

*34° Congresso Nazionale
Società italiana di Farmacologia*

*Scientific activity public funding and global economic
crisis: individual measures and their integration*

Rimini October 14, 2009

Institute of Cell Biology
National Research Council
Italy

Giovina Ruberti
Italian Representative
Innovative Medicines Initiative



Joint Technology Initiatives

Novel long term European public-private partnerships in the field of industrial research

To support trans-national cooperation in key areas where research and technological development can contribute to European competitiveness and quality of life

Building on European Technology Platforms that achieve an ambitious scale and scope and require the mobilisation of high investments and research resources

To be implemented through new legal entities - Joint Undertakings

European Technology Platforms may be proposed to be established as Joint Technology Initiatives via Art. 171 of the EC Treaty

Basis for decision:

- ✓ European added value
- ✓ Inability of existing instruments to achieve its objectives
- ✓ Degree and clarity of definition of objectives to be pursued
- ✓ Strength of financial/resource commitment by industry
- ✓ Contribution to broader policy objectives
- ✓ Scale of the impact on industrial competitiveness and growth

IMI History

2000:
Lisbon strategy

"Make Europe, by 2010, the most competitive and the most dynamic knowledge-based economy in the world"

2004:
ETP

Informal networks led by industry
Strategic research agendas

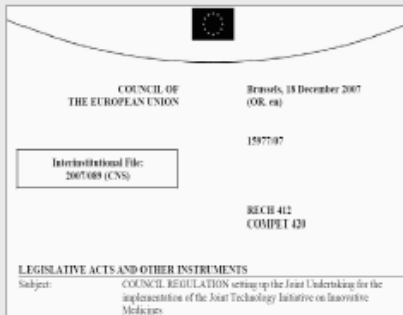
2007-2013:
FP7 JTI

JTI: new instrument of FP7 for integrated projects
Public-Private Partnership as legal entities

2008-2017:
IMI JU

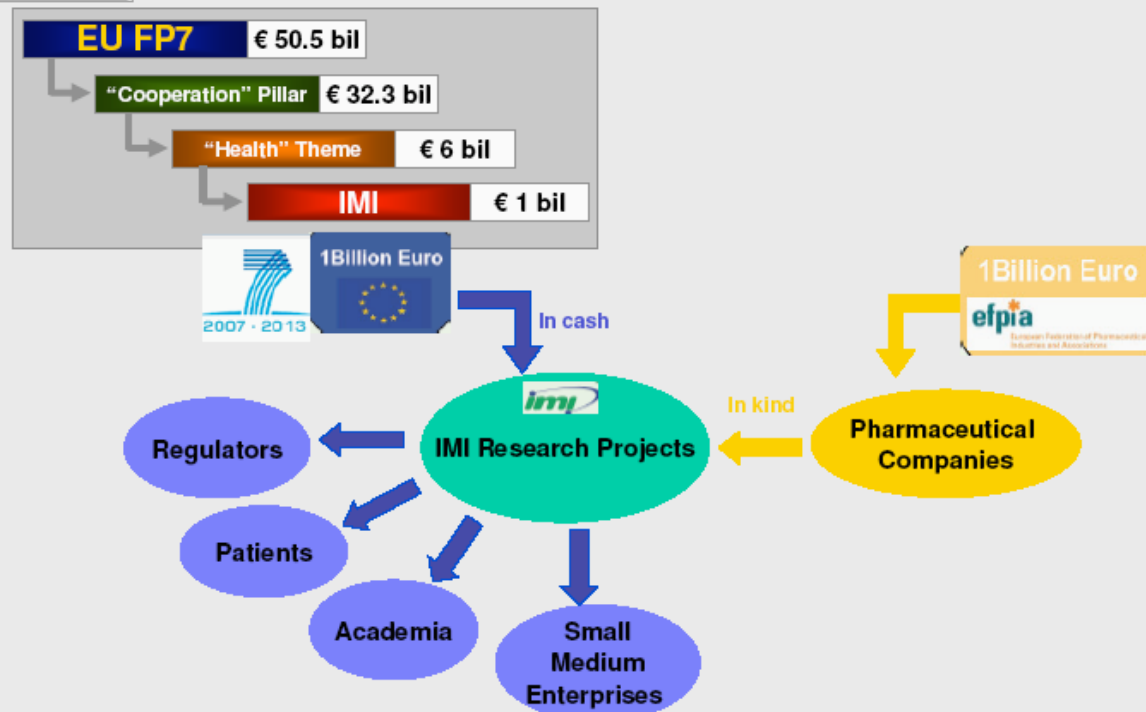
Public-Private Partnership founded by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Commission

