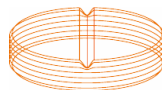


IV Jornada de Proyectos Europeos
Univesidad de Murcia

Innovative Medicines Initiative (IMI)

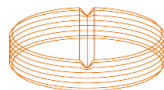
Amelia Martín Uranga

**Plataforma *Medicamentos Innovadores*,
Farmaindustria**



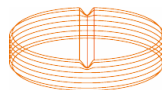
Contenido de la presentación

- *Innovative Medicines Initiative*
 - Qué es, origen, SRA, financiación,
 - Estructura y gobernanza
 - Prioridades Científicas 2008
 - Reglas de participación y convocatorias
- Plataforma Tecnológica Española Medicamentos Innovadores
 - Objetivos
 - Actividades Grupos de Trabajo
 - Difusión



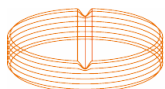
IMI

- IMI es un **partenariado público-privado** entre la Comisión Europea y la Industria Farmacéutica Europea (EFPIA). Aprobado formalmente 20/12/2007.
- Objetivo: revitalizar la investigación biomédica en Europa para conseguir **medicamentos más seguros y eficaces** en tiempos más cortos.
- Propone un enfoque coordinado para superar los cuellos de botella a través de la realización de **proyectos de investigación pre-competitivos*** y en colaboración entre todos los sectores implicados.
 - I+D farmacéutica precompetitiva*: investigación de los instrumentos y metodologías empleados en el proceso de elaboración de medicamentos.



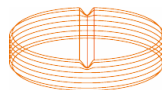
IMI

- En 2008 se crea un nuevo organismo comunitario definido como “**empresa común IMI**” - ***IMI Joint Undertaking (IMI JU)*** – con sede en Bruselas.
- IMI JU: organizará **convocatorias de propuestas competitivas**
- Hasta el **31 de diciembre de 2017** para garantizar una gestión adecuada de las actividades de investigación que se hayan iniciado, pero que no hayan concluido, durante el VII Programa Marco de I+D (2007-2013)

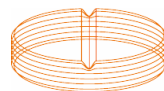
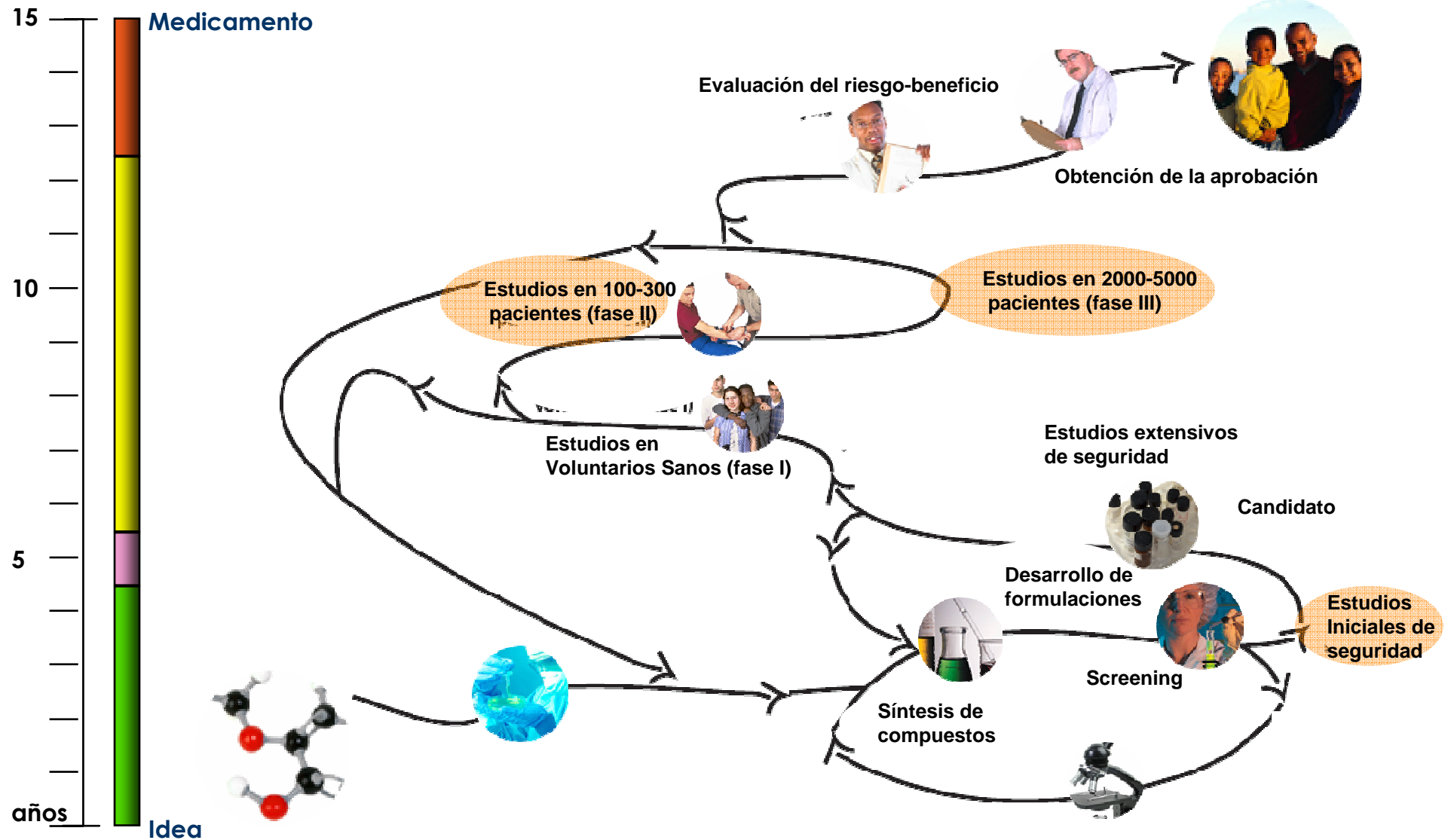


IMI – Principales desafíos

- Mejorar la previsión en materia de **seguridad y eficacia** de los nuevos medicamentos en las fases preliminares de desarrollo, antes del inicio de los ensayos clínicos (validación de nuevas herramientas)
- Evitar duplicación actual de los esfuerzos de investigación, tanto en el sector público como privado, mediante sistemas de **gestión del conocimiento** elaborados conjuntamente (validación de biomarcadores)
- Colmar lagunas en **E&F** de los profesionales del sector para disponer en Europa de una mano de obra más cualificada.
- **IMI no desarrollará ni nuevos medicamentos, ni nuevas vacunas**

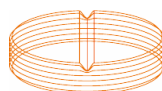
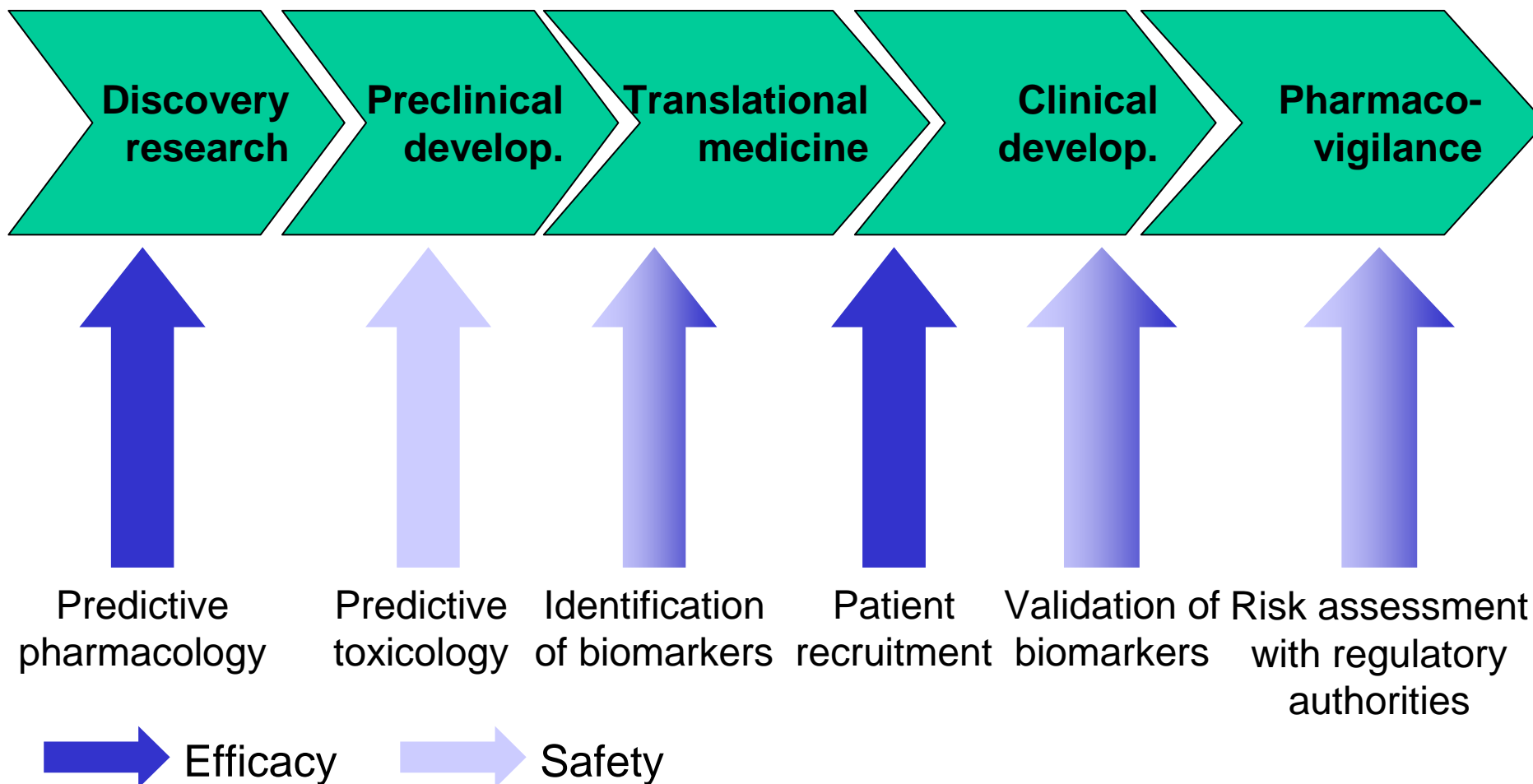


