

# The Innovative Medicines Initiative (IMI)

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## Call Submission and Evaluation Process

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December 10<sup>th</sup>, 2007



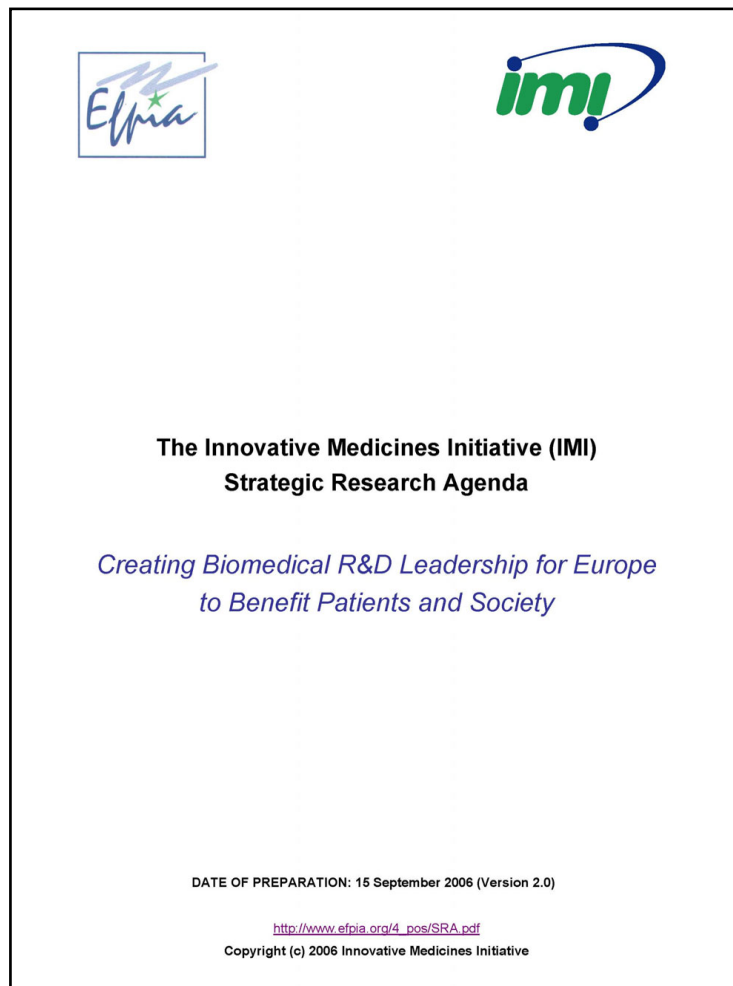
