

The Innovative Medicines Initiative (IMI)



Last update

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Bio-Entrepreneur March 19th , 2008

The IMI- What is it? What does it do?



-
- Public Private Partnership between EFPIA and the EU
 - Will fund collaboration pre-competitive to drug development
 - Address causes of delay or bottlenecks in the R&D process
 - Accelerate discovery and development of more effective innovative medicines with fewer side-effects
 - Foster Europe as the most attractive place for pharmaceutical R&D

IMI History (1)



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- | | |
|----------------|---|
| June 2004 | ETP launched under the Sixth Framework Programme for Research (FP6) as a gathering of stakeholders led by the pharmaceutical industry |
| November 2004 | Submission of pilot project InnoMed to the EC |
| December 2004 | Publication of IMI Vision Paper |
| August 2005 | Publication of IMI Strategic Research Agenda developed through broad consultation |
| October 2005 | Start of pilot project InnoMed funded under Framework Program 6 (€ 18 million) |
| September 2006 | Publication of IMI Strategic Research Agenda version 2 |

IMI History (2)



-
- | | |
|---------------|---|
| May 2007 | Commission Proposal for a Council Regulation setting up the Innovative Medicines Initiative Joint Undertaking -

Submission of proposal to the EU Council and European Parliament |
| August 2007 | Adoption of IMI Intellectual Property Policy |
| November 2007 | Adoption of IMI legal package by the EU Competitiveness Council |
| December 2007 | Decision by the European Parliament and the EU Council to establish IMI Joint Undertaking |

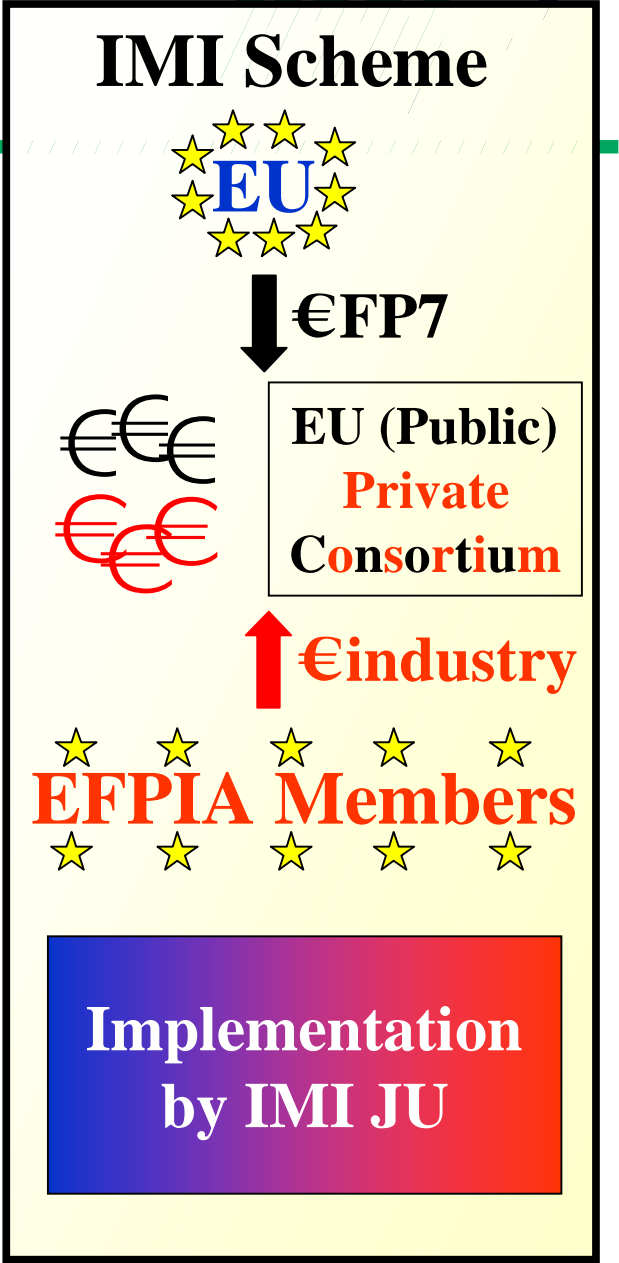
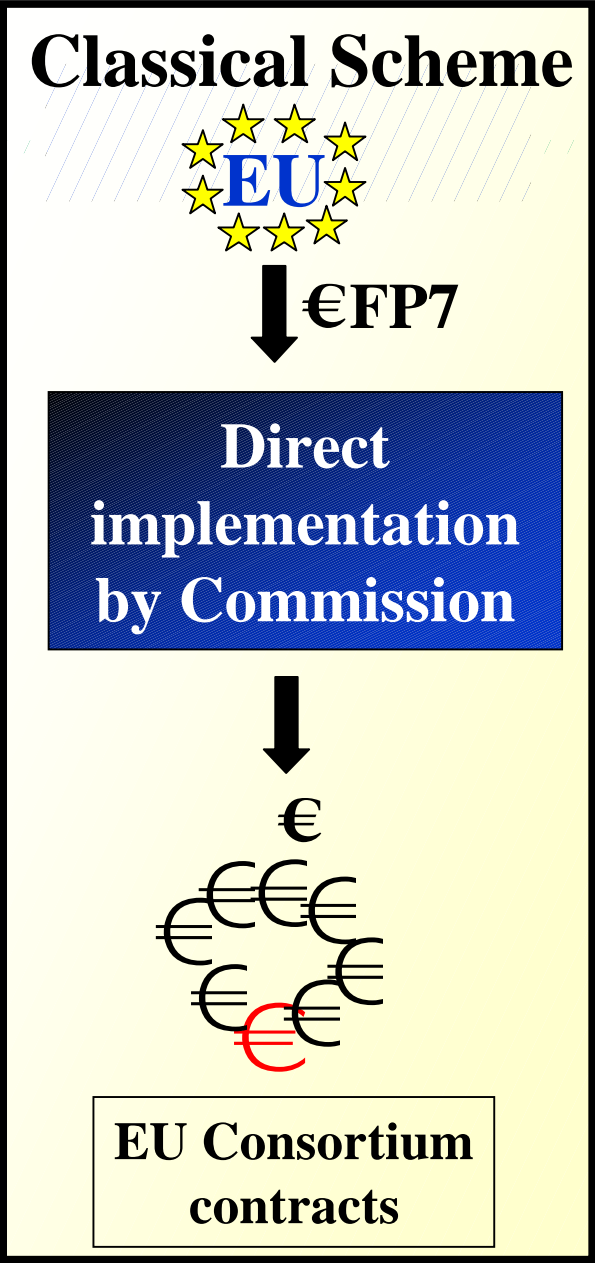
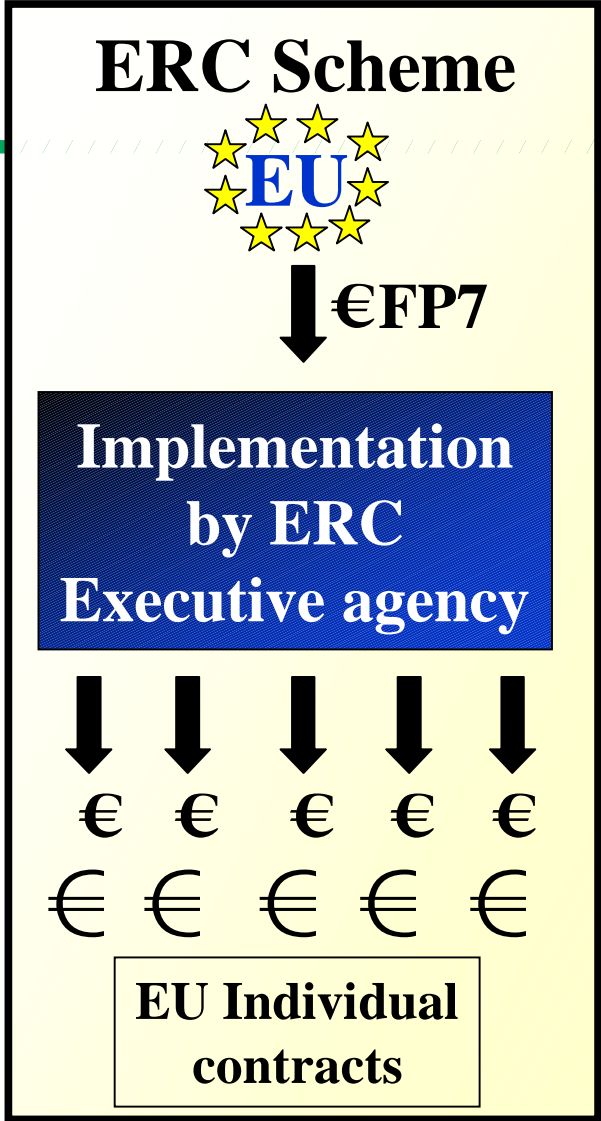
26 Potential EFPIA Participants