Developing medicines is a long, risky and expensive endeavour



The approach

The bottlenecks: focus on pre-competitive research



Bottlenecks in R&D supported by...

Predictive
pharmacology

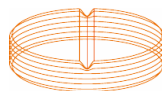
Predictive
toxicology

Identification
of biomarkers

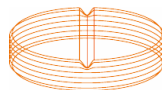
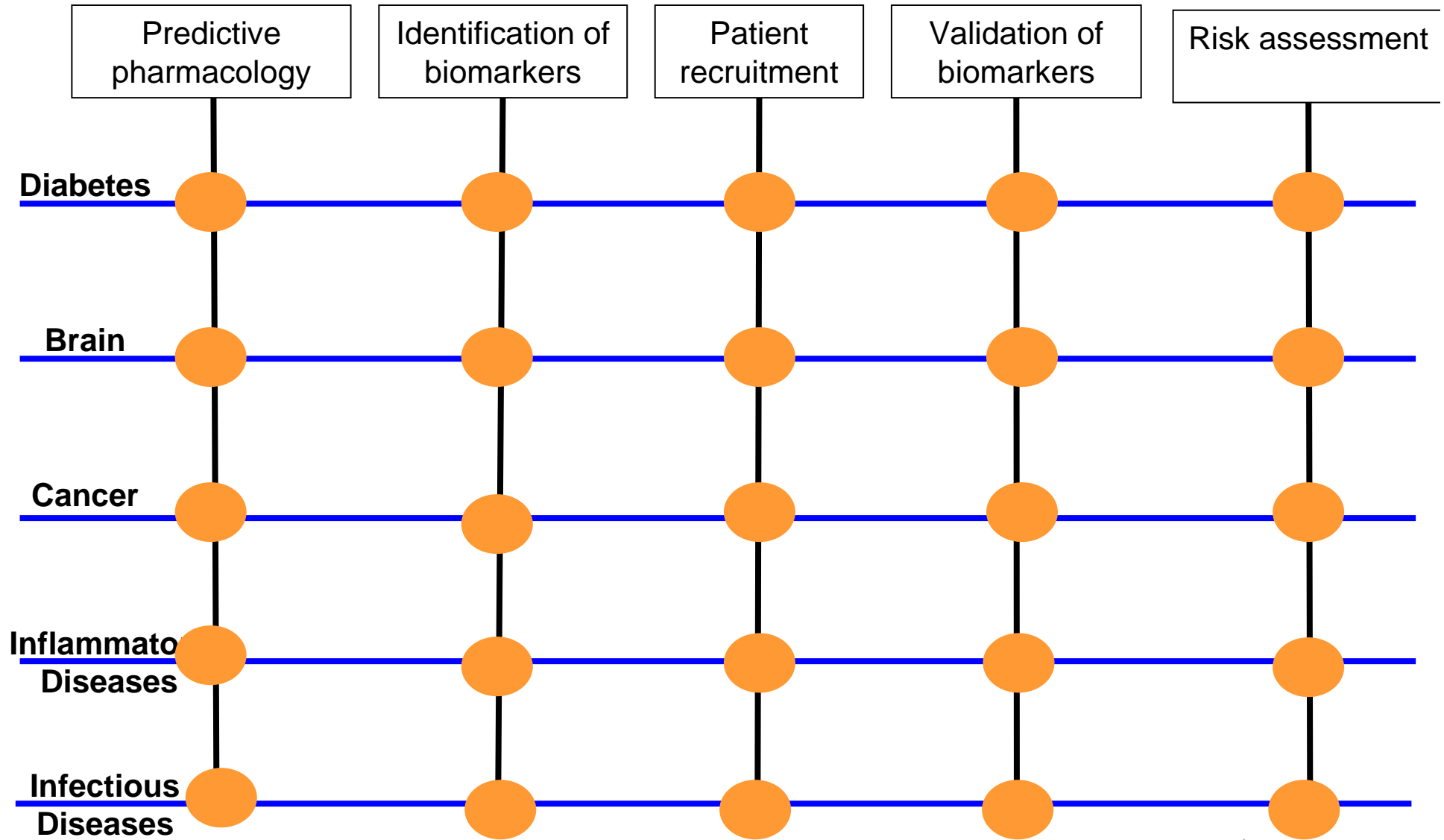
Patient
recruitment

Validation of
biomarkers

Risk assessment
with regulatory
authorities



Disease Areas and Bottlenecks



Strategic Research Agenda
2008-2017:
“Living document”
www.imi-europe.org



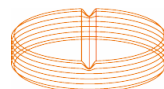
**The Innovative Medicines Initiative (IMI)
Strategic Research Agenda**

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

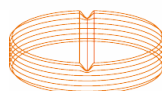
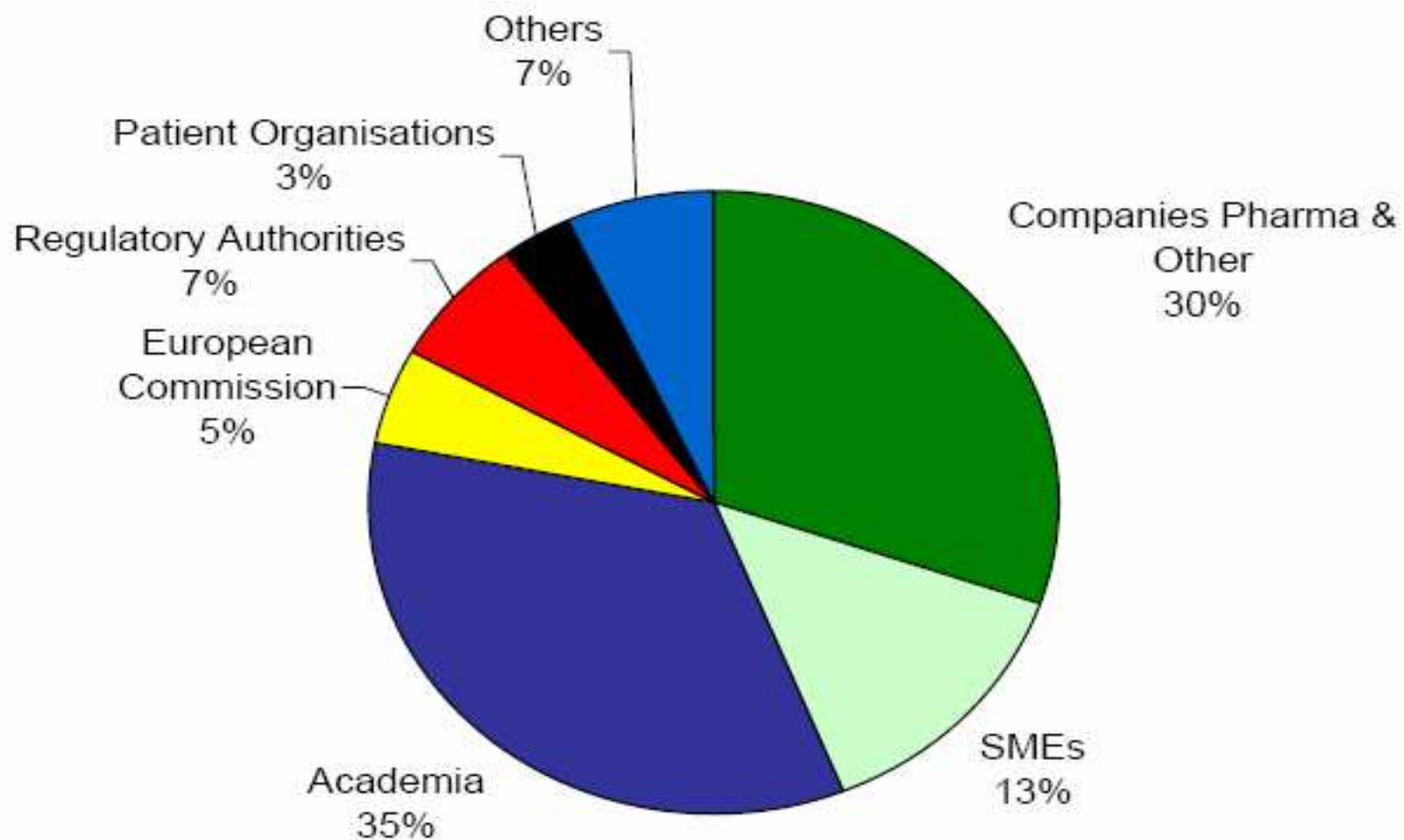
DATE OF PREPARATION: 15 September 2006 (Version 2.0)