# Agenda



- Introduction
- Call Process
- IMI Scientific Priorities for 2008

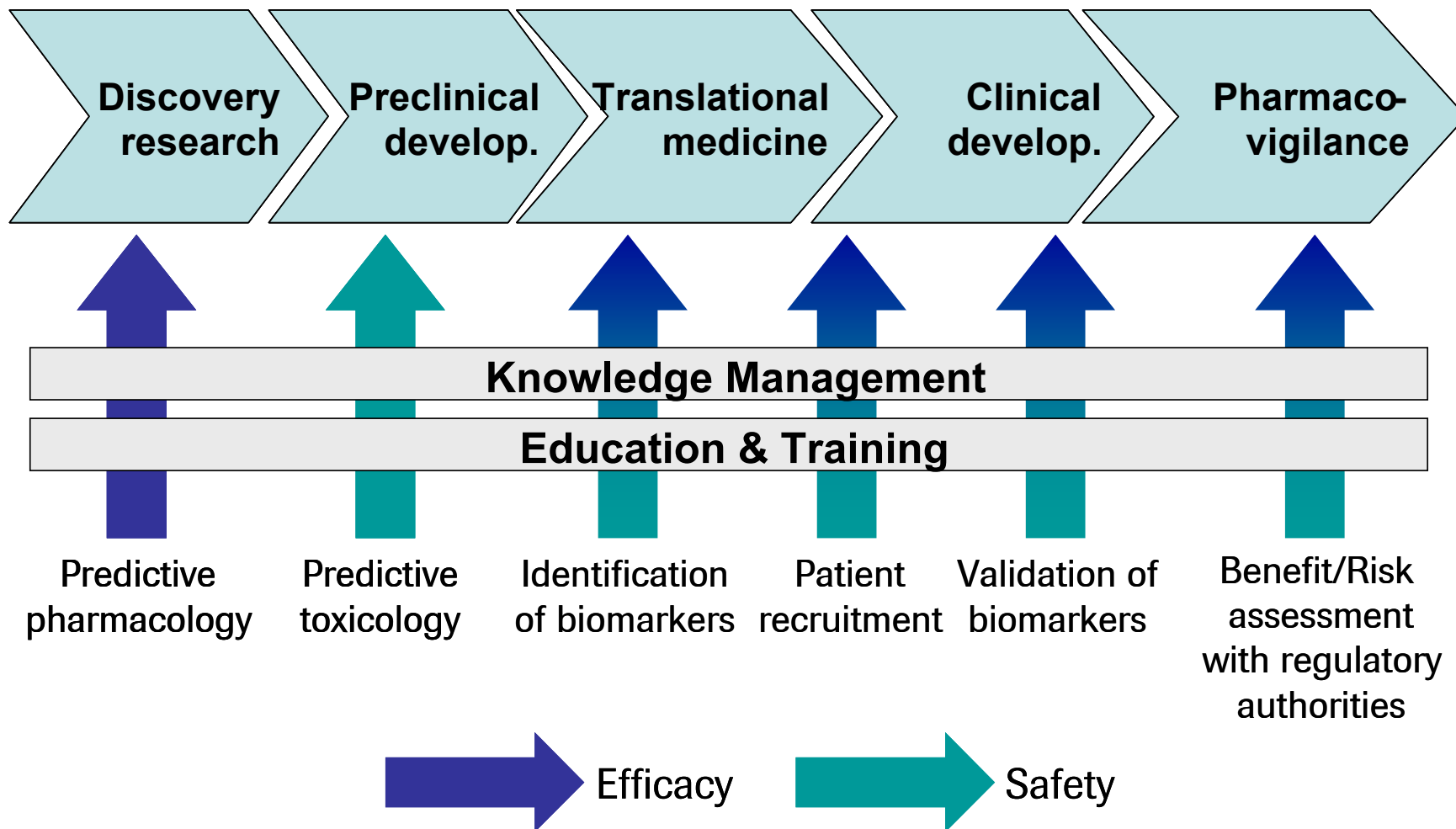
# IMI Strategic Research Agenda

<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

