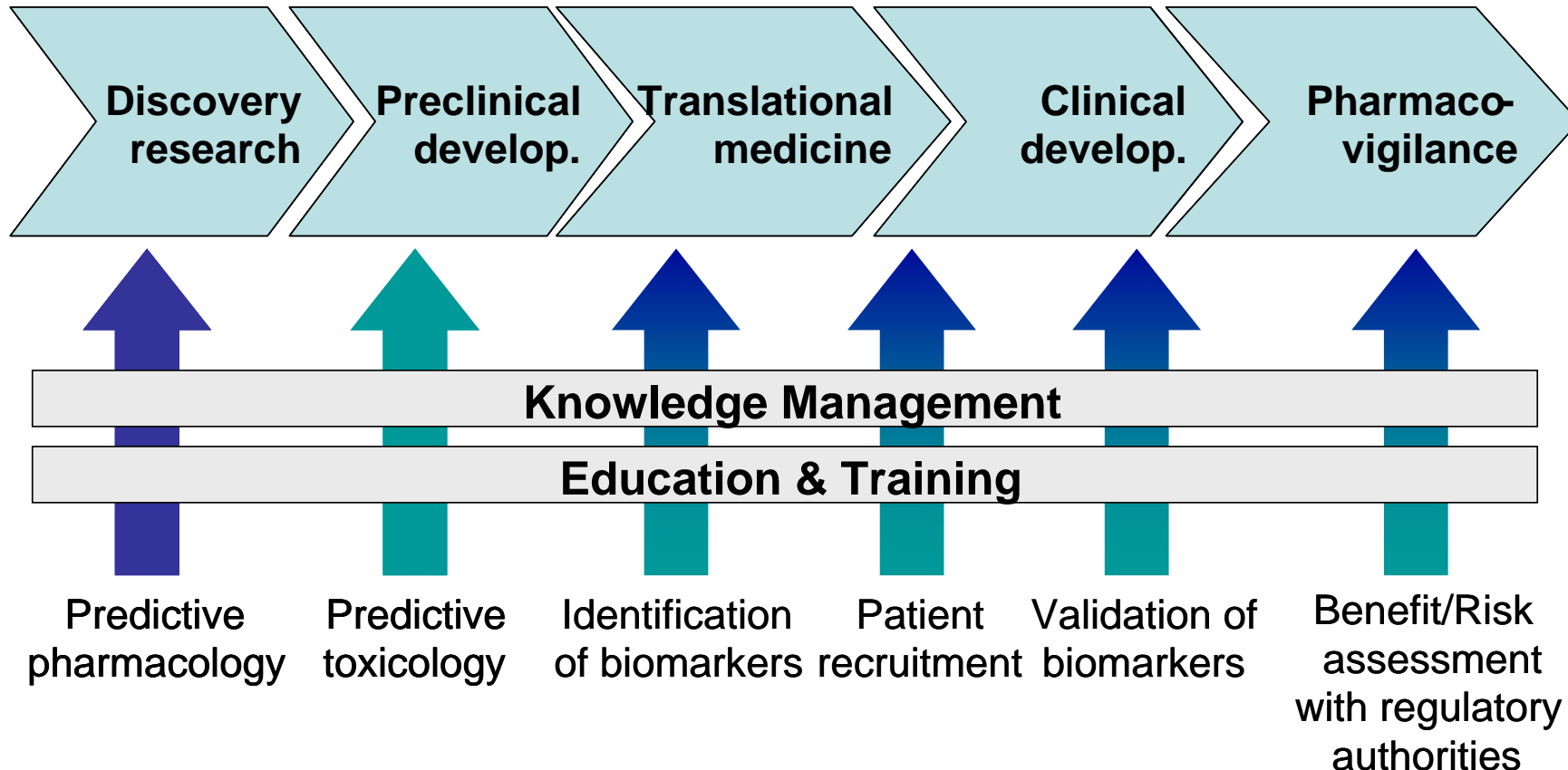
Enhanced **European competitiveness & competitive advantage** for companies (including SMEs, spin-offs and start ups) by collaboration with a multitude of stakeholders



- The call & evaluation process is tailor made to serve the objectives of IMI
- The IMI IP policy is aligned with the objectives of IMI - findings (Foreground) must be widely and readily available for research into the discovery and development of medicines
- The IMI IP policy provides incentives for all actors to participate (i.e. the ownership interest, direct exploitation and the fair return on investment must be preserved)



# The Research Focus of IMI



Efficacy



Safety





**IMI First Call  
published on April 30, 2008**

**18 topics** based on IMI's Scientific Priorities for 2008 / derived from the IMI Research Agenda.

Areas not addressed in 2008 will be addressed in consecutive calls.