Pierre Fabre



Examples of research funding schemes in FP7

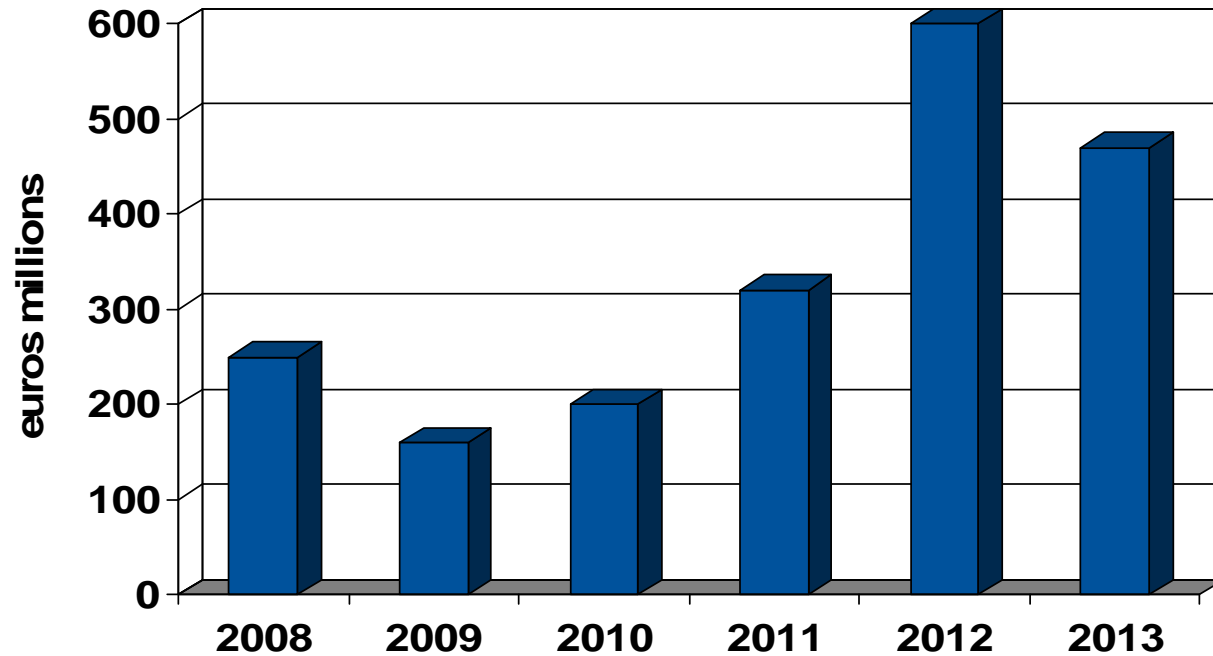


Academic or SME
 Large company

Funding will be allocated to IMI projects until 2013 but research will be supported until 2017



Total Annual Budget



The EFPIA IMI Priorities for 2008



-
- IMI was adopted by the EU Member States on December 20th, 2007
 - In the context of the full implementation of the Strategic Research Agenda the IMI Priorities for 2008 are:
 - To get quality IMI research projects started with a minimum of bureaucracy
 - Progress IMI from its interim period to autonomy

Key Milestones for 2008



-
- 1st Board meeting on March 3. Jonathan Knowles was elected chair of the IMI Board
 - Official launch of the IMI Call: Event with the EFPIA President and the Research Commissioner planned for April 30th, 2008
 - Recruitment of the Executive Director
 - Process still being finalised in the European Commission

Members of the IMI Governing Board



- Brian Ager, EFPIA Director General
- Andreas Busch, EFPIA Presidency, RDG member, Bayer HealthCare
- Jackie Hunter, RDG Member, GSK
- Carlo Incerti, EBE President, Genzyme
- Jonathan Knowles, RDG Chair, Roche
- Franco Biscontin, DG Research, Director "Resources"
- Daniel Jacob, DG Research, Deputy director general in charge of the political framework and simplification
- Georgette Lalis, DG Enterprise, Director Consumer goods (including legislation)
- Andrzej Jan Rys, DG SANCO, Director Public health and risk assessment
- Zoran Stancic, DG Research, Deputy Director general in charge of scientific advances