# Pre-competitive bottlenecks in the R&D Process

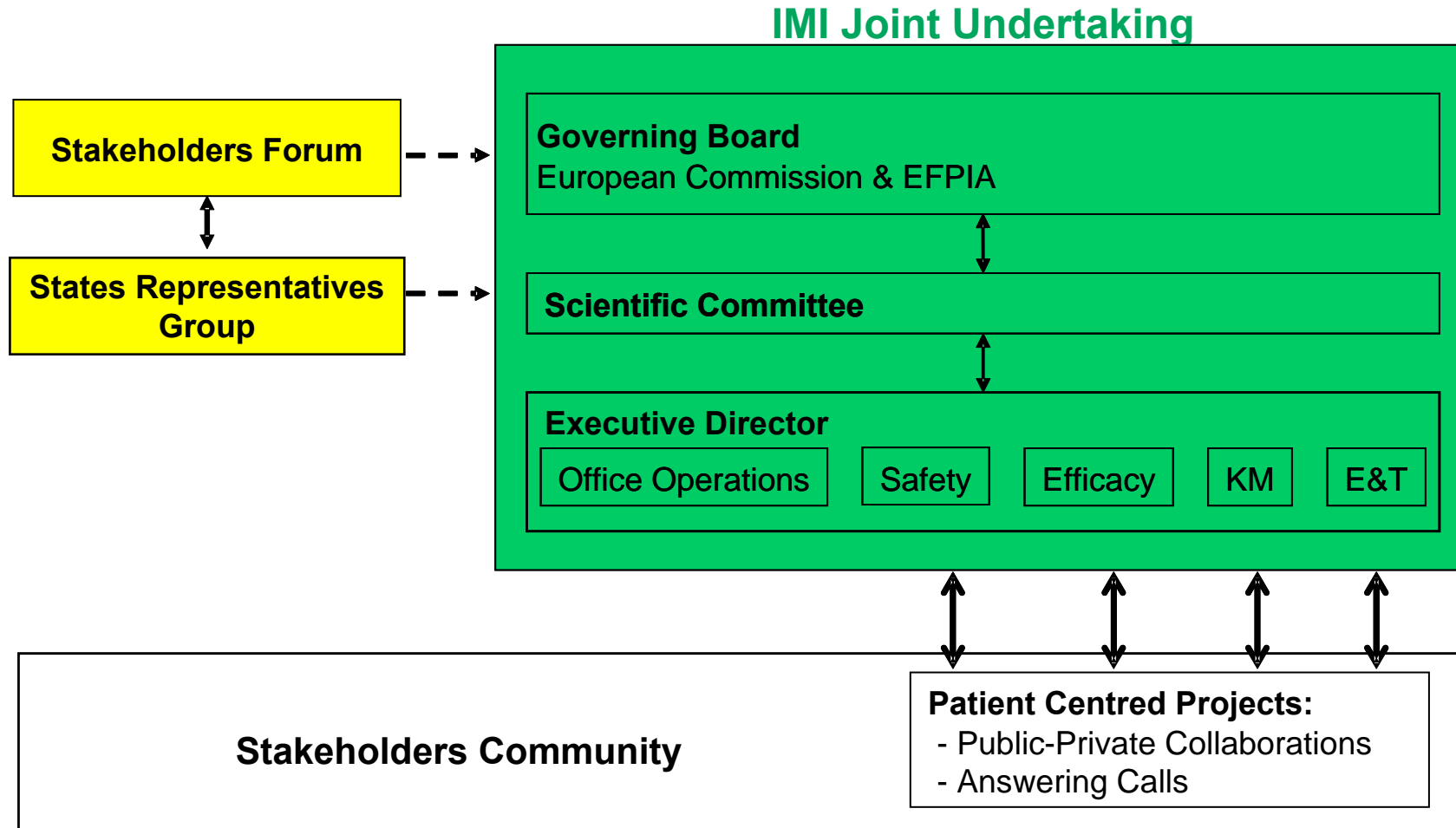


# IMI Status & Plan 2007-2008

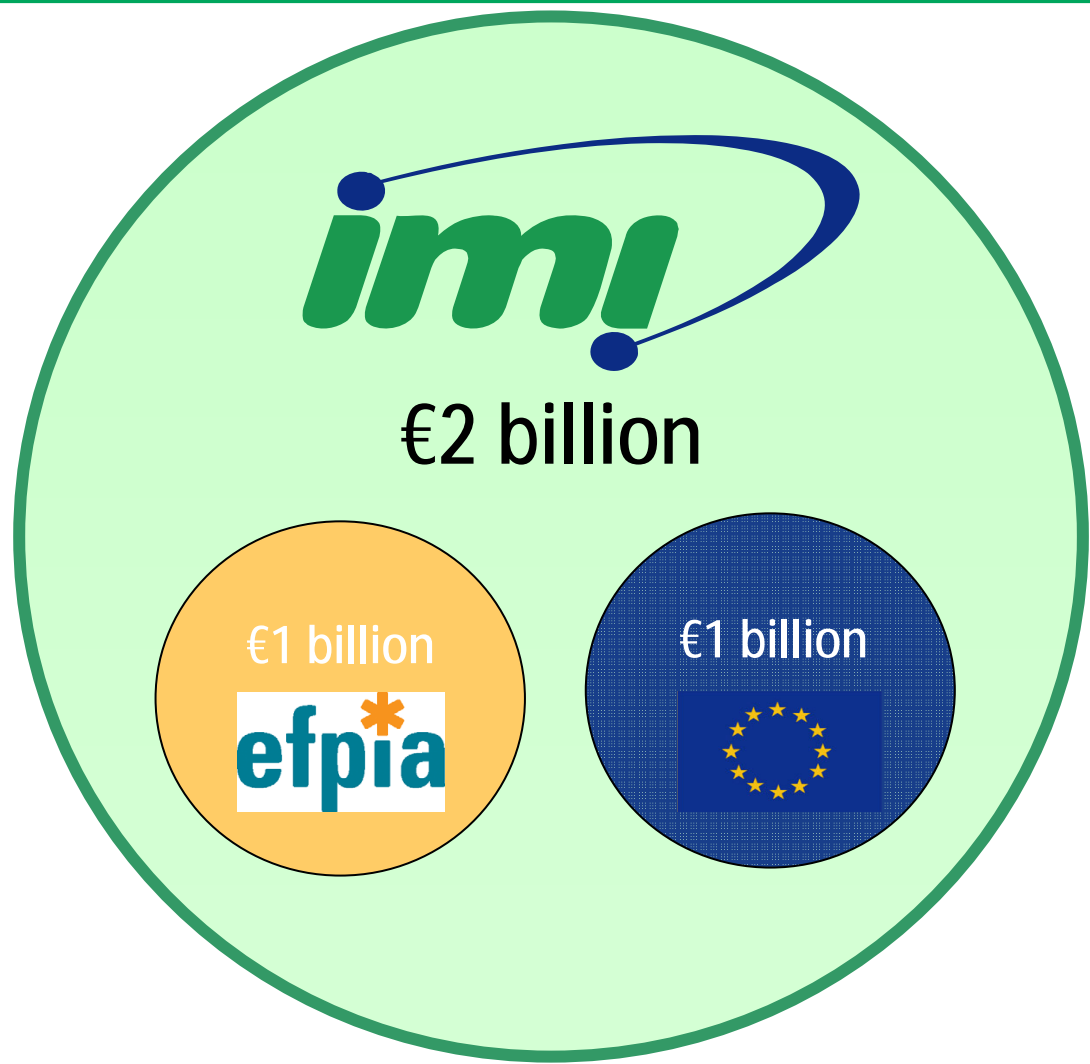


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- ✓ Adoption by the European Commission May
  - ✓ Submission to the Competitiveness Council May
  - ✓ Submission to the European Parliament May
  - Opinion from the European Parliament December
  - Approval by the Competitiveness Council January
  - First call for proposals February
  - Start of first research projects November