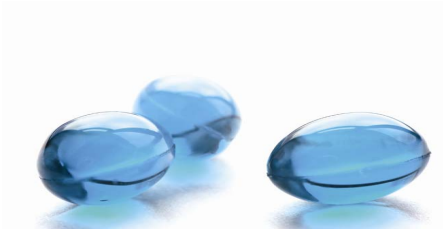
## IMI Safety Pillar



**Objectives** : to improve the predictivity of Safety evaluation during the R&D process.

**6 topics** : immunogenicity, non-genotoxic carcinogenesis, *in silico* toxicity prediction, safety biomarkers & pharmaco-vigilance methodologies.

**Expected outcomes** : to improve attrition rates during early development and to strengthen the evidence base in pharmaco-vigilance.



## IMI Efficacy Pillar



**Objectives** : to address bottlenecks related to predictive pharmacology, the identification and validation of biomarkers & patient recruitment.

**7 topics** : diabetes (Islet Cell, Surrogate Markers for Vascular Endpoints), brain (Pain, Psychiatric Disorders, Neurodegenerative Disorders) & respiratory (Severe Asthma, COPD) disorders.

**Expected outcomes** : to develop animal models & early predictive clinical endpoints, through extensive translational medicine approaches



## IMI Education & Training Pillar



**Objectives** : to bridge identified gaps within education & training in support of the medicines development process

**5 topics** : establishment of a European Medicines Research Training Network, training programmes in safety sciences, pharmaceutical medicine, integrated medicine & pharmaco-vigilance.

**Expected outcomes** : to support the education and training of current and future professionals involved in biomedical R&D



## **IMI Call Process is Different from the FP7 Process**

1. Research topics are approved by the IMI Governing Board (EFPIA and European Commission) based on proposals from the EFPIA Research Directors Group and after consultation with IMI Member State Representatives & IMI Scientific Committee
2. A consortium of EFPIA companies is established for each topic & a coordinator proposed