Innovative Medicines Initiative: Funding of Research Projects



The objective of the IMI Joint Undertaking should be achieved through support of research activities by pooling resources from the public and private sectors. To this end, the IMI Joint Undertaking should be capable of organising competitive calls for proposals for supporting the research activities. Such research activities should respect fundamental ethical principles applicable in the Seventh Framework Programme.

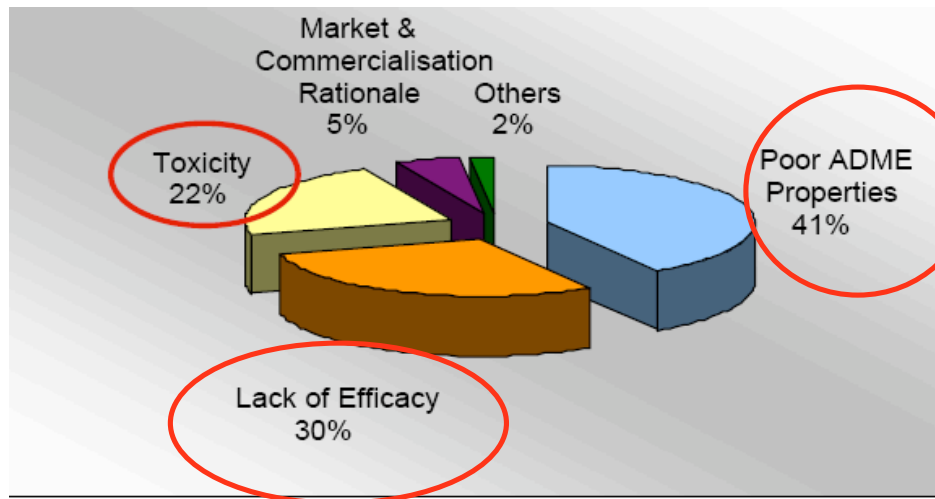
Founding members of the IMI Joint Undertaking should be the Community and EFPIA.



Why IMI?

- The drug development process is very long, complex and costly
- Despite global increases in R&D expenditure over the past ten years, the output of new medicines has not matched this increase
- Europe's R&D investment is furthermore characterised by a much lower investment level than in other regions of the world.

Reasons for Failure in Clinical Development



Sources: Frost & Sullivan, 2007
Rang, H.P. (Ed.): Drug Discovery and Development; Churchill Livingstone, Elsevier, 2006

- Approximately **92%** of compounds fail during clinical development.
- Nearly **22%** of compounds fail due to toxicity related issues.
- Nearly **30%** of compounds fail due to lack of efficacy.
- Nearly **41%** of compounds fail for poor ADME (absorption, distribution, metabolism, excretion)
- Increased need to identify more effective innovative medicines with fewer side-effect at early stages of drug development to reduce development cost.

IMI: AIM, GOAL and BENEFIT

Aim

Removing major bottlenecks in drug development, where research is the key.

Long term goal

Re-invigorate the European bio-pharmaceutical sector and foster Europe as the most attractive place for pharmaceutical R&D; thereby, long term, enhancing access to innovative medicines.