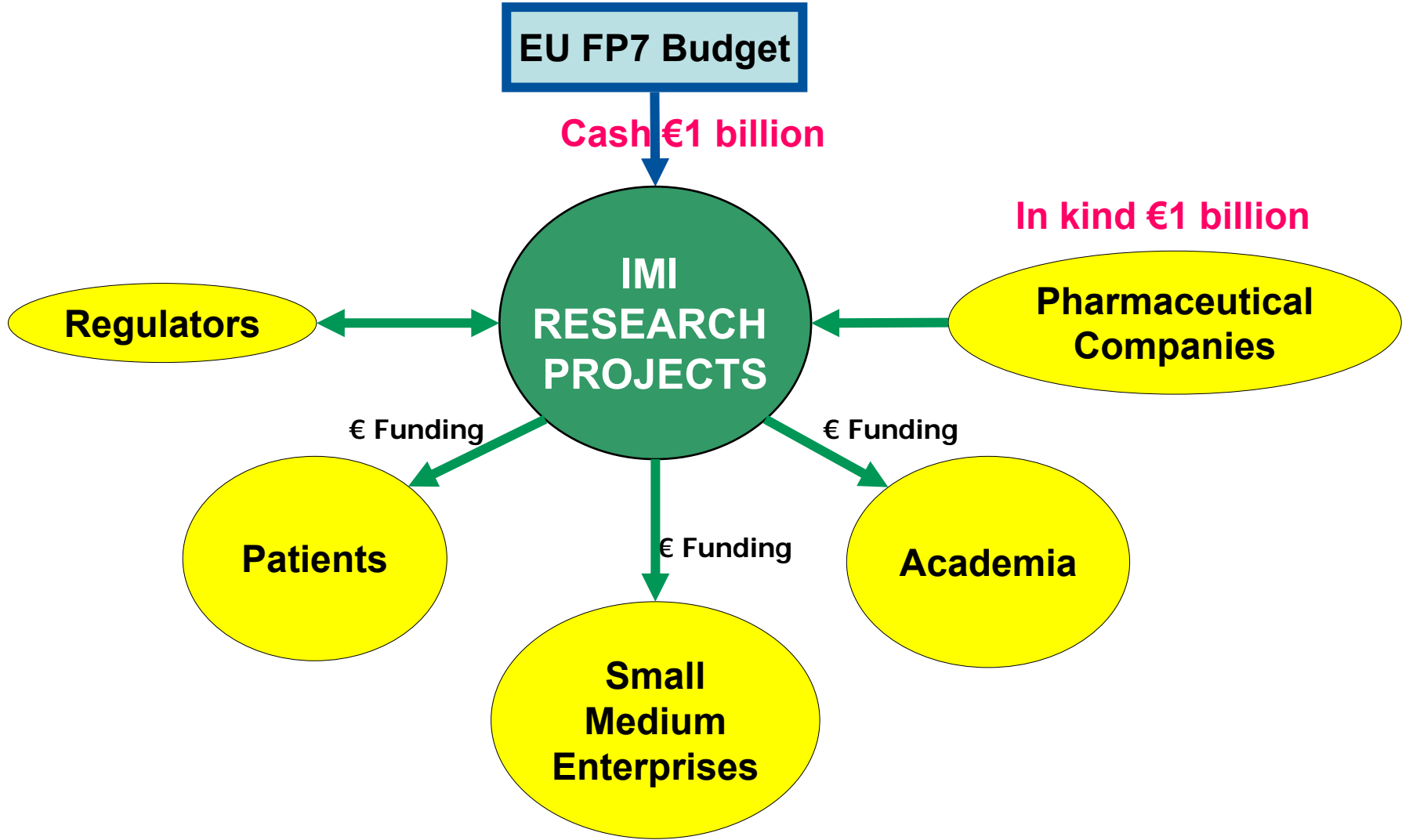
# Structure and Governance



IMI Financing:  
€2 billion over a period of 10 years



# IMI Total budget of € 2 billions to support research projects over a period of 10 years



# 26 Potential EFPIA Participants



Pierre Fabre



## Rules for Participation



- Independent legal entities
- Capacities to carry out work themselves
- Research performed in Europe or country associated with the 7<sup>th</sup> framework programme
- At least 2 EFPIA legal entities and 2 non-EFPIA legal entities per project

# Amount of funding – according to EU State Aid rules



Research Activities Maximum 75%	Management activities Maximum 100%
Indirect costs max 20% of direct costs	

# Eligibility for IMI funding



<b>Eligible for funding</b>	<b>Non-eligible for funding</b>
<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>