## 26 Potential EFPIA Participants



Almirall

AMGEN

AstraZeneca INTERNATIONAL

Bayer

Boehringer Ingelheim

Fondazione CHIESA

A lot to discover ESTEVE

genzyme

gsk GlaxoSmithKline

Johnson & Johnson

Lilly

Lundbeck

MERCK SERONO

MERCK SHARP & DOHME

NOVARTIS

NOVO NORDISK

ORION

Pierre Fabre

Pfizer

Roche

sanofi aventis

SERVIER

Sigma-tau

SOLVAY

UCB

Wyeth

imi

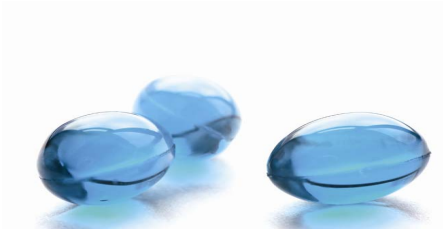


## Description of the Call Topics

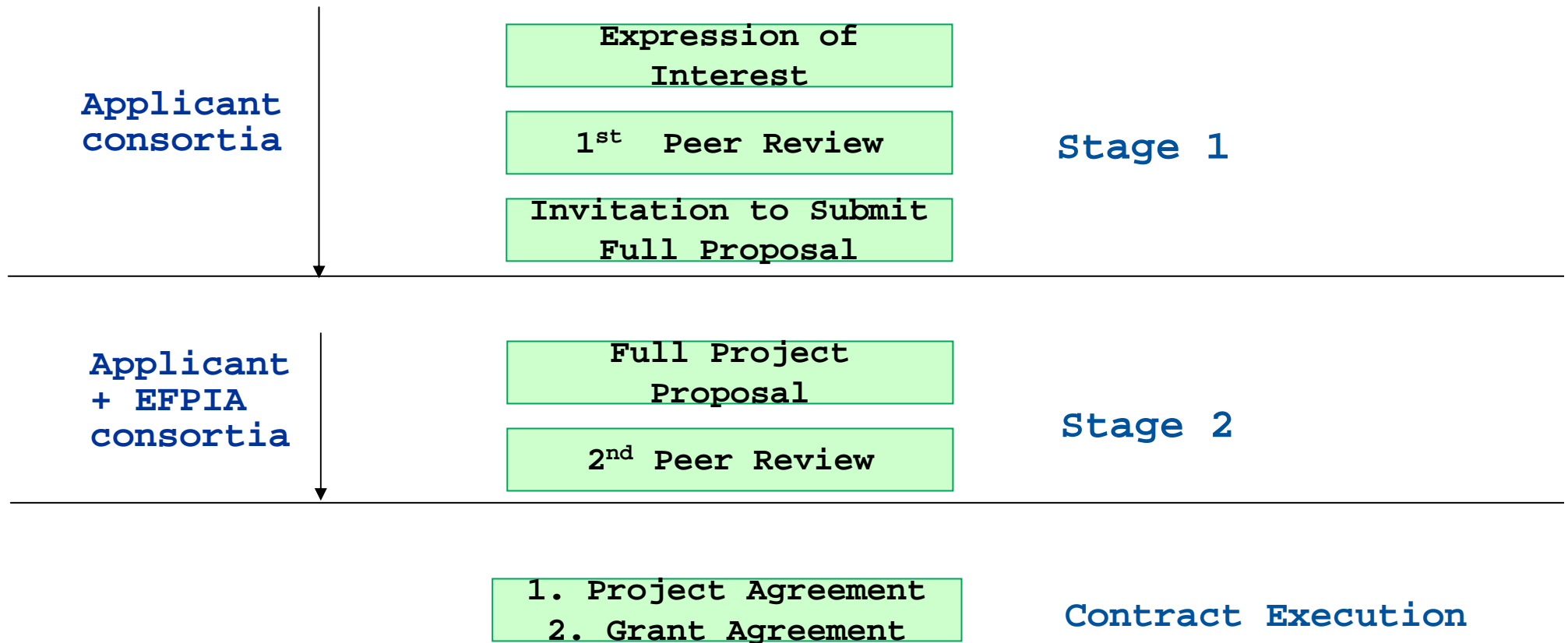


1. Title
2. Project description
3. Key deliverables
- 4. EFPIA companies participating in the project**
- 5. Role of EFPIA companies in the project**
6. Duration of the project
- 7. Total in kind contribution from the EFPIA companies**
- 8. Expectations from the Applicant consortium**





## Call & Evaluation Process





# Description of the Expression of Interest



## 1. Scientific Case

1. Innovative approaches to meet the project objectives (2 pages)
2. Composition of the Applicant Consortium (1/2 page per member)
3. Unique features & complementarities of the Consortium (1 page)
4. Summary work plan (2 pages)

## 2. Declaration of ethical issues (1/2 page)

## 3. Provisional budget table

Estimated cost per Consortium member & requested IMI contribution

Written by the Applicant Consortium (without EFPIA)  
i.e. academia, SMEs, regulators, patients organisations



## Description of the Full Project Proposal



- Full description of research activities, budget,...
- Will need a draft Project Agreement before submission
  - IPR sharing agreed between all partners
- Expectation of high probability of success

**Written by the Full Project Consortium:**

EFPIA Consortium & the winning Applicant Consortium



## Rules for Participation in IMI Consortia

- Any entity carrying out work relevant to the IMI JU in a Member State or country associated with the 7th Framework Programme
  - Anyone else with the agreement of the IMI JU
- BUT**
- Not all participating entities are eligible for funding



# Eligibility for IMI funding

Eligible for funding	Non-eligible for funding
<ul style="list-style-type: none"><li>- Academia</li><li>- SMEs (EU definition)</li><li>- Patient Organisations</li><li>- Other non-for-profit legal entities</li></ul>	<ul style="list-style-type: none"><li>- EFPIA companies</li><li>- Other companies not falling within the EU definition of SMEs</li></ul>



## Eligible Consortia

Consortia must comprise:

- At least 2 legal entities eligible to receive funding
- At least 2 research-based pharmaceutical companies who are members of EFPIA
- All 4 entities must be independent of each other



## Direct eligible costs

- Actual
- Incurred by the claimant
- Incurred during the project
- Incurred for work in a Member State or country associated with FP7
- Incurred for the achieving the objectives of the project



**Total eligible costs**



**Direct Eligible  
Costs**

**Indirect Costs**  
max 20% of Direct  
**Eligible Costs**, excl.  
subcontracting

**These apply equally to all participants, who receive funding or not, and to the EFPIA participants to calculate their in-kind contribution**



# Upper Funding Limits

For participants eligible for funding by IMI

<p><b>Research Activities</b> <i>Maximum 75% of total eligible costs</i></p>	<p><b>Other Activities,</b> including Management and Training Activities <i>Maximum 100% of total eligible costs</i></p>
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# Tentative timelines for First Call



April 30th



	May	June	July	August	Sept	October	Nov.	Dec.	January	February
Publication of Call										
Submission period for Expressions of Interest										
Evaluation Stage 1										
Submission period for Full proposals										
Evaluation Stage 2										
Negotiation, signature of Grant Agreements, first payments										

**Thank you**

**For further information**

**[www.imi.europa.eu](http://www.imi.europa.eu)**

The IMI logo is located in the bottom right corner. It consists of the lowercase letters 'imi' in a bold, green, sans-serif font, enclosed within a white oval shape. The oval has a slight 3D effect with a shadow on the right side. The background of the entire slide features several large, overlapping, semi-transparent spheres in shades of yellow, green, and blue, with a pattern of fine, curved lines radiating from the right side.

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