Technical Outcomes from the First IMI Governing Board Meeting



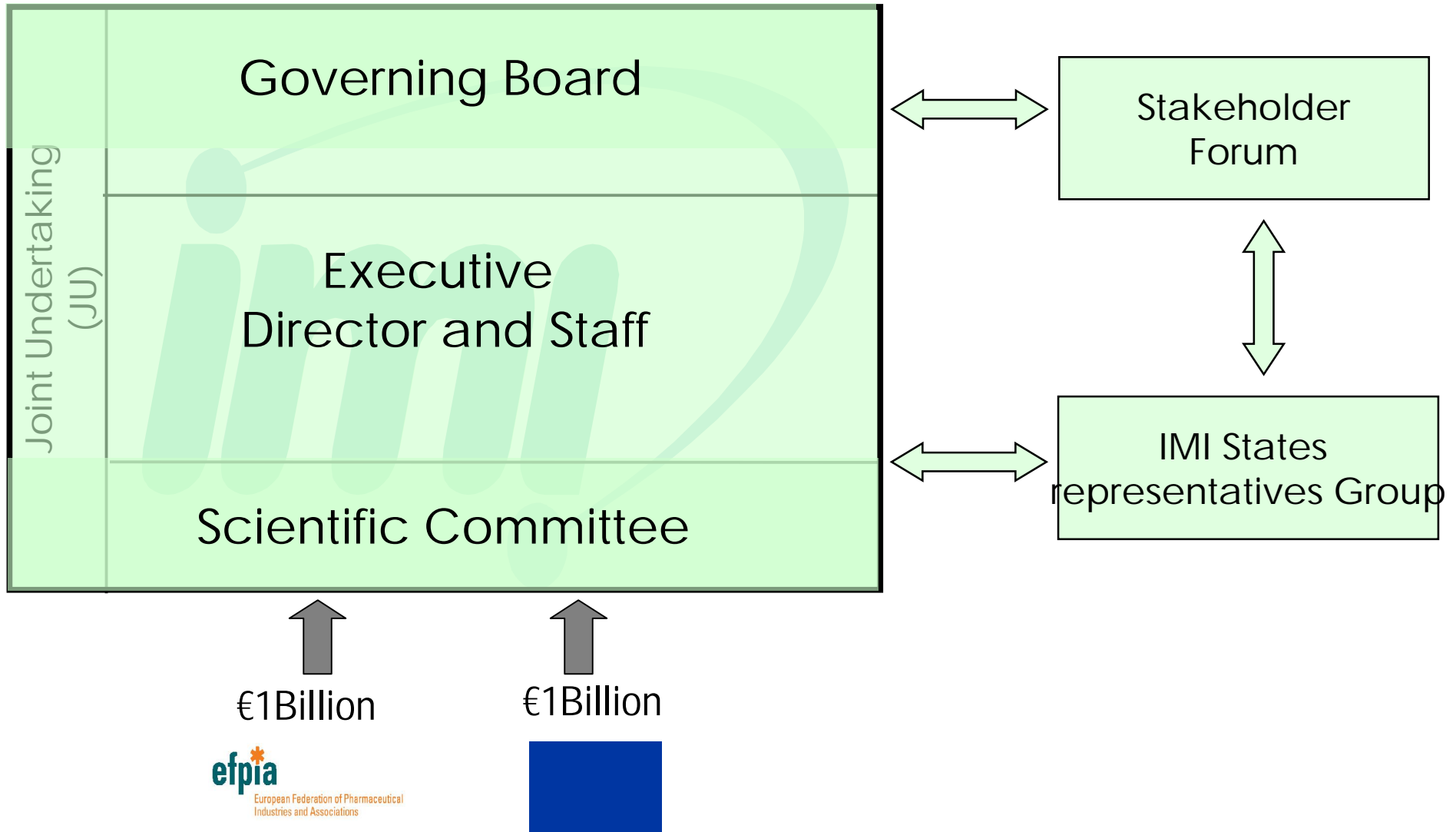
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- IMI Research Agenda defined by industry has been adopted by the IMI Governing Board
 - IMI Call Topics 2008 defined by industry has been adopted by the IMI Governing Board
 - 18 research topics (safety, pharmacovigilance, diabetes, brain disorders, respiratory disorders and Education & Training)
 - Average contribution per company per project €850'000 over 5 years

Starting Research Projects – Expected timelines



March 3 rd , 2008:	First IMI Governing Board meeting
March 2008:	Consultation of Member States Representatives
April 2008:	Publication of the IMI Call
April 30 th , 2008:	Call launch event in Brussels
July 2008:	Deadline for Expressions of Interest
November 2008:	Deadline for Full Project Proposals
Early 2009:	Signature of Project/Grant Agreements
	Start of research projects
February 2009:	Publication of the second IMI Call