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

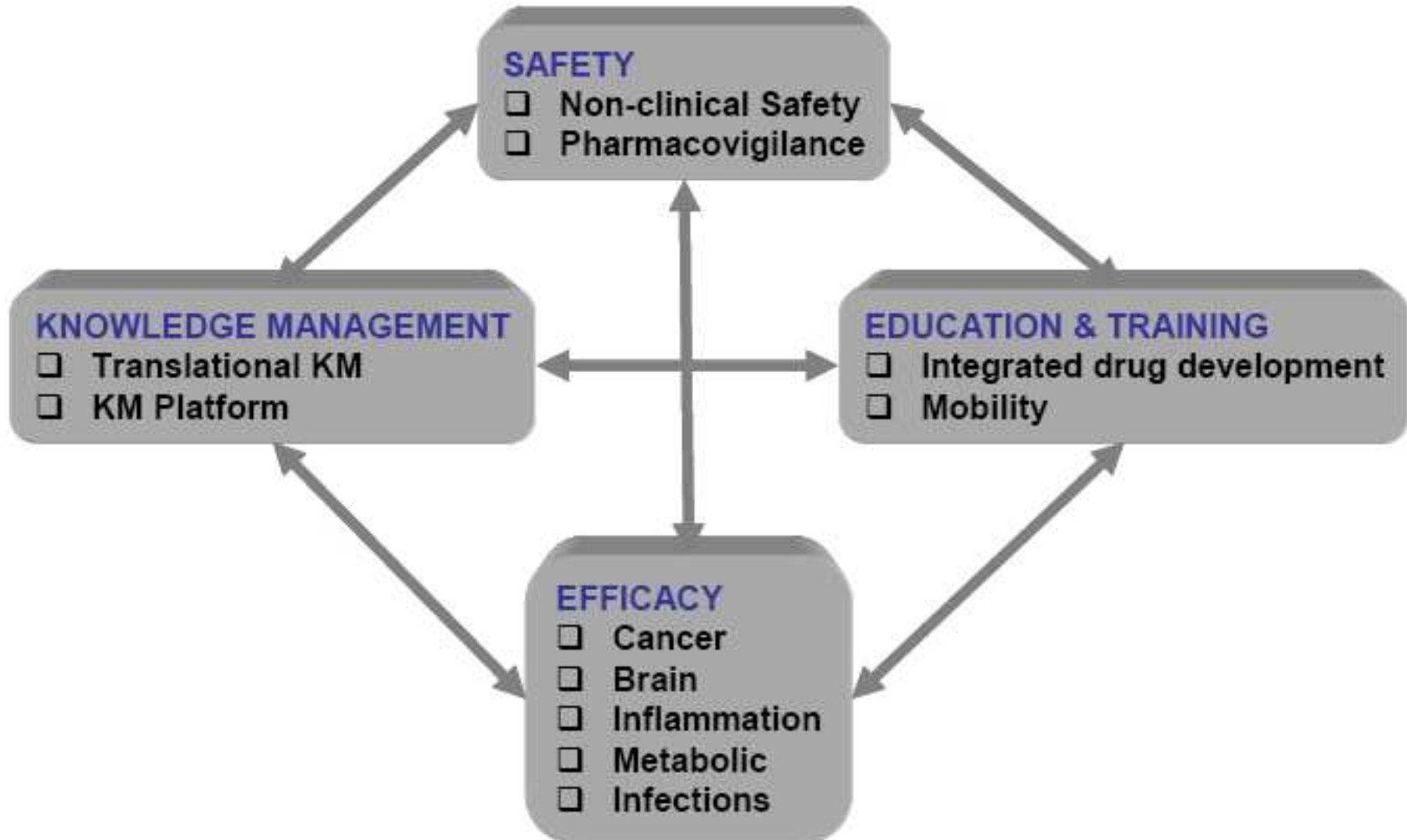
Copyright (c) 2006 Innovative Medicines Initiative



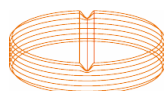
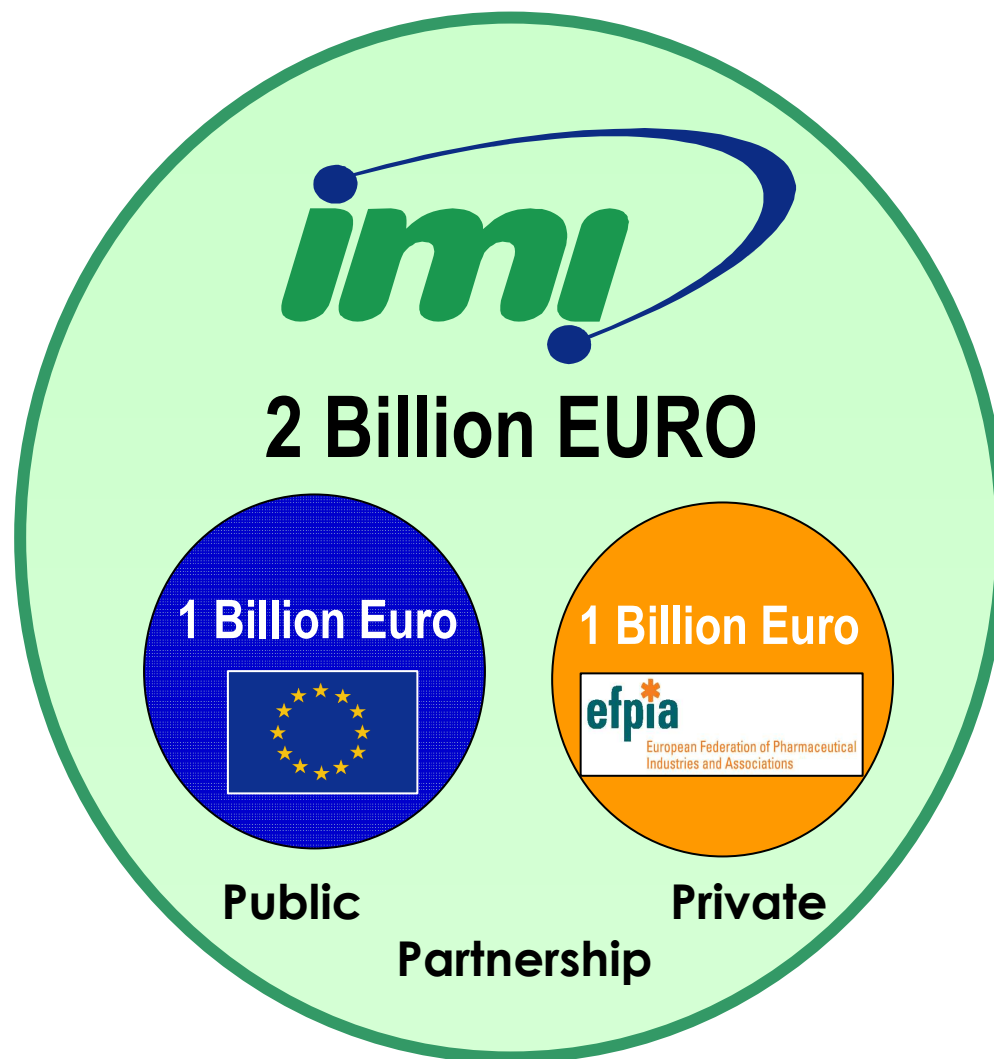
Analysis of Contributors to the SRA