Benefit for patients, scientists and European citizens

IMI Specific AIMS

- Support pre-competitive pharmaceutical research to accelerate the development of safer and more effective medicines for patients.
- Foster collaboration between all stakeholders, e.g. industry, public authorities (including regulators), Patient organisations, academia, SMEs and clinical centres.
- No new medicines will be developed. Focus on delivery of new approaches, methods and technologies, improve knowledge management of research results & data, support training of professionals

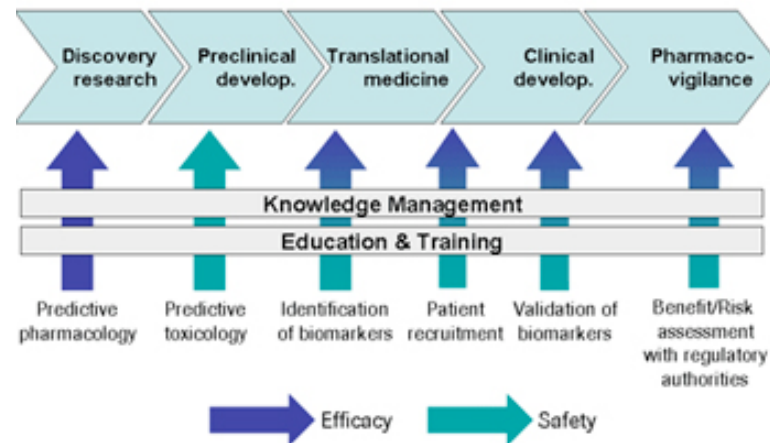
Innovative Medicines Initiative Strategic Research Agenda

A vision document, produced by EFPIA, identified the key research bottlenecks that hamper the drug development process:

Difficulty in predicting safety
Difficulty in predicting efficacy
Poor knowledge management
Gaps in education & training

Based upon these 4 pillars, a Strategic Research Agenda was developed under the lead of industry, involving all Stakeholder groups, i.e. academia, represented by universities and other public research institutions; biopharmaceutical companies and SMEs; healthcare providers and clinical centres; regulators and patients 'organisations.'

The pillars of the Strategic Research Agenda in the drug development



Disease areas:

cancer, brain disorders, inflammatory, metabolic, infectious/anti-bacterial

Initiatives in pre-competitive pharmaceutical research outside Europe

✓ Importantly, the need to collaborate to address the bottlenecks in the biomedical R&D process has been recognized globally and important initiatives in pre-competitive pharmaceutical research are under development outside Europe in the US and Asia;

✓ The U.S. Food and Drug Administration launched the Critical Path Initiative in March 2004 with an important report entitled: *Innovation or Stagnation? Challenge and Opportunity on the Critical Path to New Medical Products (1)*. This document diagnosed with concern the scientific reasons for the recent decrease in the number of innovative medical products submitted for approval "...the applied sciences needed for medical product development have not kept pace with the tremendous advances in the basic sciences. The new science is not being used to guide the technology development process in the same way that it accelerating the technology discovery processNot enough applied scientific work has been done to create new tools to get fundamentally better answers about how the safety and effectiveness of new products can be demonstrated, in faster time frames, with more certainty, and a lower cost. In many cases, developers have no choice but to use the tools and concepts of the last century to assess this century's candidates ...The report was intended to highlight the need for targeted collaborative efforts to modernise the tools, techniques and methods used to evaluate the safety and efficacy of drug products (2).