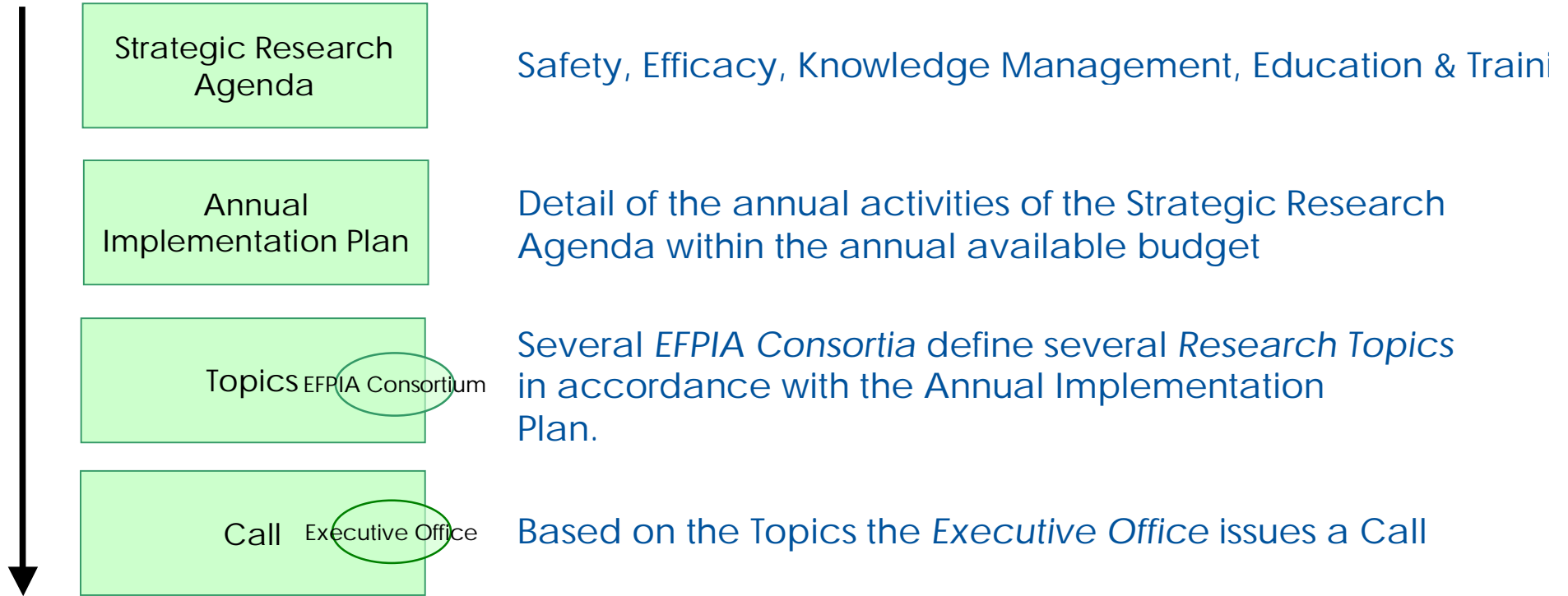
Structure and funds



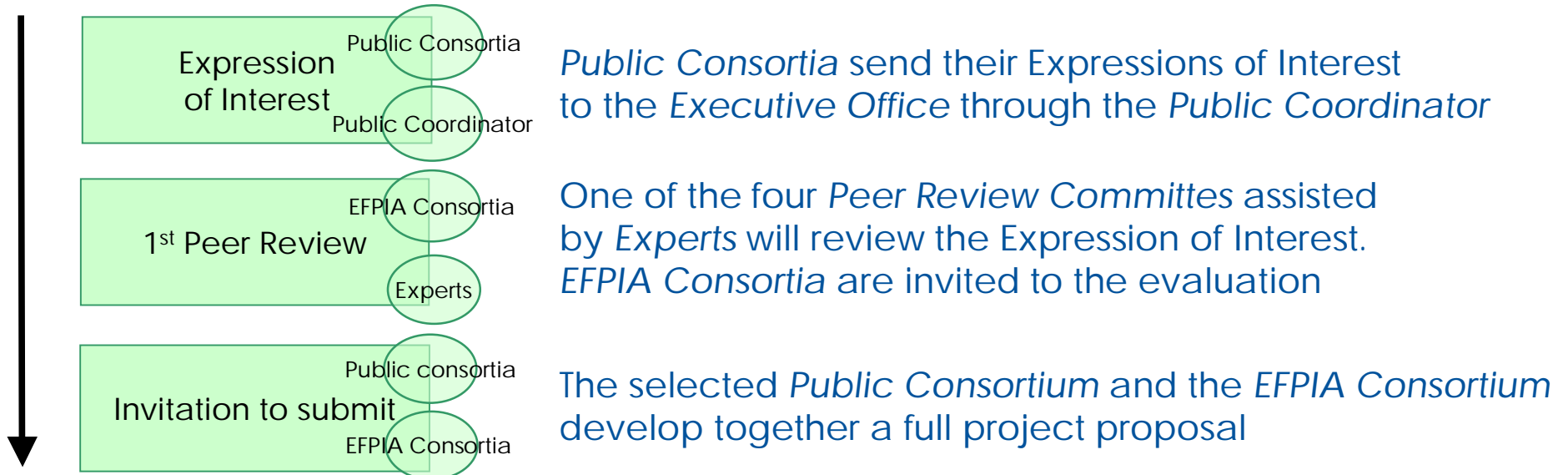
Call and Evaluation Process



Call Definition



Phase 1

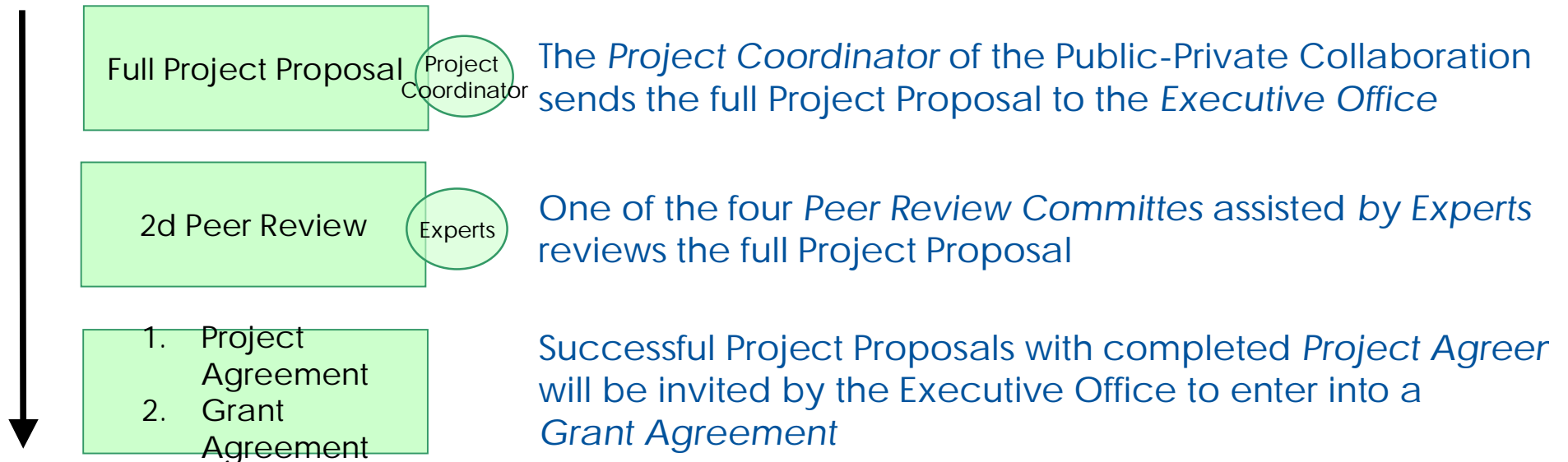


Call & Evaluation Process

Stage 1



Phase 2 and Contract negotiation

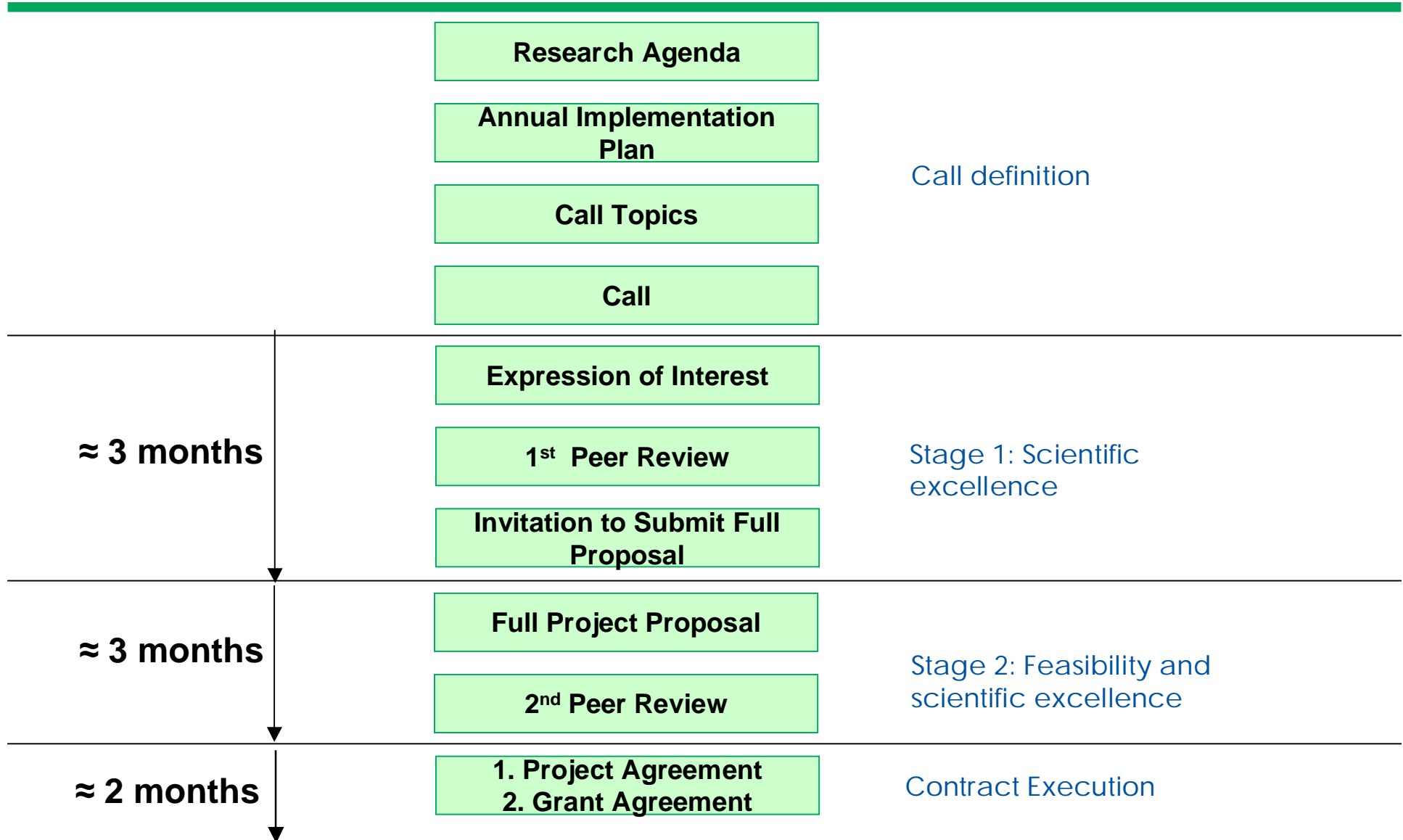


Call & Evaluation Process

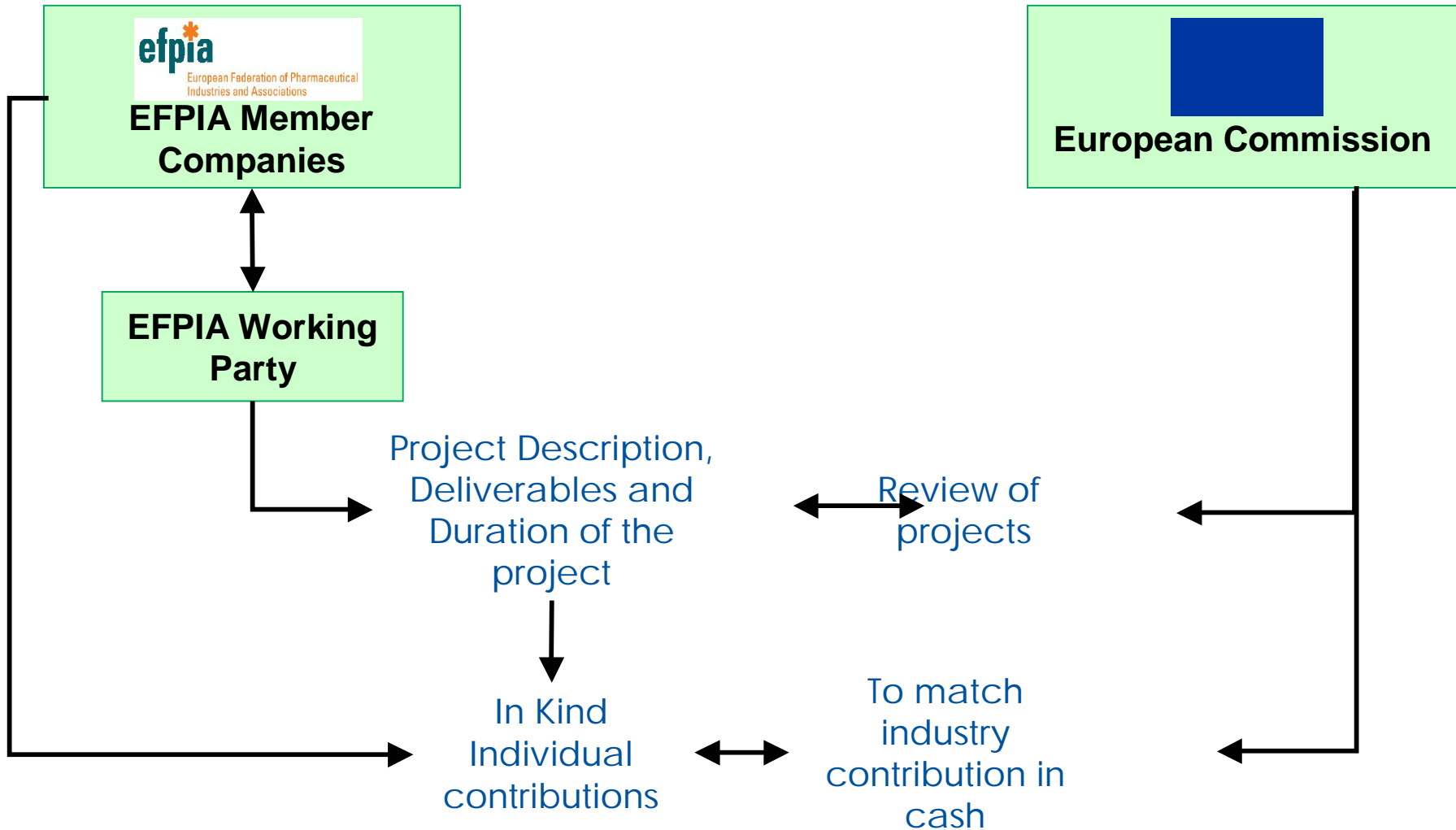
Stage 2



Call & Evaluation Process



How call topics are written



IMI First Year Expected Topics



-
- 5 in Safety
 - 1 in Pharmacovigilance
 - 2 in Diabetes
 - 3 in Brain Disorders
 - 2 in COPD & Asthma
 - 1 in Education & Training

Information provided on the topics



1	Topic Title	<i>Provide with a clear topic title</i>
2	Project Description	<i>Describe the envisaged research program What approaches are envisioned (Maximum 2 pages)</i>
3	Key Deliverables of the project	<i>What the project aims to achieve after completion (Maximum 1 page)</i>
4	EFPIA Participants in the project	<i>Name EFPIA companies which plan to participate in the project</i>
5	Role of EFPIA Participants in the project	<i>EFPIA Participants in the project will contribute (Maximum 2 pages)</i>
6	Indicative duration of the project	<i>X years</i>
7	Indicative total in kind contribution from the EFPIA companies	<i>€ X mio</i>
8	Indicative expectations from the Public Consortium	<i>What are the deliverables expected from the Public Consortium (Maximum 1 page)</i>

Expressions of Interest



-
- Short – few pages only (5-10)
 - Describes how the Public Consortium will address the topic
 - outline Work Packages and Budget