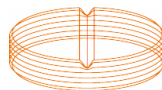
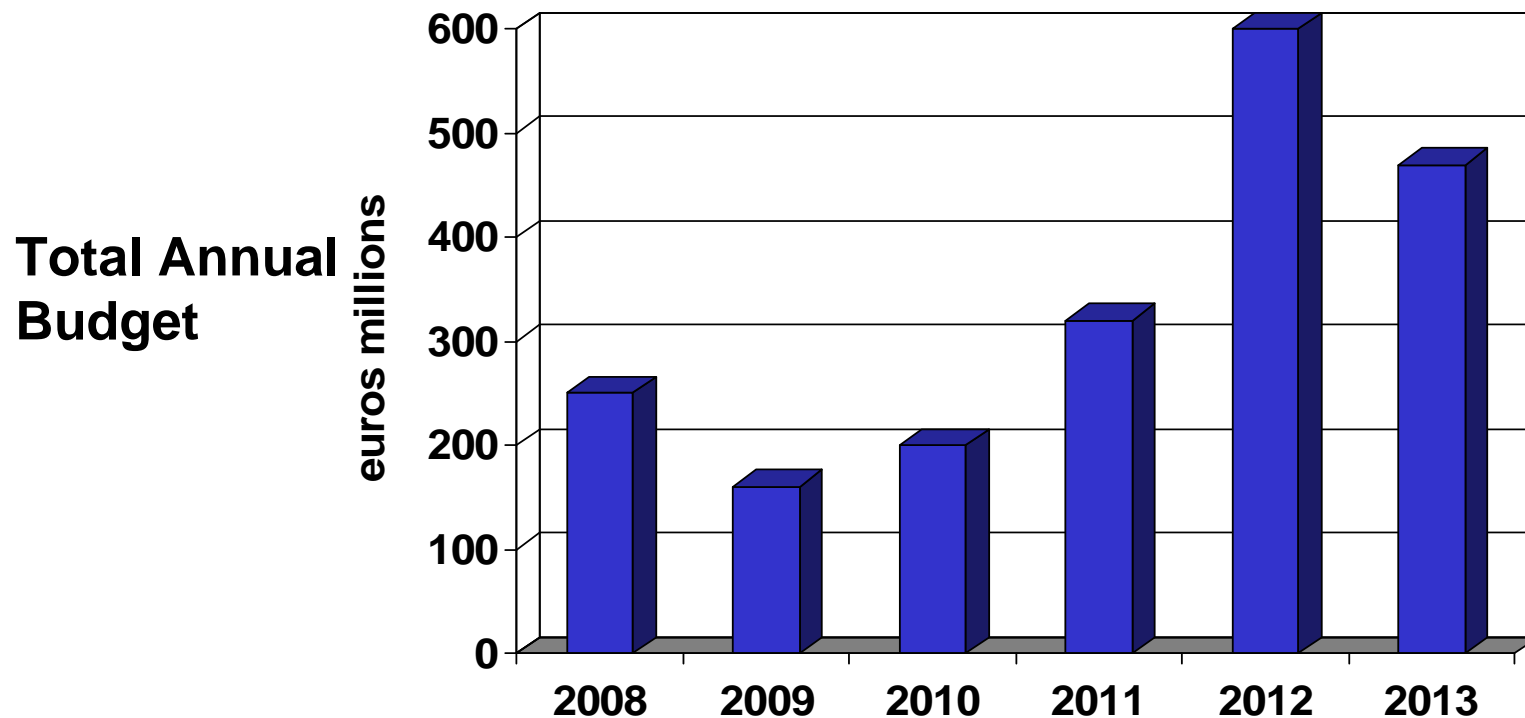
Interdependencies between the Pillars of the Strategic Research Agenda



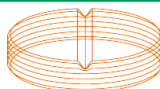
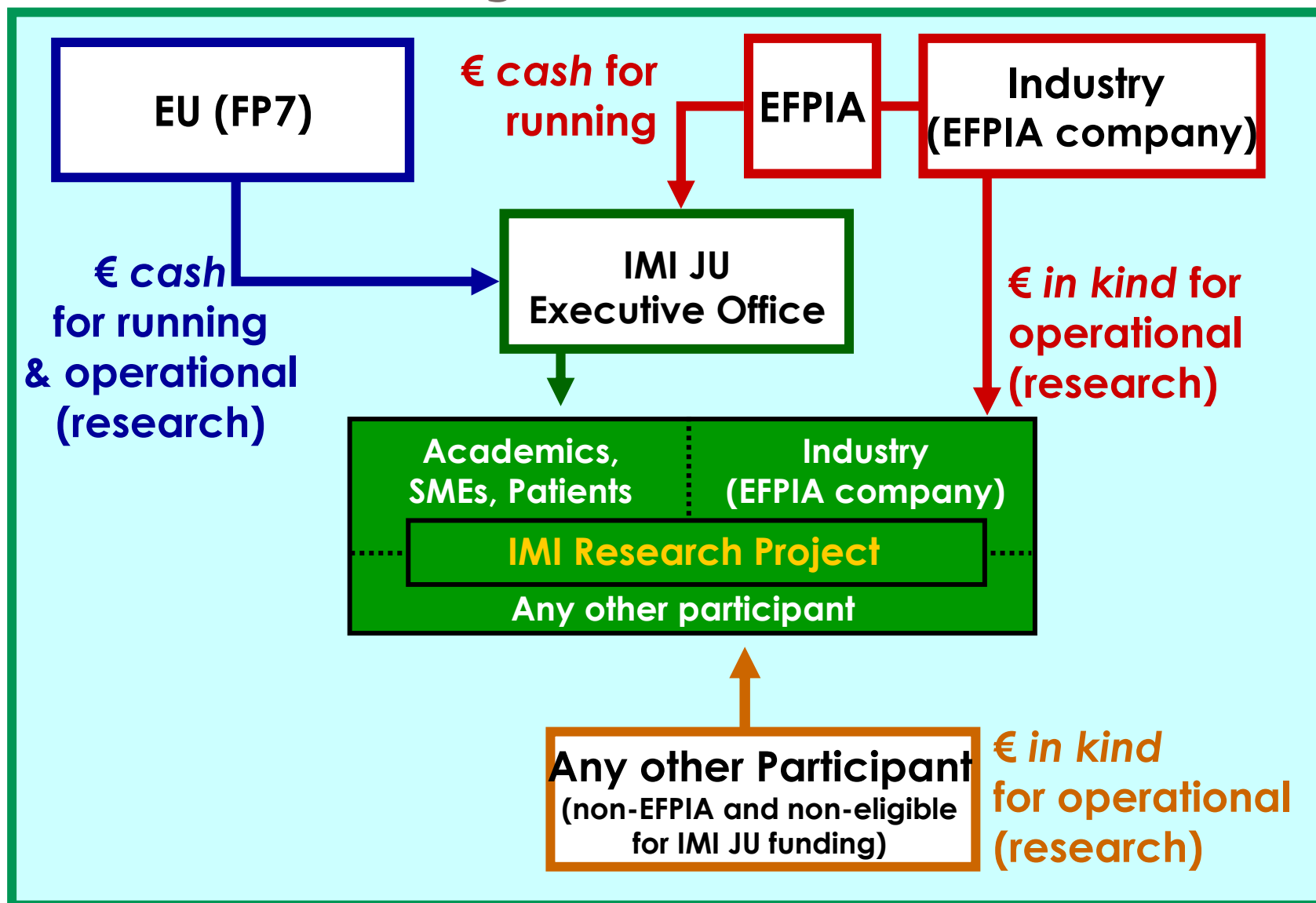
Funds