# Agenda



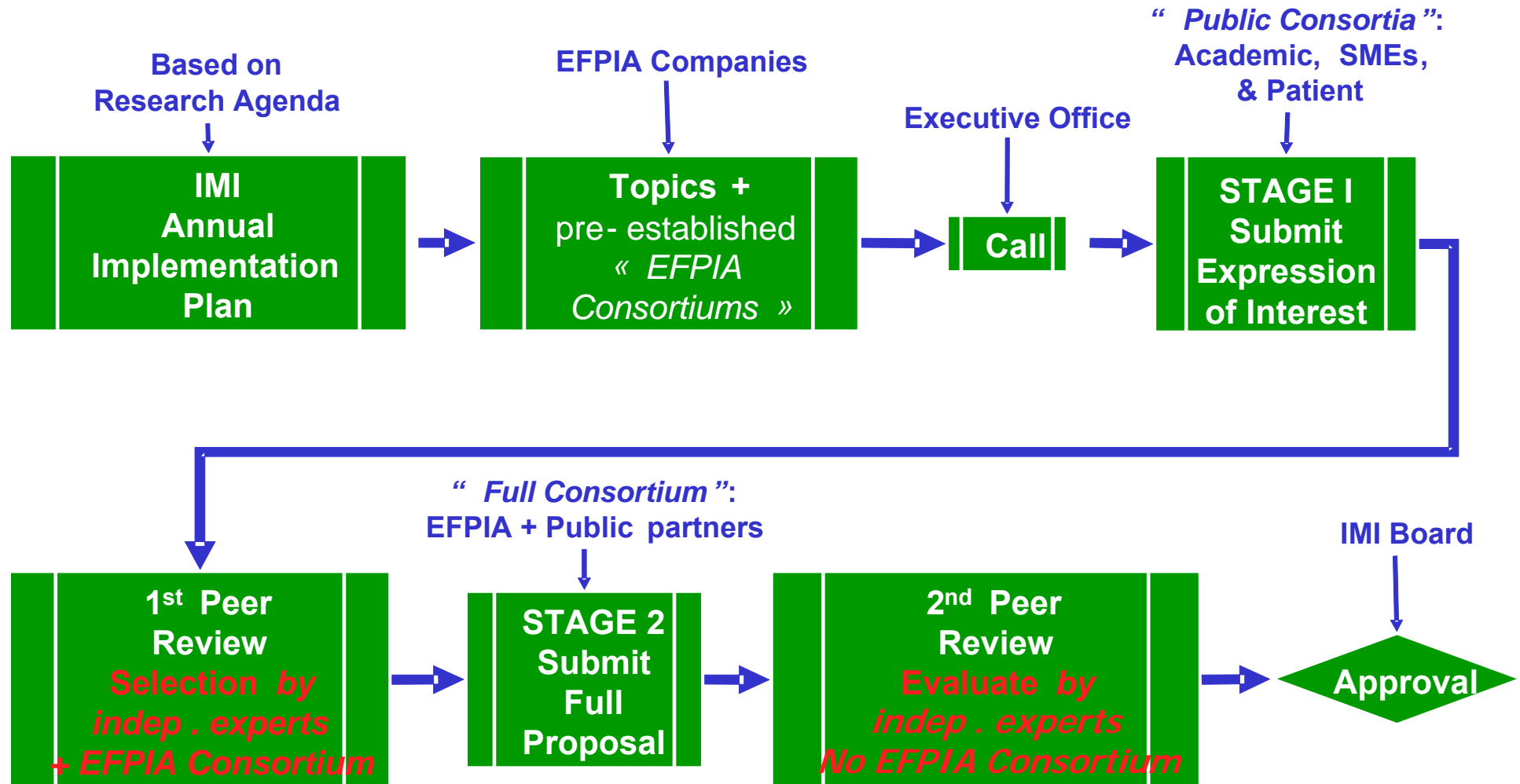
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  - Call Process
  - IMI Scientific Priorities for 2008

# IMI Call Process is Different from FP7 Call Process



1. Research Topics are approved by the IMI Governing Board (EFPIA and European Commission) based on a proposal from EFPIA Research Directors Group.
2. The private consortium is established by the EFPIA Research Directors Group
3. The public consortium submits an Expression of Interest without involving the private consortium
4. The public-private consortium is established at the stage 1 of the peer review process.