 - Identifies the members of the Public Consortium and the Public Coordinator
 - Identifies Knowledge Management and Education and Training needs
 - Reviewed by Peer Review, ad hoc experts including representatives of the EFPIA Consortium

Competition between the Expressions of Interest from the public consortia

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
- Peer Reviewed independently of EFPIA involvement
 - Judged against absolute standard
 - Expectation of high success rate

Minimize competition at this stage in order not to waste effort

Peer Review



-
- 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 only in evaluation of Expressions of Interest
 - Responsibility
 - To evaluate science of Expressions of Interest
 - 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

Public consortium – Eligible for public funding



-
- Consortium of e.g. Academia, SMEs, patient organisations. I.e. stakeholders eligible for *public funding*.
 - Answer calls through submission of Expression of Interest to the Executive Office
 - Consortia need to be formed *before* application
 - How to form a public consortium? Search engine on the IMI website after publication of call, similar to FP6.

EFPIA consortia – Providing in-kind funding



-
- EFPIA companies funding topic through in-kind contributions
 - Meet Public consortium after selection of best Expression of Interest to produce together full project proposal

The Innovative Medicines Initiative (IMI)



Back up

For info

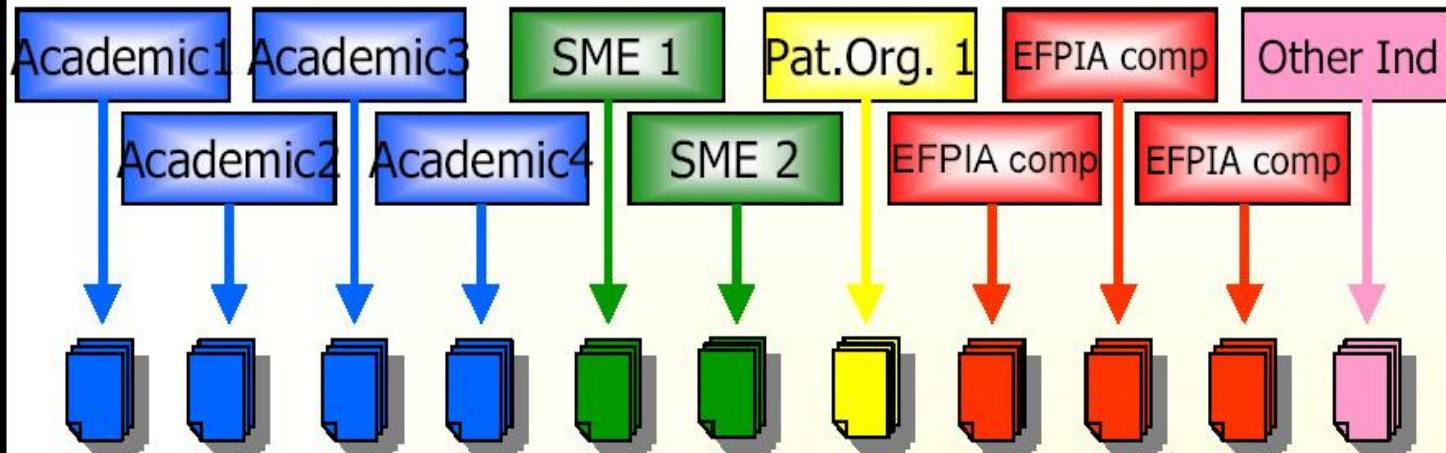
Research Project Funding



Research performed by pharmaceutical industry funded by own resources (= in kind contribution)