1. FDA (2004) *Innovation Stagnation - Challenge and Opportunity on the Critical Path to New Medical Products*.

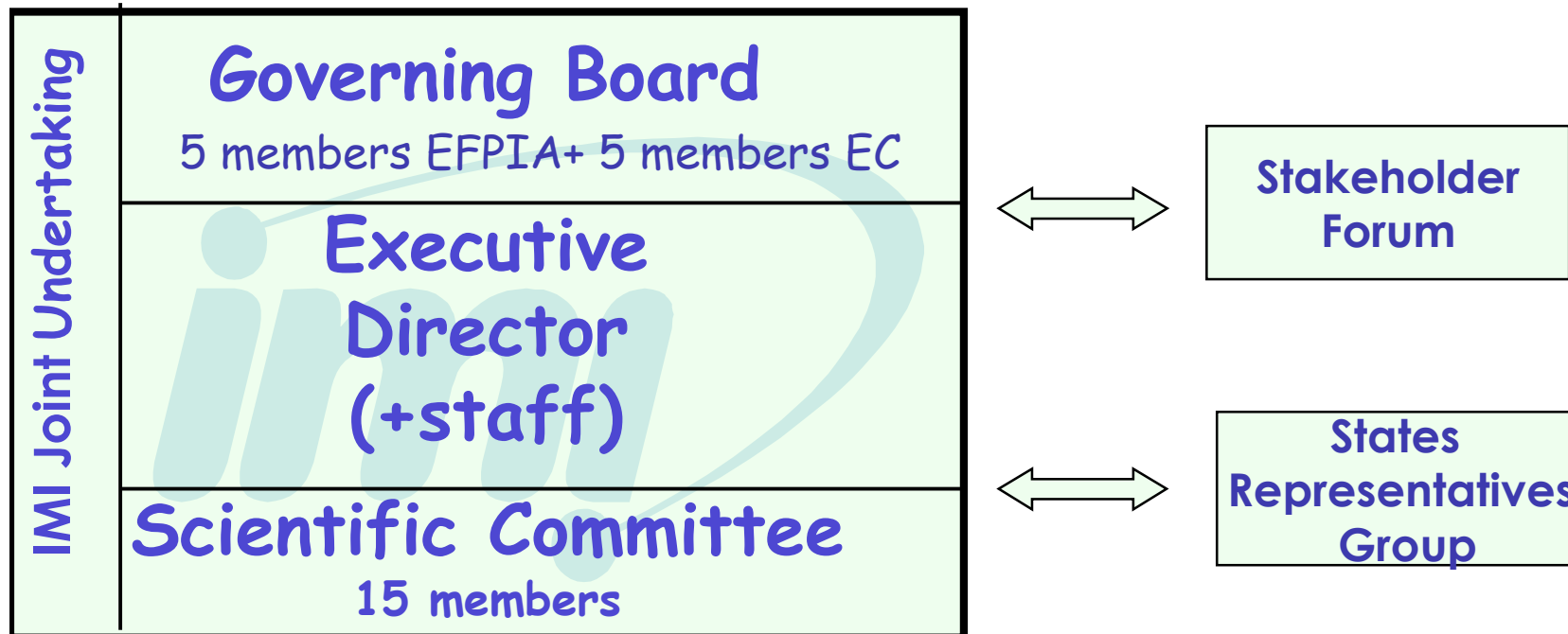
2. FDA (2006). *Critical Path Opportunities List*

Critical Path Opportunities List

In March 2006, the FDA published "Critical Path Opportunities Report and List". The document presented 76 specific opportunities that if undertaken, would help modernize the Critical Path sciences. The opportunities were identified through extensive outreach with patient groups, the pharmaceutical industry, academia, other financial agencies and other health related organizations. Currently, more than 40 Critical Path collaborations and research activities are underway with FDA participation. The activities linked to one of the 76 specific scientific opportunities or one of the priority topics are described in the FDA website (<http://www.fda.gov/default.htm>). The priority topics - consistent with the Four Pillars of the IMI SRA - include the following:

- ✓ Better Evaluation Tools - Developing New Biomarkers and Disease Models to improve Clinical Trials and Medical Therapy;
- ✓ Streamlining Clinical Trials - Creating Innovative and Efficient Clinical Trials and Improved Clinical Endpoints;
- ✓ Harnessing Bioinformatics - Data Pooling and Simulation Models;
- ✓ Moving Manufacturing into the 21st Century;
- ✓ Developing Products to Address Urgent Public Health Needs Specific At-Risk Populations

IMI Management





At its meeting of 10 June 2009 the IMI-JU Board took the decision to appoint Professor Michel Goldman as Executive Director of the IMI JU.