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



IMI Funding Flow and Contributions



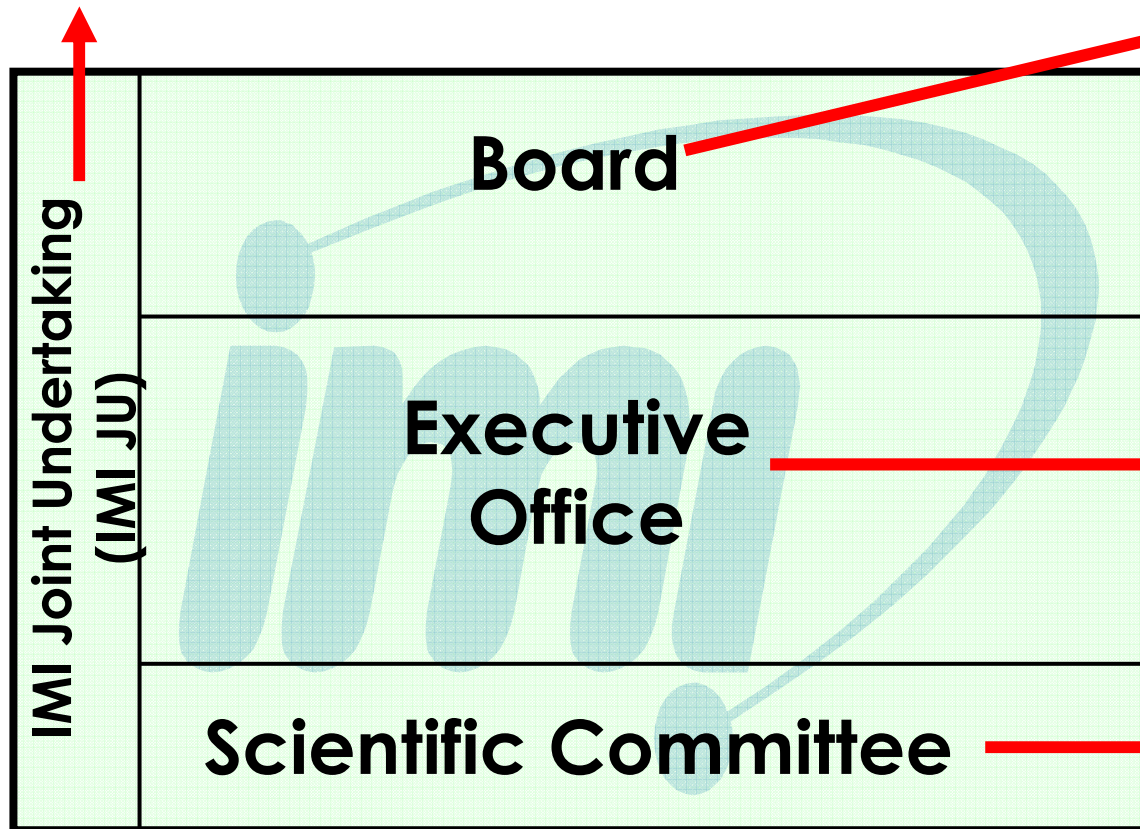
Governance

= legal entity by decision of European Council

2 Founding Members

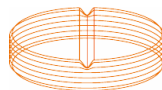


With full responsibility in IMI

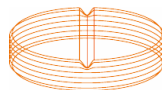
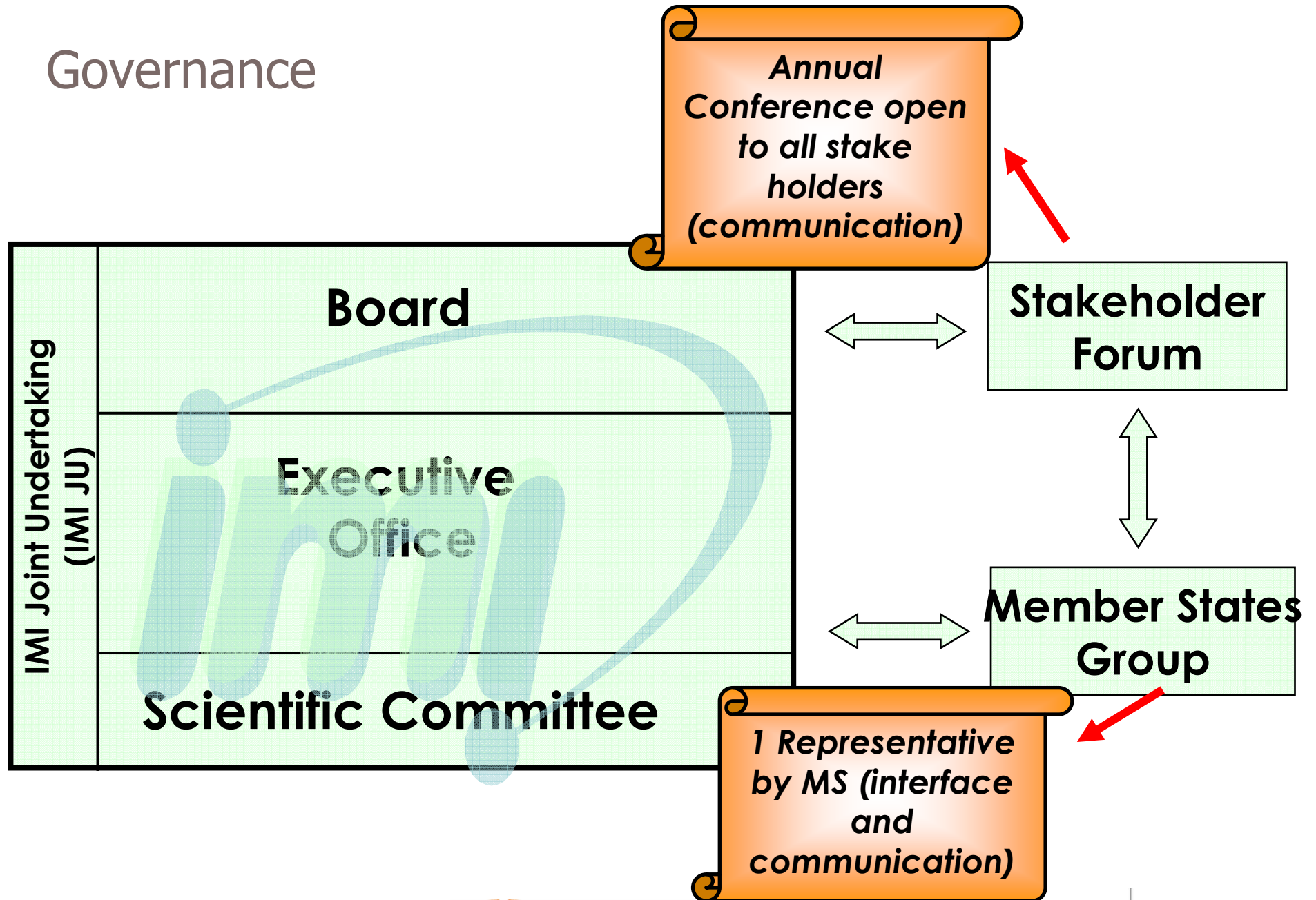


Executive Director +staff Management

15 members advisory mission to Board and Executive Office



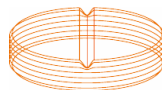
Governance



26 Potential EFPIA Participants



IV Jornada de Proyectos Europeos.
 Universidad de Murcia, 17 de abril de 2008



MEDICAMENTOS INNOVADORES
 Plataforma Tecnológica Española

farmaindustria

Possible topics for the 1st IMI Call

EFFICACY:

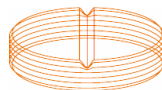
DIABETES

Islet cell research
Surrogate markers for vascular endpoints

BRAIN

Pain Research
Psychiatric disorders
Neurodegenerative disorders

ASTHMA & COPD



Possible topics for the 1st IMI Call

SAFETY- PRECLINICAL

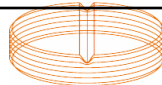
Translational Safety Biomarkers from Non-Clinical to Early Clinical Studies
Prediction and Minimization of Immunogenicity of Biotherapeutics in Man
Non-genotoxic carcinogenesis: Identification of early markers
Development of expert (QSAR) systems for <i>in silico</i> toxicity prediction
Improved Predictivity of Non-Clinical Safety Evaluation

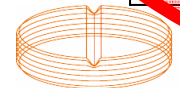
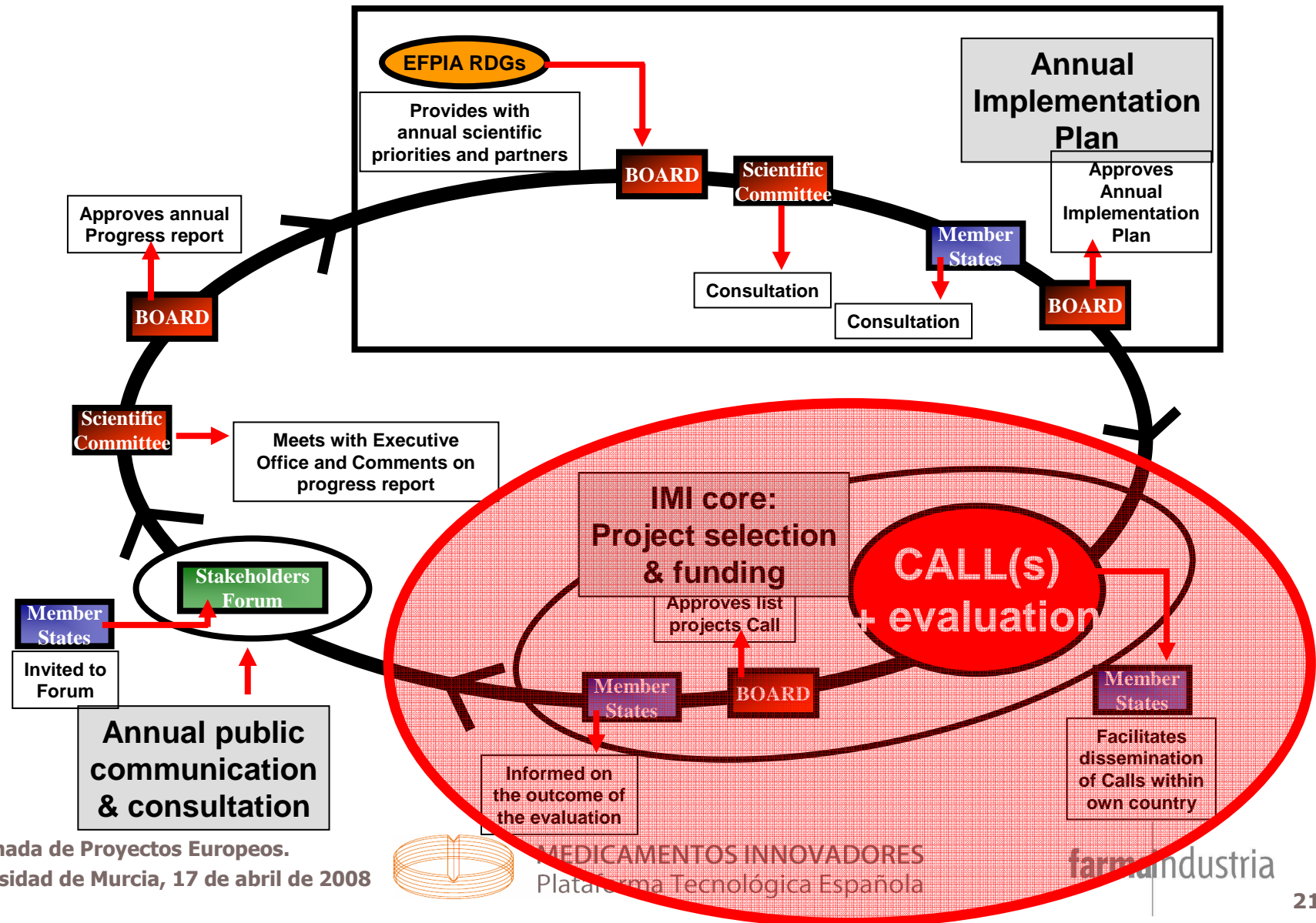
SAFETY- PHARMACOVIGILANCE