Research performed by public sector and SMEs funded by European Community (= cash contribution)

Financial reporting for participants in an IMI project & *in kind* contribution from industry



Composition of a typical IMI project

Financial reports

- Cost statement
- Audit certificate

IMI JU contributes up to:

- 75% for RTD costs
- 100% for management and training costs

Contribution counted as
« EC contribution »

IMI JU contributes up to:

- 0% for any costs

Only EFPIA member
companies costs counted as
« EFPIA *in kind* » contribution

IMI JU
Research
expenditure

Amount of funding – according to EU State Aid rules



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

Eligible costs



Direct eligible Costs			Indirect Costs
Activities	Category	Details	
Research activities	Personnel	FTEs in hours	Flat rate of 20% of Direct eligible costs, excluding subcontracting
	Equipment	Option 1 Purchase of equipment Option 2 Depreciation of equipment Option 3 Leasing of equipment	
	Protection of knowledge	Patent searches, filing of patent (or other IPR) applications (only IMI foreground within scope of the IMI IPR policy)	
	Consumables & Materials		
	Other	E.g. Subcontracting for services	
Management activities	Personnel	FTEs in hours	
	Travel and subsistence	Meetings, workshops	
Training activities	Courses	FTEs in hours for teachers, fees for participants, travel and subsistence for participants, facilities, equipments. Salary costs of those being trained are not eligible	

Rules for participation



- Independent legal entities
- Capacities to carry out work themselves
- Research performed in Europe or country related to FP7
- 2 EFPIA legal entities and 2 non-EFPIA legal entities per project

Eligible for IMI funding	Non-eligible for IMI funding
<ul style="list-style-type: none">– SMEs– Academia– Patient Organisations– Other non-profit public entities	<ul style="list-style-type: none">– EFPIA companies– Other pharmaceutical companies not falling within definition of SMEs

IPR- definitions



data, know how and information...

- Background:
held by a Participant prior to the Grant Agreement,
necessary for carrying out the project and identified in
the Project Agreement
- Foreground:
generated under the project and excluding Sideground
- Sideground:
generated by a Participant under the Project but outside
of the Project Objectives

IPR-Ownership



	Background	Foreground	Sideground
Ownership	Each participant remains exclusive owner of its Background	The participant who generated it. If several participants: joint ownership. Possible to agree otherwise in Project Agreement	The participant who generated it. Possible to agree otherwise in Project Agreement
Right for a participant to transfer its ownership	Free to transfer ownership, subject to rights and obligations of the Grant/Project Agreement (i.e. buyer accepts the same legal position in relation to project). Notify the other participants after transfer	Only transfer if OK in Grant Agreement, Project Agreement or all participant agreed. Only deny to agree if affected. OK to affiliate.	
Right for a participant to license, use and exploit independently of the other participants	Right to independently non-exclusive license and otherwise use	Right to independently non-exclusive license and otherwise use	

IPR-Access Rights



	Background	Foreground	Sideground
Access rights for participants for the <u>purposes of completing the project</u>	Royalty free and non exclusive license for Background needed for carrying out the project	Royalty free and non exclusive license	
Access rights for participants (and affiliates) for <u>Research Use</u> during the project or after completion of the project	Non exclusive license on fair and reasonable terms or royalty free for Background needed for using Foreground, as determined in the Project agreement	Non exclusive license on fair and reasonable terms or royalty free, as determined in the Project agreement	
Access rights for Third Parties for <u>Research Use</u> after completion of the project	Non exclusive license on fair and reasonable terms for Background needed for using Foreground, as determined in the Project agreement	Non exclusive license on fair and reasonable terms, as determined in the Project agreement	
Rights for participants (and affiliates) or Third Parties for <u>Direct Exploitation</u> after completion of the project	NO access rights. Subject for commercial negotiation	NO access rights. Subject for commercial negotiation	

IMI in FP7



	IMI JU	FP7
Funding	Industry contribution 100% of own costs	Industry funded by 50% by public money
IPR	Broader access to Foreground for « Research Use »	Limited access to Foreground for « Use »
Content	Education & Training Knowledge Management	

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
 - è Generation of More Innovative Solutions

Benefits of IMI for the Biopharmaceutical Industry



- Validation of new assessment methods such as biomarkers
- Faster interpretation of safety findings through sharing pre-competitive toxicology data
- Reduced attrition rate in late-stage development
- Reduction of animal use in safety evaluation
- Fewer patients needed in pivotal trials
- Faster approvals through better collaboration with EMEA
- Fewer post-marketing withdrawals
- More skilled professionals
- Increased collaboration with all relevant stakeholders
 - è More cost-efficient R&D

Benefits of IMI for Academia



-
- Source of funding for research
 - Improved infrastructure with state-of-the-art technological equipment
 - Opportunity to establish infrastructure for GLP/GCP compliant drug development
 - Access to pre-competitive knowledge that was previously out of reach
 - Increased mobility between the public and private sectors
 - Increase co-ordination internationally on medical research topics
 - Faster application of research results
 - Increased collaboration with all relevant stakeholders

è More funding for research

Benefits of IMI for Small & Medium-sized Enterprises (SMEs)



-
- Lower risk of technology development as shared with end-users
 - Lower costs of technology development through IMI funding
 - Easier access to Venture Capital funds for SMEs involved in IMI
 - Easier access to relevant experts in the pharmaceutical companies
 - Easier development of given technology for new application
 - Clear Intellectual Property Rights policy from the onset
 - Increased collaboration with all relevant stakeholders