Michel Goldman is Professor of immunology at the Faculty of Medicine of the Université Libre de Bruxelles (ULB) in Belgium.

His achievements in the fields of immune-mediated disorders and immune-based biotherapies resulted in more than 380 articles in peer-reviewed journals.

Since 2007, Michel Goldman serves the European Research Council as member of the Advisory panel on Immunology and Infectious Diseases.

In 2004 he started up the Institute for Medical Immunology (Charleroi, Belgium) as the first public-private partnership in the biomedical sector in the Walloon Region.

In 2006, he was appointed as vice-president of the BioWin Health Cluster created to foster networks between industries and academic institutions in Wallonia. Having a strong interest for academia-industry collaborations, he was appointed to coordinate two large research projects supported by the EU Framework Programme on immuno-toxicology and organ transplantation.

Governing Board:

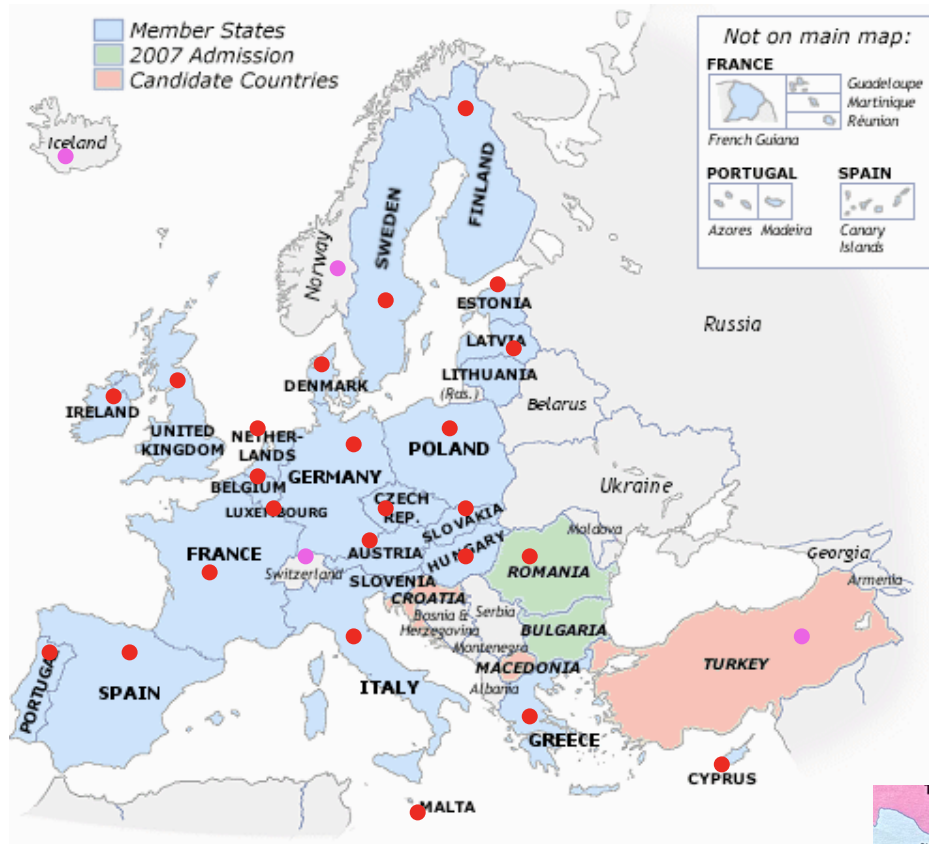
- Brian Ager, Director General - EFPIA,
- Franco Biscontin, Director - Resources, DG RTD,
- Andreas Busch, Executive Vice President - Head of Global Drug Discovery - BAYER Health-Care,
- Ruxandra Draghia-Akli, Director - Health, DG RTD - EC,
- Jackie Hunter, Senior V-P & Head, Neurology Centre of Excellence for Drug Discovery - GSK,
- Carlo Incerti, Head of R&D Europe - GENZYME,
- Jonathan Knowles, Head of Group Research - ROCHE,
- Georgette Lalis, Director - Consumer Goods, DG ENTR,
- Andrzej Jan Rys, Director - Public Health and Risk assessment, DG SANCO,
- Zoran Stančić, Deputy Director-General - Scientific advances, DG RTD.