Monitoring of the benefit/risk of marketed medicines
--

EDUCATION AND TRAINING

European Medicines Research Academy (EMRA)
Safety Sciences Training Programme
Pharmaceutical Medicine Programme
Integrated Medicines Development Training Programme
Pharmacovigilance Training Programme

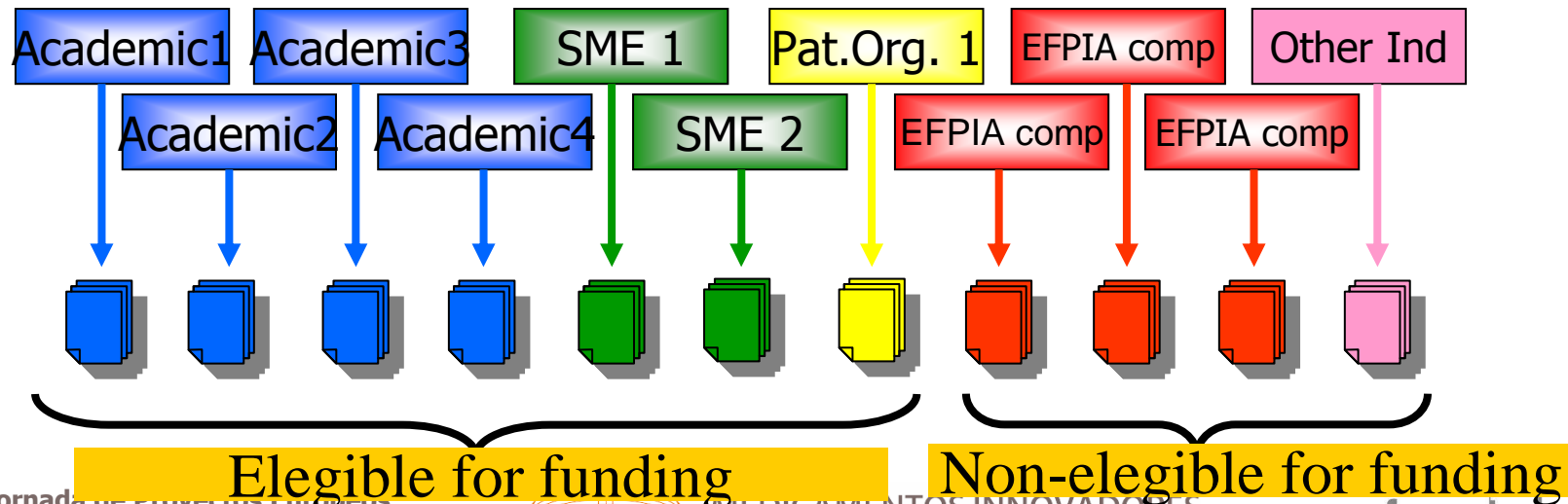




Rules for Participation in IMI Consortium & Eligibility for IMI funding

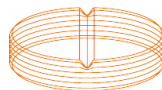
Rules for Participation in IMI Consortium

- Independent legal entities
- Capacities 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

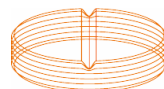
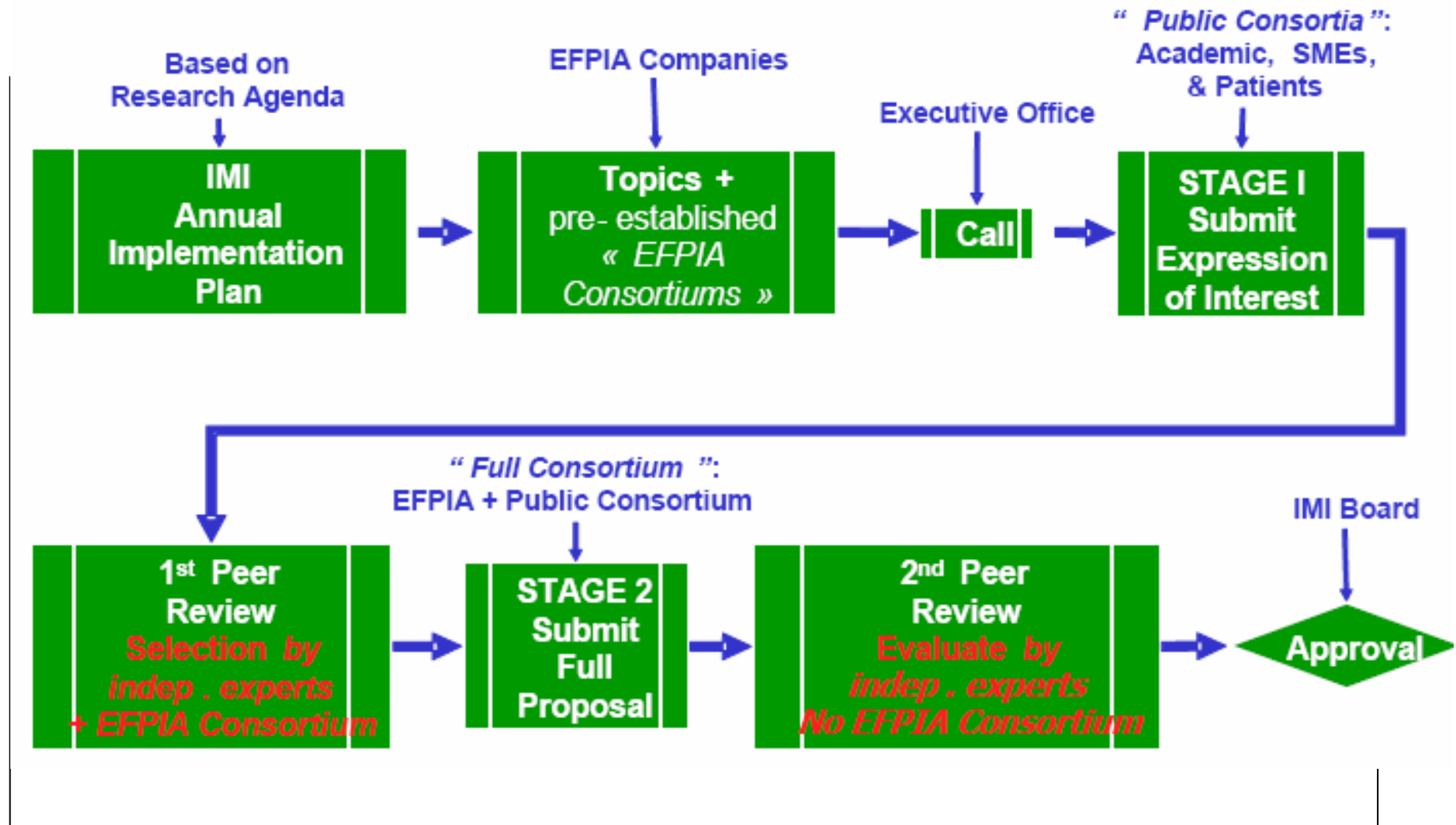


IMI –Call & Evaluation Process

- Call Definition
- Stage 1: Scientific Excellence
- Stage 2: Feasibility & Scientific Excellence
- Contract execution