è Better Investment Environment

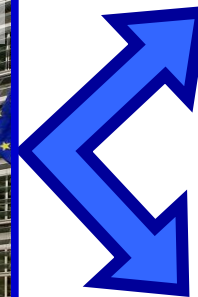
Transparency



clarity of rules,
open communication



EC will present
regularly reports
about status and
activities on the IMI
JU

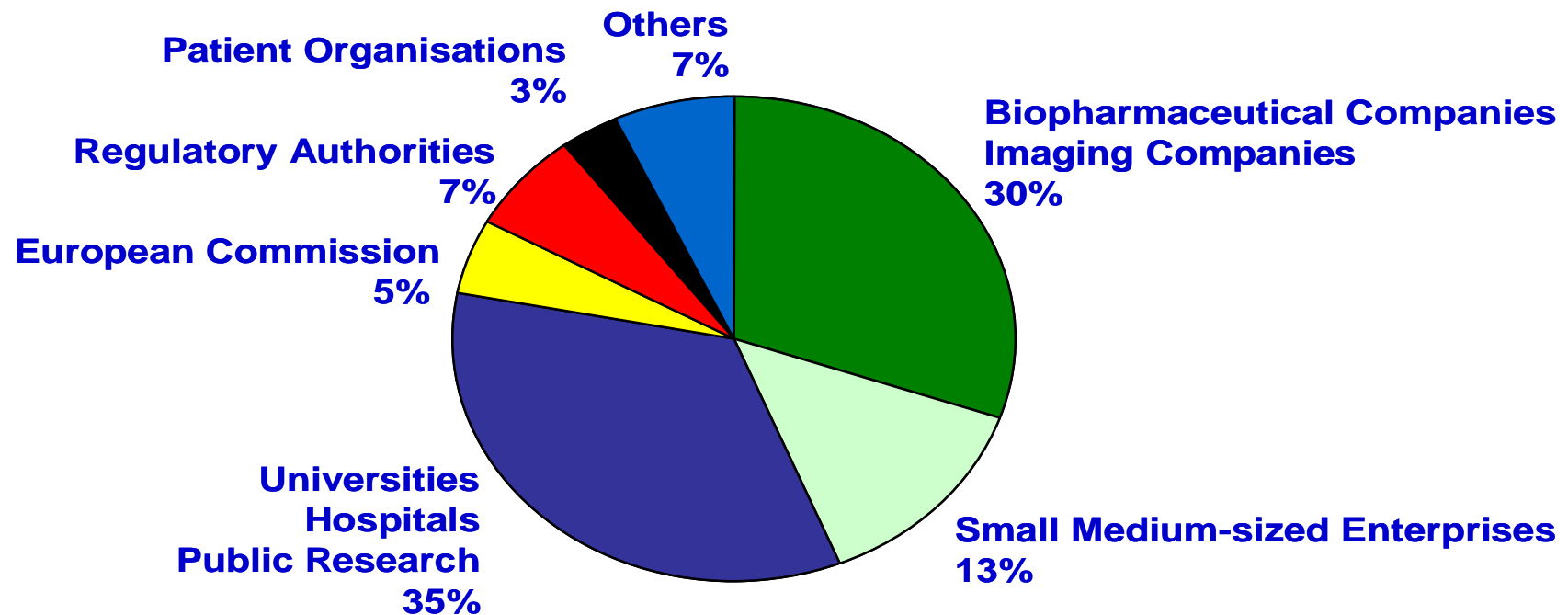


Transparency



-
- Annual activity report
 - Annual report to the Council and European Parliament
 - Accountability to the Council and European Parliament
 - Mid-term and final evaluation

Broad Consultation to develop the IMI Strategic Research Agenda



Total of 350 participants

IMI Strategic Research Agenda



**The Innovative Medicines Initiative (IMI)
Strategic Research Agenda**

*Creating Biomedical R&D Leadership for Europe
to Benefit Patients and Society*

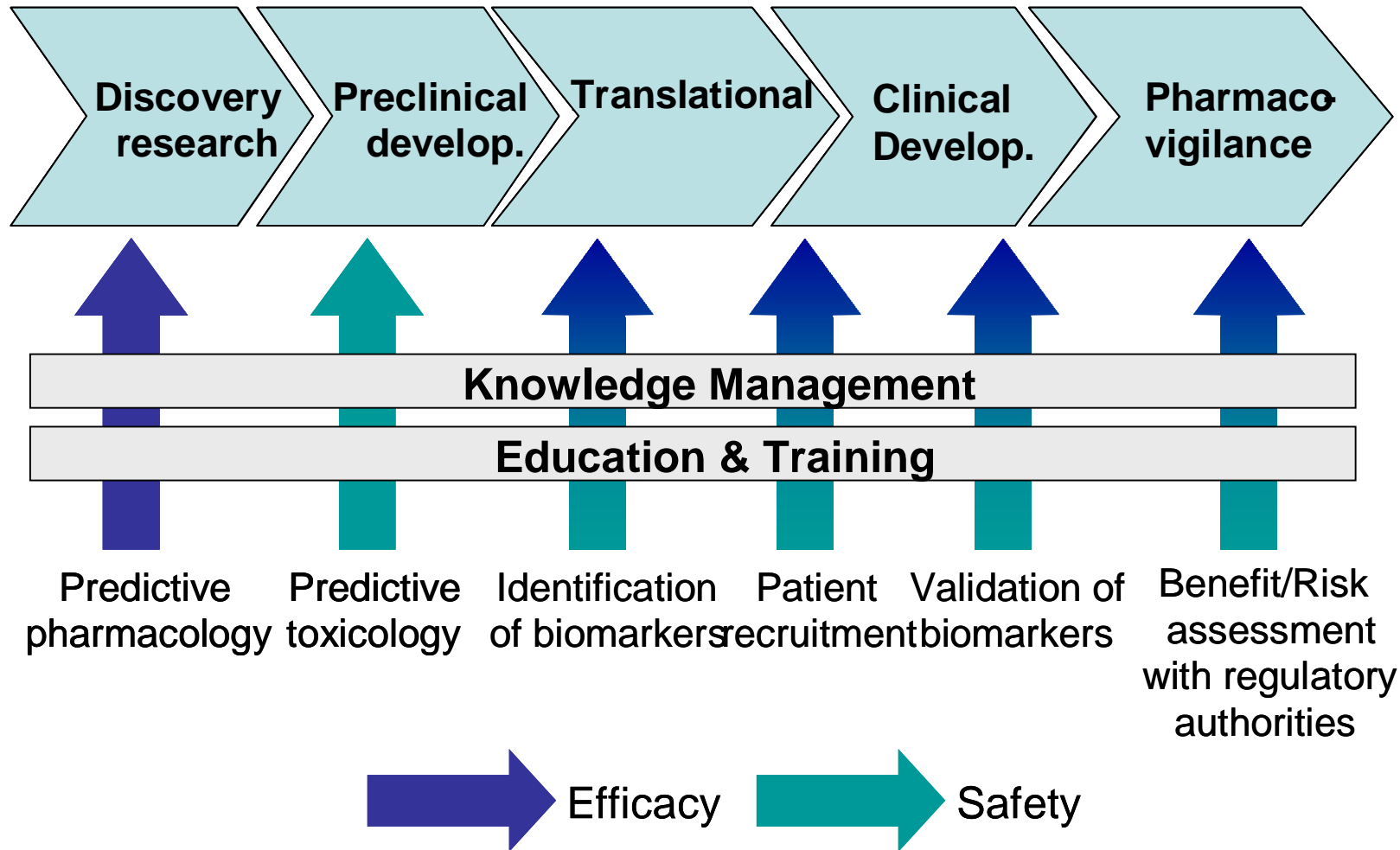
DATE OF PREPARATION: 15 September 2006 (Version 2.0)