# Call & Evaluation Process Overview



# Call & Evaluation Process

## *Call definition*



**Research Agenda**

**Annual Implementation Plan**

**Call Topics**

**Call**

Call definition

# Description of the call topics



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

# Call & Evaluation Process

## Stage 1



# Description of the expression of interest



1. Composition of the public consortium
2. Abstract (1/2 pages)
3. Science (3 pages)
4. Knowledge Management (1/2 page)
5. Training and Education (1/2 page)
6. Outstanding issues (1/2 page)
7. Budget plan (1/2 page)

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

# Peer Review Stage 1



- Peer Review Committees
  - One Standing Peer Review Committee per Pillar of the Strategic Research Agenda
  - Assisted by ad hoc experts relevant to the call topics
  - EFPIA Consortia members participate in evaluation of Expressions of Interest
- Responsibility
  - To evaluate science of Expressions of Interest
- Composition
  - Members reflecting a balance of public-private research expertise
- Decision Making
  - By consensus between all experts

# Call & Evaluation Process

## Stage 2



# Description of the full project proposal



- Written jointly by the EFPIA Consortium and Public Consortium members
- Full description of research activities
  - Who, when, and how much
- Will need a draft Project Agreement before submission
  - IPR sharing agreed between all partners

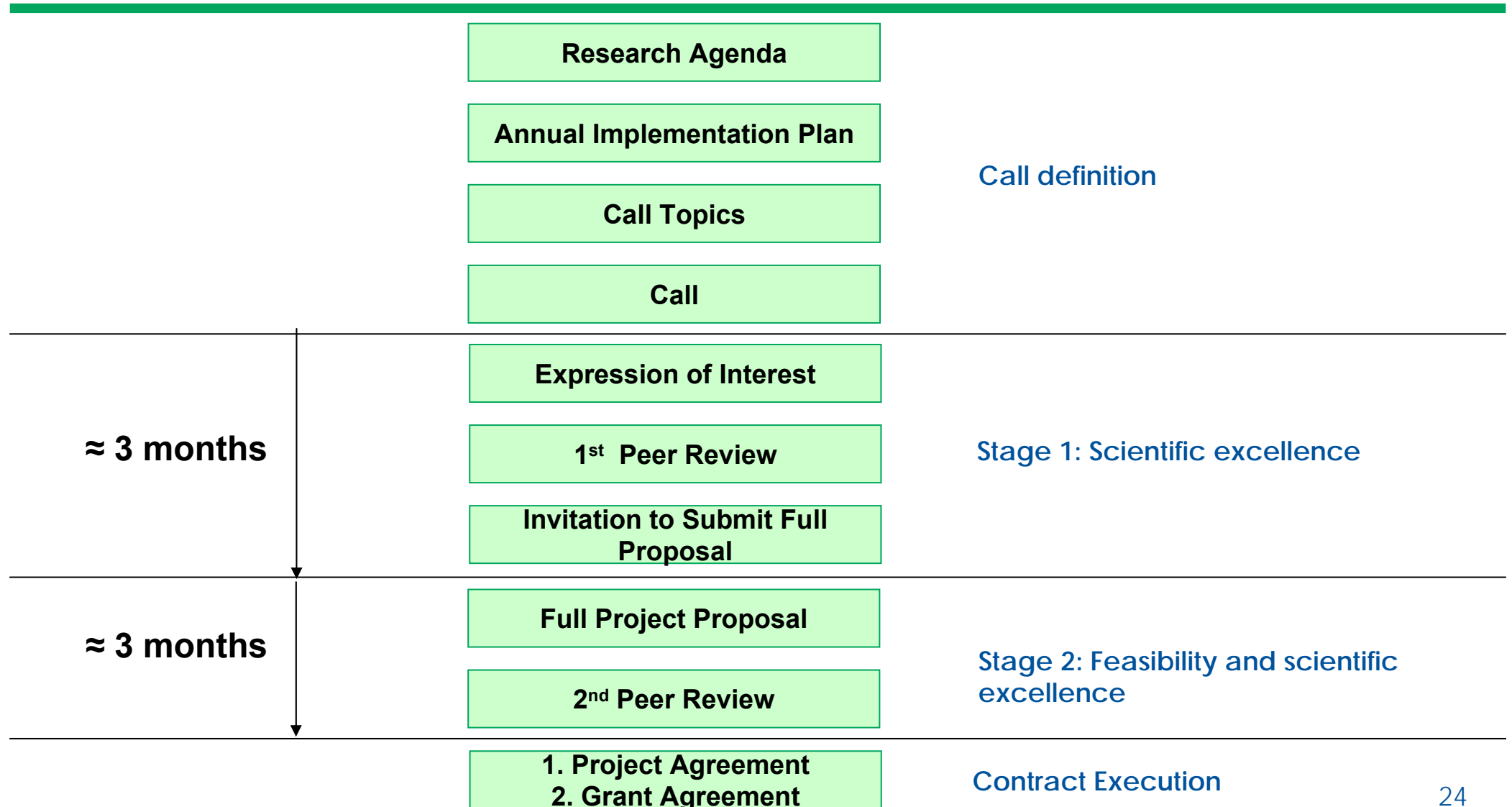
**Written by the Public Private Consortium:  
i.e. academia, SMEs, regulators, patients organisations with EFPIA**