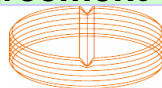
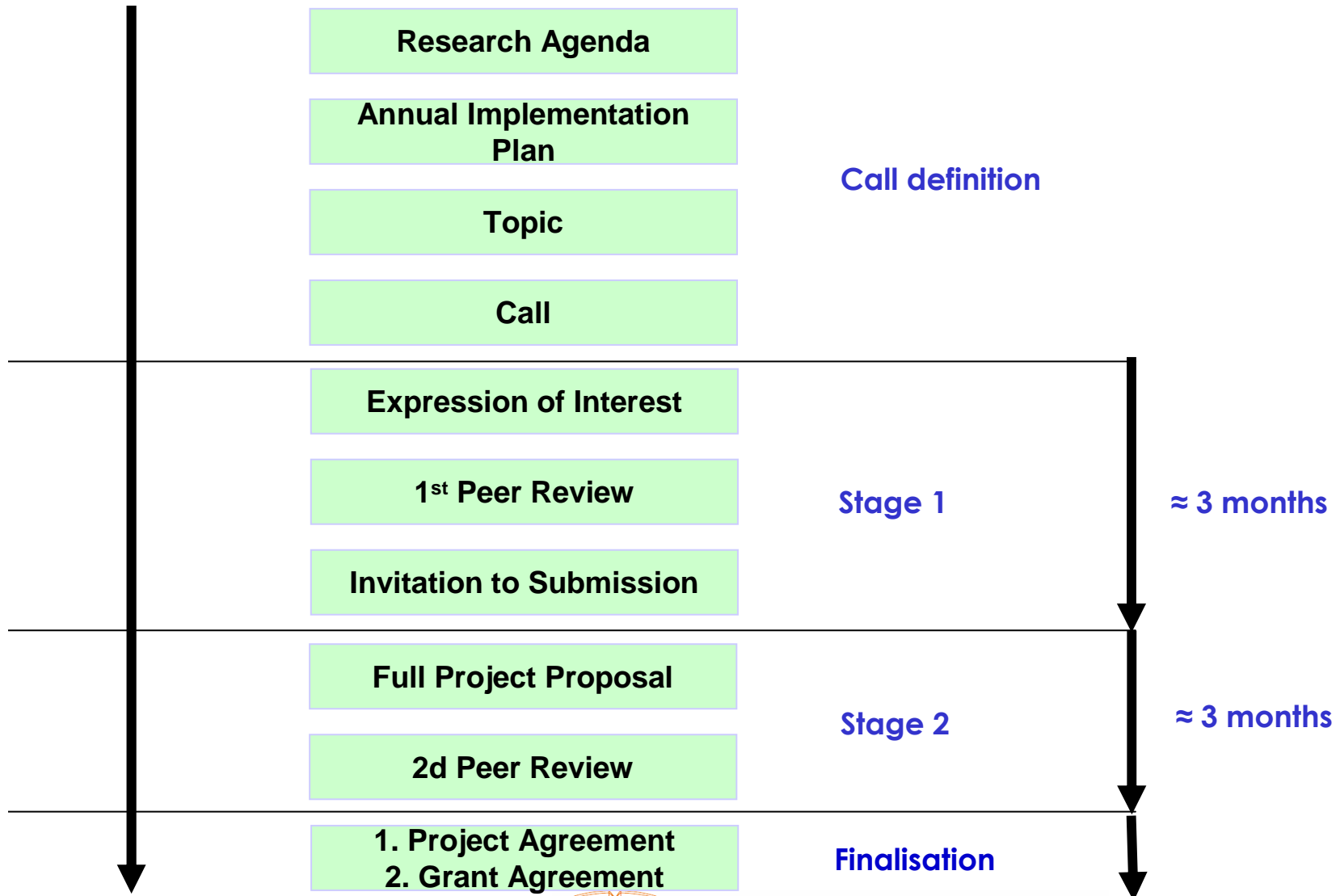


Call & Evaluation Process Overview



dlf1

IMI: Call and Evaluation Process



Diapositiva 25

dlf1

keine änderung des textes

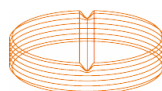
farbliche änderung für eine bessere lesbarkeit
laubeda; 27/09/2007

Call definition

Research Agenda
Annual Implementation Plan
Topic
Call

Description of the Call Topics

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. Indicative duration of the project
7. Indicative total in kind contribution from the EFPIA companies
8. Indicative expectations from the public consortium



dlf2

Stage 1: Scientific excellence. Description of the Expression of Interest

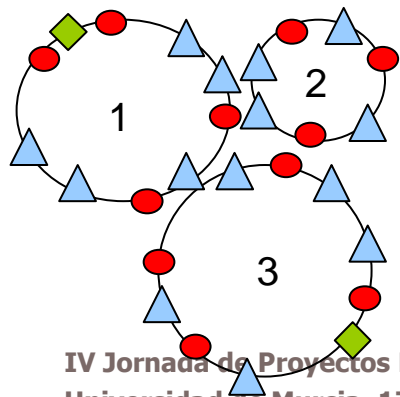
Research Agenda
Annual Implementation Plan
Topic
Call

Stage 1 ≈ 3 months

Expression of Interest
1 st Peer Review
Invitation to Submission

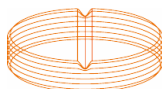
Description of the Expression of Interest

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 Consortium:

i.e. academia, SMEs, regulators, patients organisations, industry (without EFPIA)



Diapositiva 27

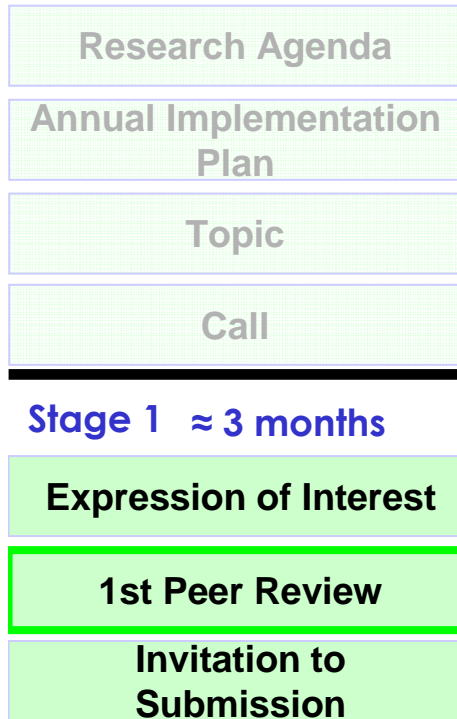
dlf2

keine änderung des textes

farbliche änderung für eine bessere lesbarkeit
laubeda; 27/09/2007

dlf3

Stage 1: *Scientific excellence. 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



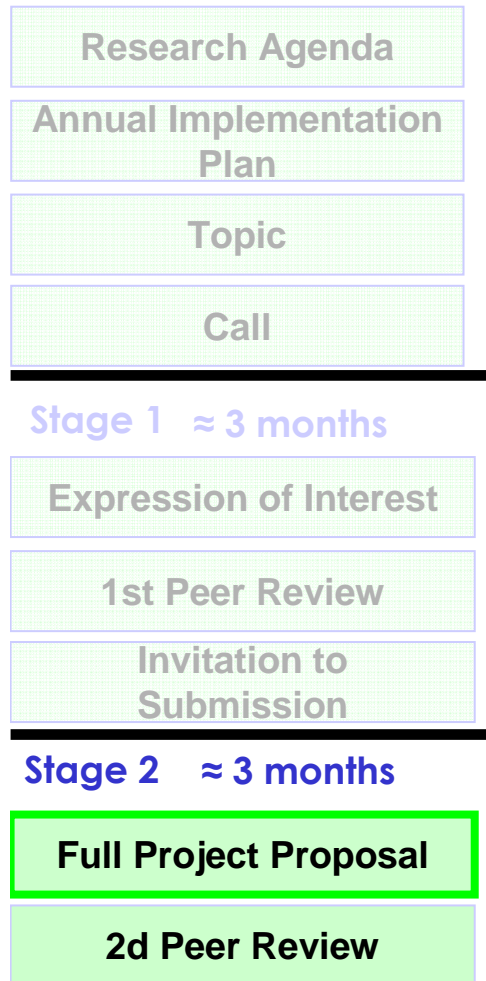
Diapositiva 28

dlf3

keine änderung des textes

farbliche änderung für eine bessere lesbarkeit
laubeda; 27/09/2007

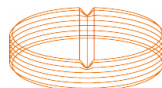
Stage 2: Feasibility and scientific excellence



Description of the Full Project Proposal

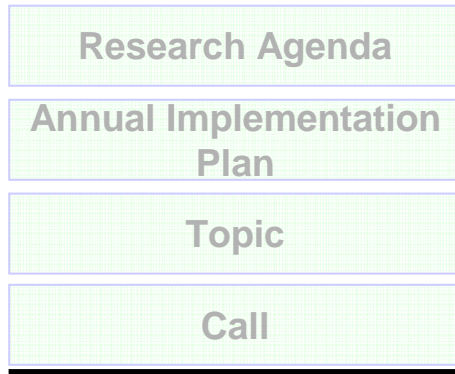
- Written jointly by the EFPIA Consortium and Public Consortium members
- Full description of research activities
 - Who, when, and how much
- Will need a draft Project Agreement before submission
 - IPR sharing agreed between all partners

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



Stage 2: *Feasibility and scientific excellence. Peer Review*

Stage 2



Stage 1 ≈ 3 months



Stage 2 ≈ 3 months



- 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

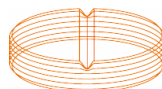
- To evaluate Full Proposals based on science and feasibility

- Composition

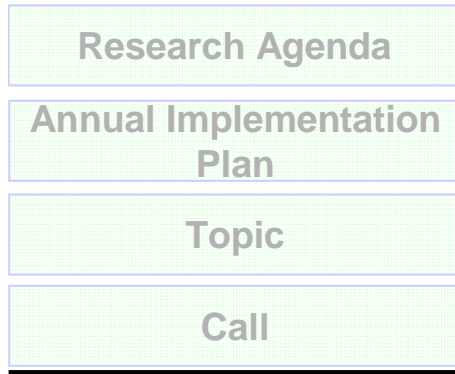
- Members reflecting a balance of public-private research expertise