IMI-JU Scientific Committee (15 members) Constitution 9 december 2008

Christian NOE, chair and Daan CROMMELIN, vice-chair; 8LS, 3Ph, 2SME, 1R, 1P

AVENDANO Cristina - R
BAKER Mary Geraldine - P
BELL John - LS
CROMMELIN Daan - LS
DULAK Josef - LS
GAVIRAGHI Giovanni - Ph
GEISSLINGER Gerd - LS
HØJGAARD Liselotte - LS
JONES Trevor - Ph
MAGGI Adriana - SME
NOE Christian - LS
SANZ Ferran - LS
SOKOLOFF Pierre - LS
VAS Adam - Ph
XENARIOS Ioannis - SME

IMI States Representatives Group:
Constitution IMI SRG 26 June 2008



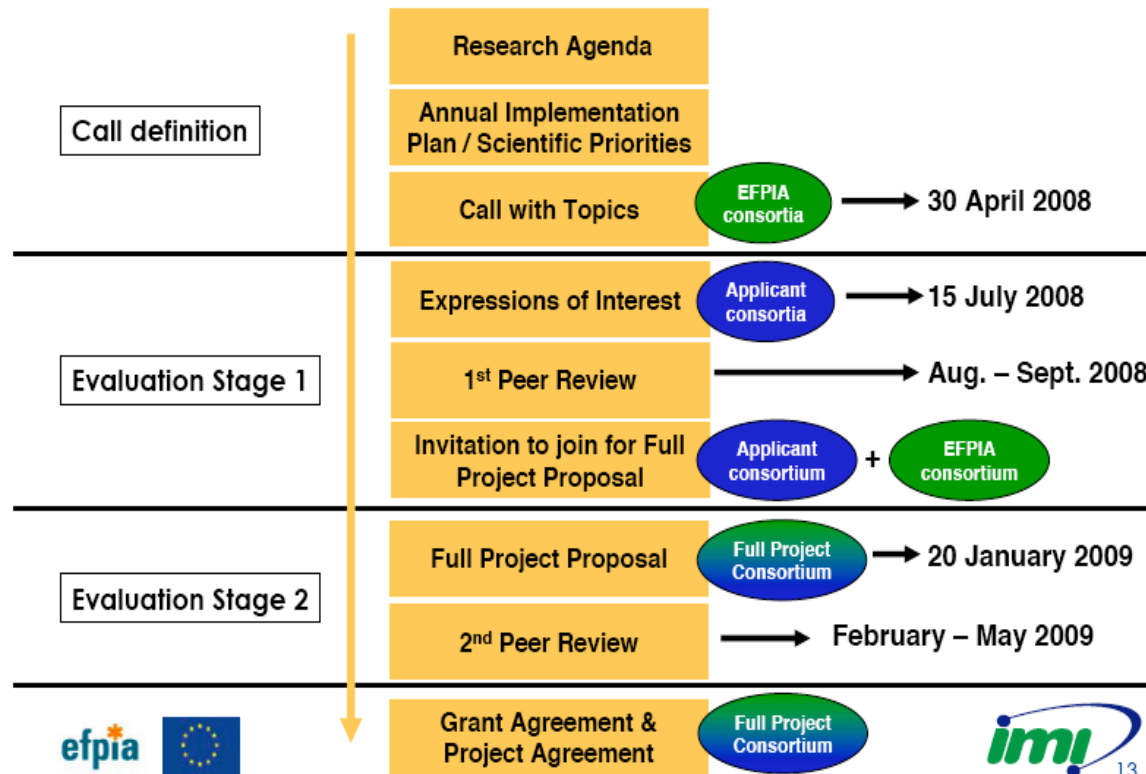
IMI STATES (29)
EU Members 24
EU Candidates/Associated 5