# Peer Review Stage 2



- Peer Review Committees
  - One Standing Peer Review Committee per Pillar of the Strategic Research Agenda
  - Assisted by ad hoc experts relevant to the call topics
  - No EFPIA Consortia members
- Responsibility
  - To evaluate Full Proposals based on science and feasibility
- Composition
  - Members reflecting a balance of public-private research expertise
- Decision Making
  - By consensus between all experts

# Call & Evaluation Process



# Expected Call Timelines



December 2007: Communication of Scientific Priorities 2008

February 2008:

- Official Launch of IMI Joint Undertaking
- Big press event on February 21
- Publication of the First IMI Call

May 2008: Deadline for Expression of Interest

August 2008: Deadline for Full Project Proposal

October 2008: Signature of project and grant agreements

November 2008: Start of research projects

January 2009: Publication of the Second IMI Call

# Agenda



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- Introduction
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  - IMI Scientific Priorities for 2008



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- Addressing bottlenecks in the R&D process
  - Need for public private collaboration
  - High interest from numerous EFPIA companies
  - Clarity concerning “role of EFPIA participants”

# Scientific Priorities for 2008



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18 research topics proposed for 2008:

- 5 safety prediction
- 1 pharmacovigilance
  
- 2 diabetes
- 3 brain disorders
- 2 respiratory diseases
  
- 5 education & training



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- Translational safety biomarkers
  - Immunogenicity
  - Non-genotoxic carcinogenesis
  - Expert systems for in silico toxicity prediction
  - Improved predictivity of non-clinical safety evaluation
  
  - Strengthening the monitoring of benefit/risk assessment

# Efficacy Research Topics



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- Islet cell research
  - Surrogate markers for vascular endpoints
  
  - Pain Research
  - Psychiatric disorders
  - Neurodegenerative disorders
  
  - Severe Asthma
  - COPD

# Education & Training Topics



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- European Medicines Research Academy (EMRA) Hub
  - Safety sciences training programme
  - Pharmaceutical medicine training programme
  - Integrated medicines development training programme
  - Pharmacovigilance training programme

# The Innovative Medicines Initiative (IMI)

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Thank you