- Decision Making

- By consensus between all experts



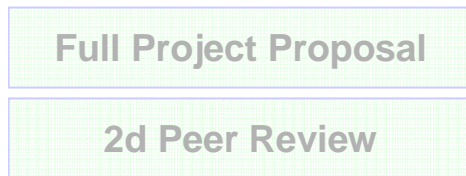
Contract Execution



Stage 1 ≈ 3 months



Stage 2 ≈ 3 months

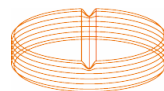


Finalisation

1. Project Agreement
2. Grant Agreement

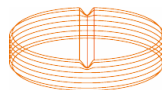
- Project Agreement
- Grant Agreement

- Contract Execution



IMI 1-year Plan

March 2008:	First IMI Board meeting
April 2008:	Publication of first IMI call
July 2008:	Expression of interest deadline
October 2008:	Signature of project & grant agreements
November 2008:	Start of Research Projects
December 2008:	IMI Executive Director on board
January 2009:	Publication of the Second IMI Call





MEDICAMENTOS INNOVADORES
Plataforma Tecnológica Española

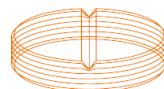


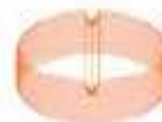
farmaindustria

***Innovative Medicines Initiative* Information Day and National Platforms Meeting Madrid, October 10th, 2007**

Venue: **Fundación Lázaro Galdiano (C/ Serrano 122, Madrid, SPAIN)**

The *Innovative Medicines Initiative* is gaining momentum and it is important to ensure dissemination of its present status and the implementation plans, as well as the coordination with other initiatives at national level. The objectives of the meeting are to share information on IMI implementation; to improve the co-ordination between IMI and IMI national platforms; to identify IMI projects initiated by national platforms; and to improve company co-ordinations (companies involved in national platforms and not in IMI and vice-versa).





MEDICAMENTOS INNOVADORES
Plataforma Tecnológica Española

II Innovative Medicines Initiative Information Day

Madrid, March 11th, 2008

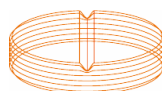
Venue: Aula Pittaluga de la Escuela Nacional de Salud - Instituto de Salud Carlos III
(C/ Sinesio Delgado, 6, Madrid, SPAIN)

11:30 – 13:00 Scientific Priorities 2008: parallel sessions therapeutical areas

<i>Aula Pittaluga</i> <i>Brain Disorders</i>	<i>Salón de Actos</i> <i>Diabetes</i>	<i>Room 1</i> <i>Respiratory Diseases</i>
---	--	--

13:00 – 14:30 Scientific Priorities 2008: parallel sessions horizontal areas

<i>Aula Pittaluga</i> <i>Non-clinical safety and safety biomarkers</i>	<i>Salón de Actos</i> <i>Farmacovigilance</i>	<i>Room 1</i> <i>Education and Training</i>
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The Innovative Medicines Initiative (IMI)



DRAFT

INNOVATIVE MEDICINES INITIATIVE

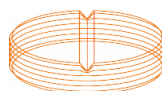
BETTER TOOLS FOR BETTER MEDICINES

Information Day

Charlemagne Building, Brussels

30 April 2008

PROGRAMME



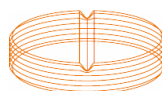
Plataforma Tecnológica Española Medicamentos Innovadores

- **Misión:**

Promover la innovación en el I+D farmacéutico, ayudando a **superar los cuellos de botella** actuales (globales y locales).

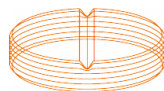
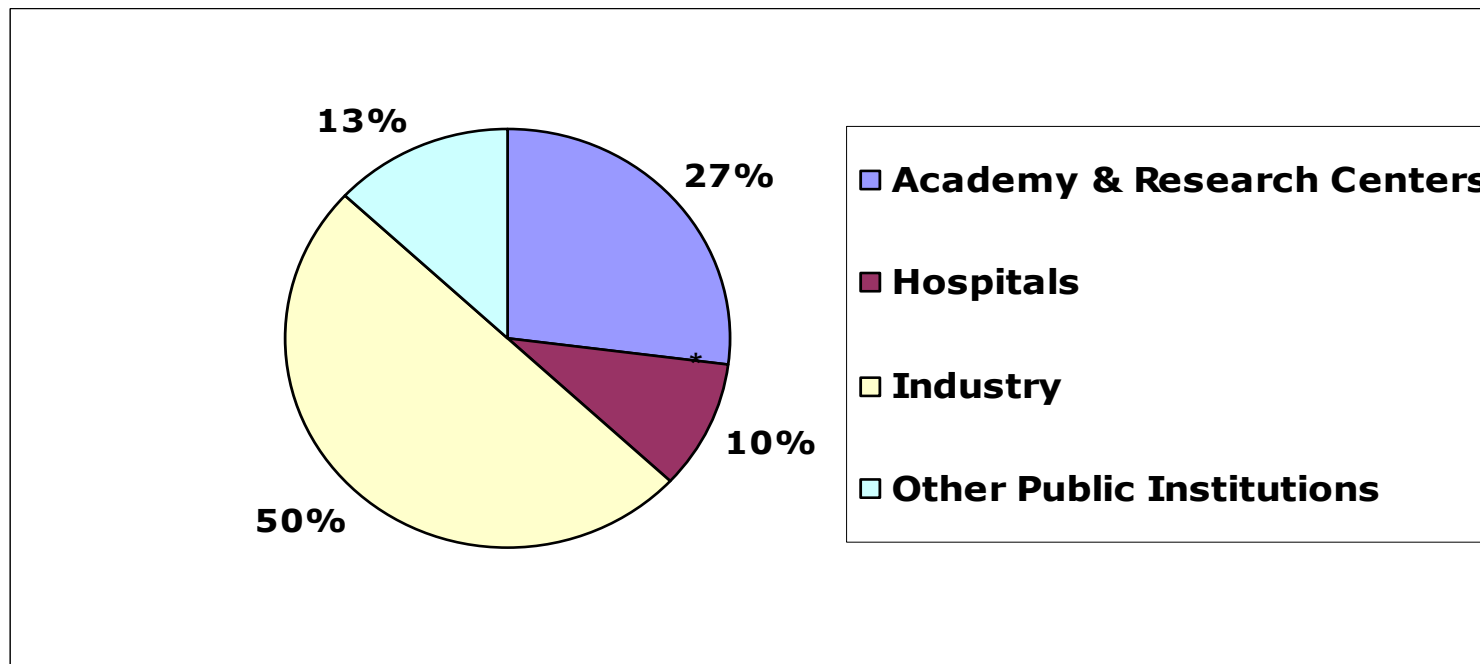
- **Objetivos:**

- Constituir un **foro para todos los actores españoles** interesados en el progreso del I+D farmacéutico.
- Promover la **colaboración** entre dichos actores.
- Facilitar el **diálogo** sobre el tema **con las autoridades españolas y con IMI.**
- Ayudas de los Ministerios de Industria y de Educación y Ciencia.



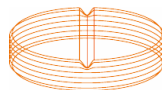
Participantes

+250 personas han participado en actividades, grupos de trabajo y proyectos



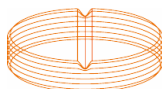
Grupos de trabajo

- Investigación clínica
- Seguridad preclínica
- Gestión del conocimiento
- Educación y formación



Other activities of the Spanish Platform

- **BEST project: Excellence in Clinical Trials**
 - BD Metrics: permanent monitoring (600 trials 30/6/2007). Modules: timing, international benchmarking and performance in patient recruitment.
- **Directory of Phase 1 Clinical Trials Units in Spain**
- **Knowledge Management**
 - *Management and integration of genomic, functional, proteomic and variability (SNPs) information in medicines R&D*, Coordinator: Joaquín Dopazo (C.I.P.F), **March 1st 2007, Valencia**
 - *Molecular perspective in Knowledge Management in medicines R&D*. Coordinator: Ferran Sanz (PRBB), **April 17th 2007, Barcelona**
 - *Management and exploitation of clinical data in medicines R&D*. Coordinator: Fernando Martín (ISCiii), **31 de mayo 2007, Madrid**
 - *Biomedical Informatics in Europe Event*, **June 25-27th 2007, Barcelona**
- **Education and Training**
 - I Workshop Education and Training in medicines R&D (Santiago de Compostela, June 6th 2006)
 - Demand and supply of R&D courses



www.medicamentos-innovadores.org

- **Activities**
- **Monthly Newsletter**
- **Events**
- **Legislation**
- **English version**



The screenshot shows the homepage of the website. At the top, there is a logo for 'MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española' and a language selector for 'español | english'. Below the header, there is a navigation menu with items like 'ORIGEN Y OBJETIVOS', 'INVESTIGACIÓN CLÍNICA', 'GESTIÓN DEL CONOCIMIENTO', 'EDUCACIÓN Y FORMACIÓN', 'EVENTOS', and 'PUBLICACIONES'. A search bar is also present. The main content area features a large image of a hand holding a tray of pills, with a 'Plataforma española' section below it. This section includes a list of stakeholders: 'Industria', 'Reguladores de diversas administraciones públicas', 'Gestores de la sanidad', 'Investigadores básicos y clínicos', 'Sociedades científicas', 'Pacientes y sus asociaciones', and 'Proveedores de bienes y servicios relacionados con la investigación'. There are also news items, such as 'Segunda versión de la Agenda Estratégica de Investigación (SRA) de la Innovative Medicines Initiative (IMI)' and 'Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios'. The footer includes the 'Proyecto BEST' logo.