http://www.efpia.org/4_coss/SRA.pdf

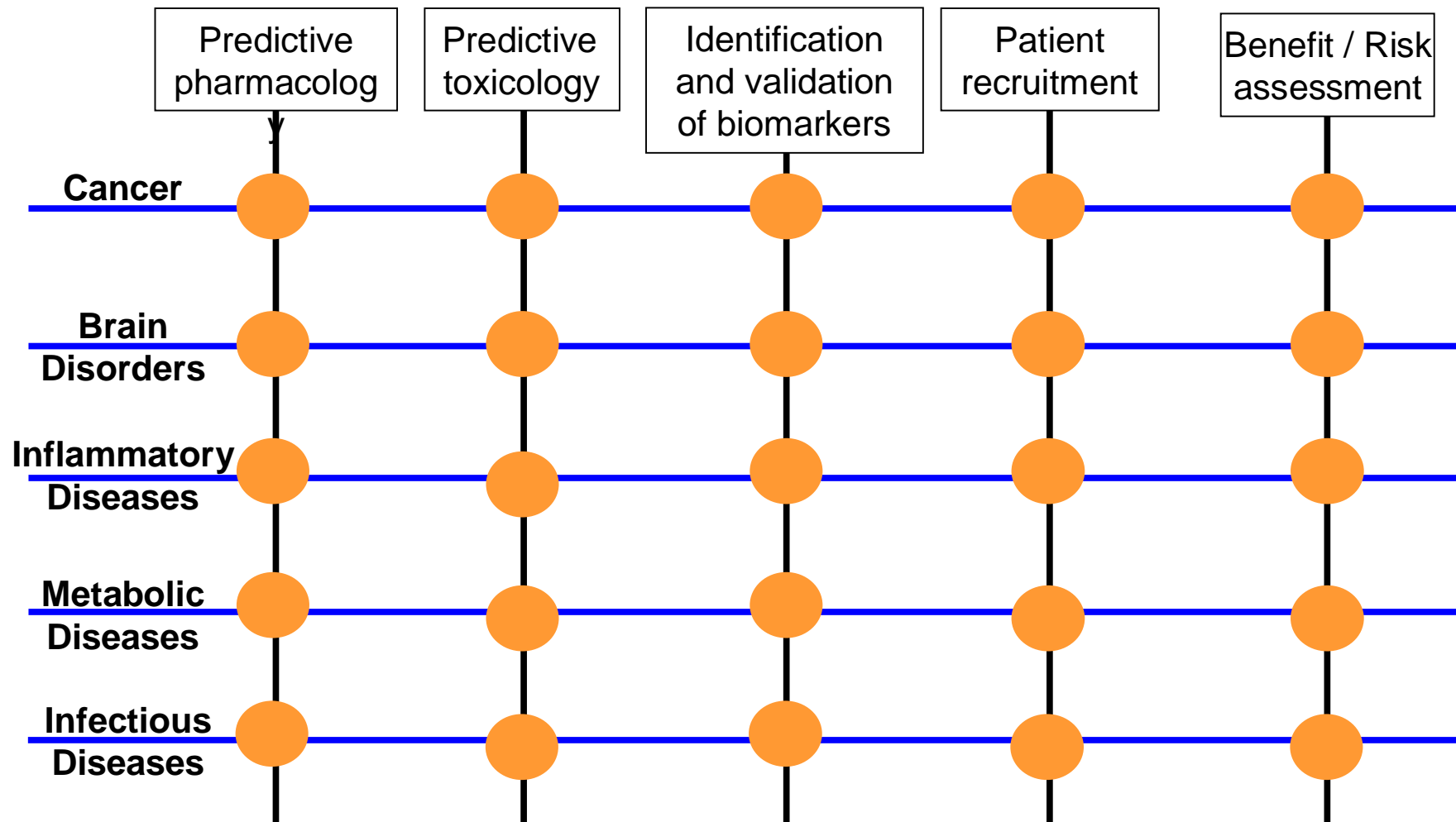
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- Identifies pre-competitive bottlenecks in the R&D process
- Proposes recommendations to address these bottlenecks
- Proposes a new model of Public-Private collaborations to implement these recommendations

Pre-Competitive Bottlenecks in the R&D Process



Focusing on 5 Disease Areas



In a nutshell...



IMI is public-private partnership between the European Community and the European pharmaceutical industry to promote biomedical innovation in Europe and to address the bottlenecks in the R&D process.

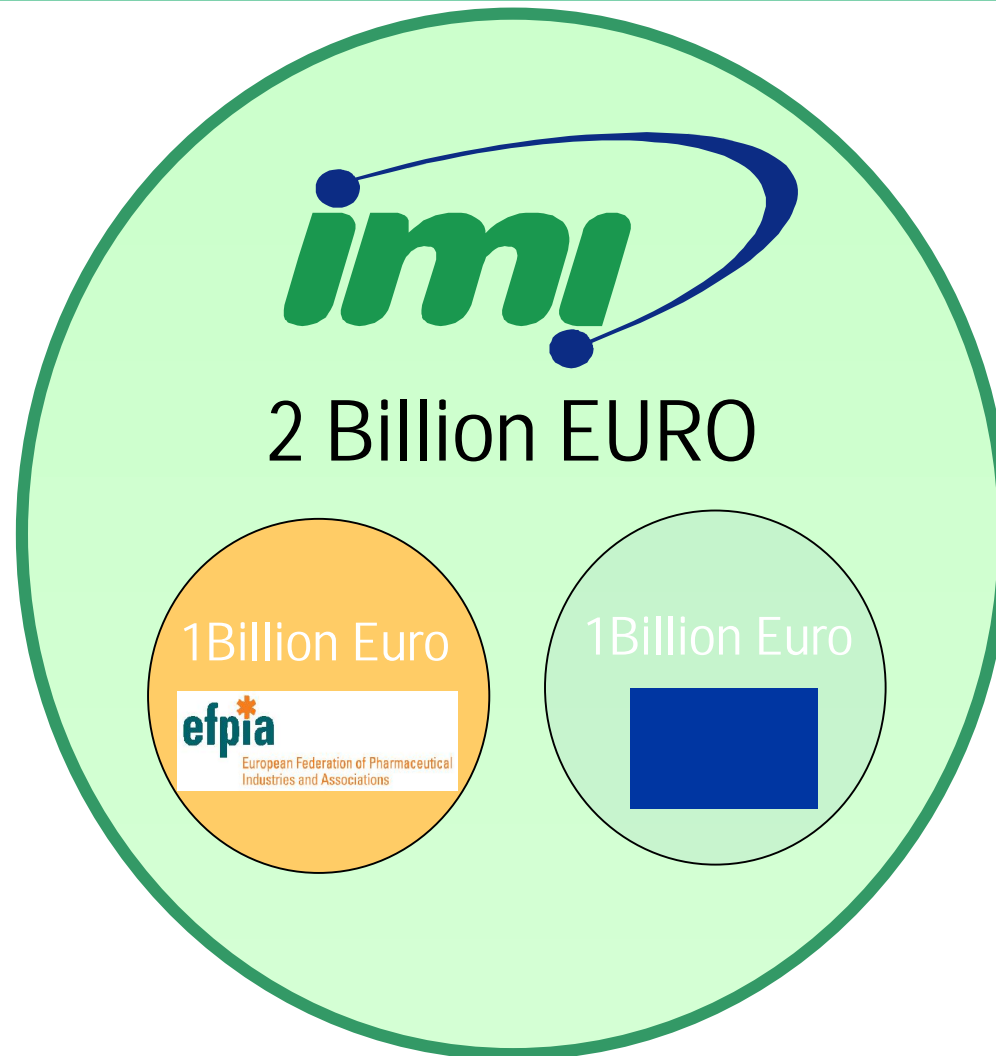
In 2008, a new Community Body, the IMI Joint Undertaking (IMI JU) will be established in Brussels to implement the recommendations of the IMI Strategic Research Agenda with a budget of € 2 billion.

Benefits of Increased Collaboration for All



- 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

è Generation of More Innovative Solutions



Eligibility for IMI funding



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

Rules for Participation in IMI Consortium



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

Funding is according to EU State Aid Rules



Research Activities Maximum 75%	Management Activities Maximum 100%
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Indirect Costs max 20% of Direct Costs
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IMI Call Process is Different from the 7th Framework Programme 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

Call definition



Research Agenda

**Annual Implementation
Plan**

Call Topics

Call

Call definition

Description of the Call Topics (1)



-
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

Description of the Call Topics (2)



-
- IMI research projects will often be multidisciplinary and addressing translation medicine challenges. Integrated approaches between nonclinical and clinical disciplines are often required.
 - The successful public consortium is expected to include expertise for all aspects of the areas mentioned in the description of the call topics.

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

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

Intellectual Property Policy *Objectives*



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

Intellectual Property Policy 'Dissemination'



-
- Participants shall disseminate the results of the project as soon as reasonably practicable but not later than one year after the termination or expiry of the Project
 - 1 year period allowed to enable protection of IP where required
 - Once knowledge is in the public domain, all can access either directly or through licence on pre-determined fair and reasonable terms

Intellectual Property 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

Licensees	Foreground IP	Background IP necessary to use
Project Participants	Made available for Research Use on a royalty free non-exclusive basis	Foreground IP 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

Intellectual Property 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.

More information...



www.imi-europe.org

www.imi.europa.eu