CHAIR:
Stavros Malas (Cyprus)

VICE -CHAIR
Kathleen D'Hondt (Belgium)

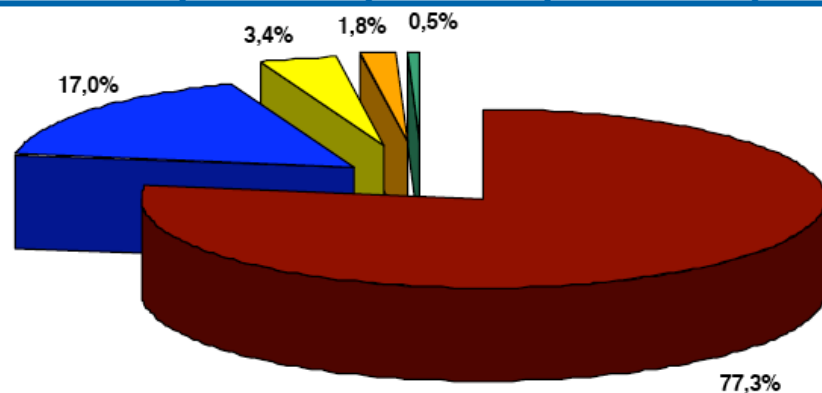


IMI JU Call process 2008



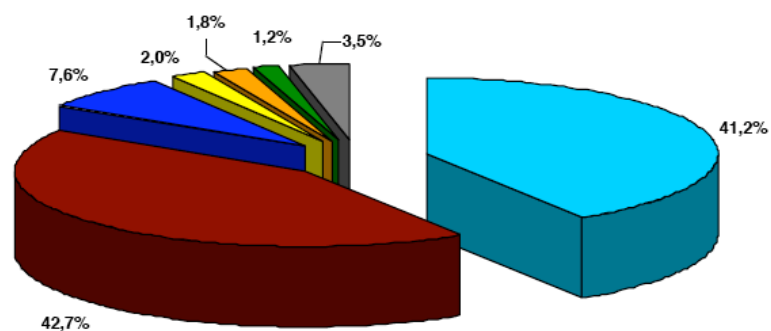
Eol: Typology of applicants

	Academia	SMEs	Patient Org.	Agencies / Regulatory	Industry / Associations	Total
Applicants	1.000	220	44	23	7	1.294
%	77.3%	17%	3.4%	1.8%	0.5%	100%



FPP: Typology of applicants

	EFPIA	Non EFPIA						
		Academia	SMEs	Patient Org.	Agencies / Regulatory	Ind./ Assoc.	Non specified	
Applicants	202	209	37	10	9	6	17	490
Total	202	288						
%	41.2%	42.7%	7.6%	2%	1.8%	1.2%	3.5%	100%



Brussels, 18 May 2009

"Innovative Medicines Initiative" (IMI): €246 million to support public-private research cooperation for a fast development of better medicines.

Today, 15 new research projects aimed at bringing innovative medicines more quickly to the market have been selected to receive €246 million from the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The projects will foster understanding of health issues such as diabetes, pain, severe asthma and psychiatric disorders while increasing drug safety. They will also help improve the training of researchers and clinicians involved in medicines development.

The Commission's contribution of €110 million is backed up with €136 million provided in-kind from the pharmaceutical industry. The successful projects will now enter into the final negotiation phase.

First IMI Call 2008: Italian participation

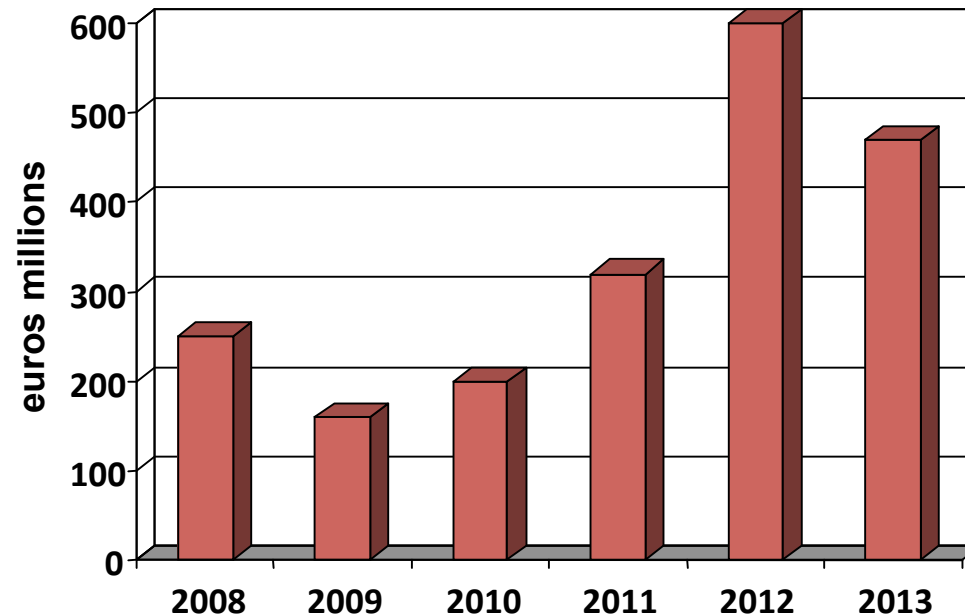
-EoIs: almost 150 Italian organizations (Academia, SME, patient organizations and agency/regulatory), first UK, second DE, third IT;

-Second stage, full project proposals: participation (6.6%), requested IMI JU contribution 4.7% - (UK 21.2%, FR15.2%, DE 12.8%);

-Italy is partner in 7 approved full projects

IMI Budget

Total Annual
Budget
EC + EFPIA



Funding is limited to € 160 millions in 2009

The 2nd IMI Call 2009 is foreseen to be launched on October 30th, the deadline for the EoIs is expected to be in January 2009.

Efficacy Pillar

Oncology

- ✓ New tools for target validation to improve drug efficacy.
- ✓ Molecular biomarkers - accelerating cancer therapy development
- ✓ Imaging biomarkers for anticancer drug development

Inflammation and Infection

- ✓ Infectious diseases: Identification and development of rapid point of care microbiologic diagnostic tests to facilitate clinical practice and conduct of clinical trials.
- ✓ Inflammation - Understanding aberrant adaptive immunity mechanisms in human chronic immune-mediated diseases: rheumatoid arthritis, systemic lupus erythematosus & inflammatory bowel disease.
- ✓ Inflammation - Translational research in rheumatoid arthritis (RA) and RA like diseases: bridging between animal models and humans.

The 2nd IMI Call 2009 is foreseen to be launched on October 30th, the deadline for the EoIs is expected to be in January 2009.

Knowledge management Pillar

- ✓ Drug/Disease Modelling: Library & Framework (DDMLF).
- ✓ Open Pharmacological Space (OPS).
- ✓ Using Electronic Health Records (EHR) to support and enhance medical research.

IMI Partnering Platform supported by the German
Federal Ministry of Education and Research

<http://www.imi-partnering.eu/>

Further Information:

http://imi.europa.eu/index_en.html

gruberti@ibc.cnr.it