Innovative Medicines Initiative

Collaborazioni pubblico-private nella ricerca biomedica: L'esperienza europea sui farmaci innovativi (IMI-JU)

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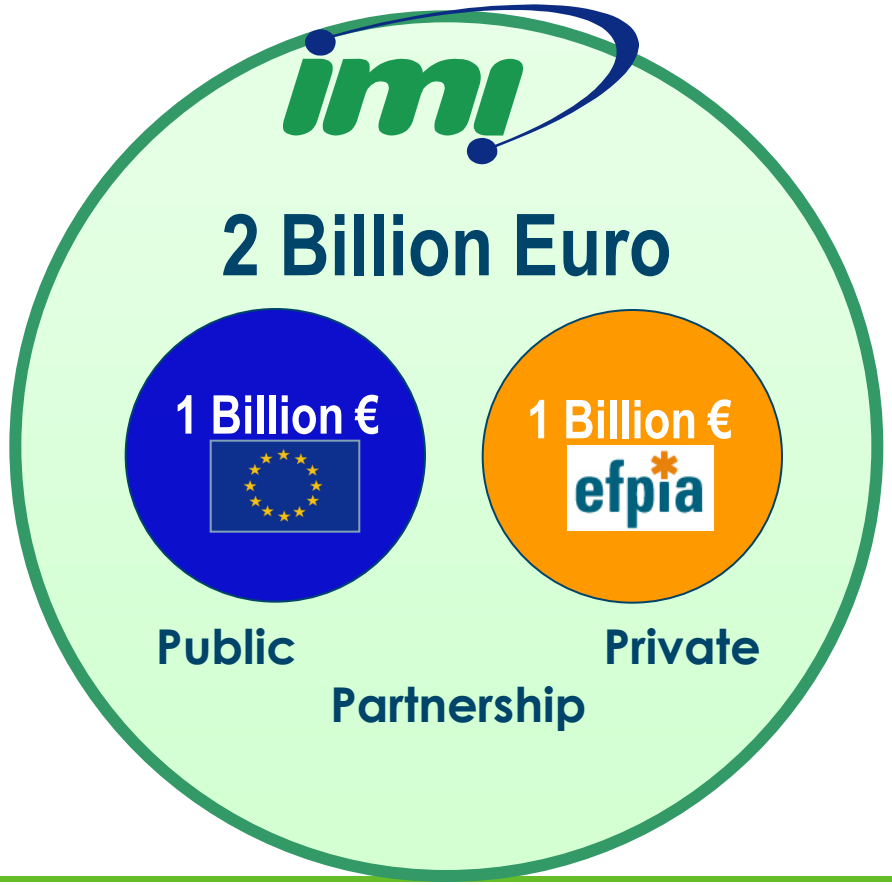
Delegato MIUR IMI

Ricerca, Innovazione e Competitività
Camera dei Deputati, Palazzo Marini 3 dicembre, 2012

Core objectives defined in 2007

- To overcome research bottlenecks in drug development through collaborative approaches
- To increase investments in the biopharmaceutical sector and provide socio-economic benefits across Europe
- To contribute to the health of European citizens

Innovative Medicines Initiative: Joining Forces in the Healthcare Sector IMI the Largest PPP in Life Sciences R&D



efpia

EFPIA Member Companies

Participating companies:

Almirall
Bristol-Myers Squibb
Together we can prevail.
Johnson & Johnson
NOVARTIS
sanofi aventis
L'essentiel c'est la santé.
AMGEN
Chiesi
Lilly
novo nordisk
SERVIER
AstraZeneca
A lot to discover
ESTEVE
Lundbeck
ORION
sigma-tau
Bayer
genzyme
MERCK SERONO
Pfizer
Boehringer Ingelheim
gsk
GlaxoSmithKline
MERCK SHARP & DOHME
Roche
ucb

efpia

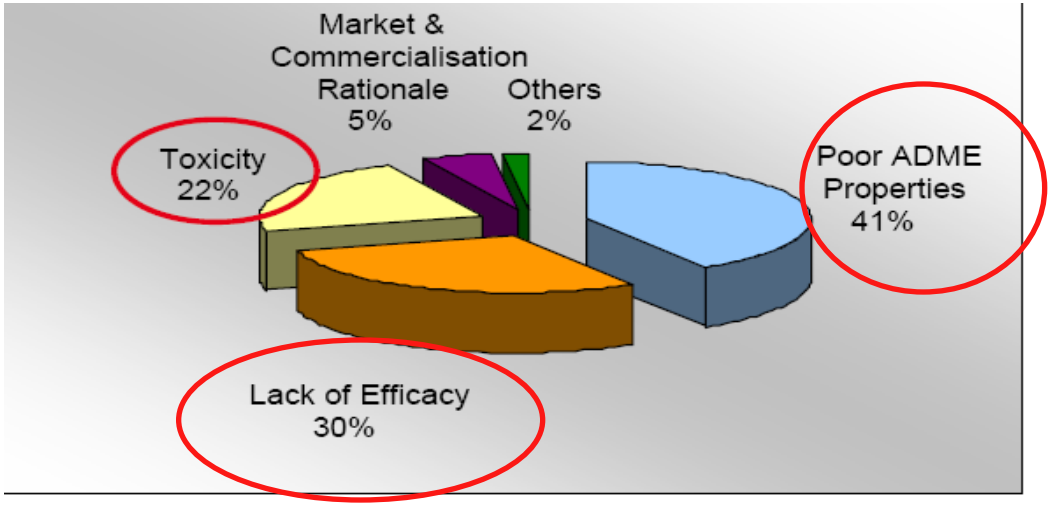
Key Concepts

- "Non-competitive" collaborative research for EFPIA companies
- Competitive calls to select partners of EFPIA companies (IMI beneficiaries)
- Open collaboration in public-private consortia (data sharing, wide dissemination of results)

WHY IMI?

- The drug development process is very long, complex and costly;
- Only one drug candidate in 10.000 will reach the market/patients;
- It takes up to 10 -13 years to develop a drug and bring it to the market;
- It requires an investment of up to € 800 million;
- 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.

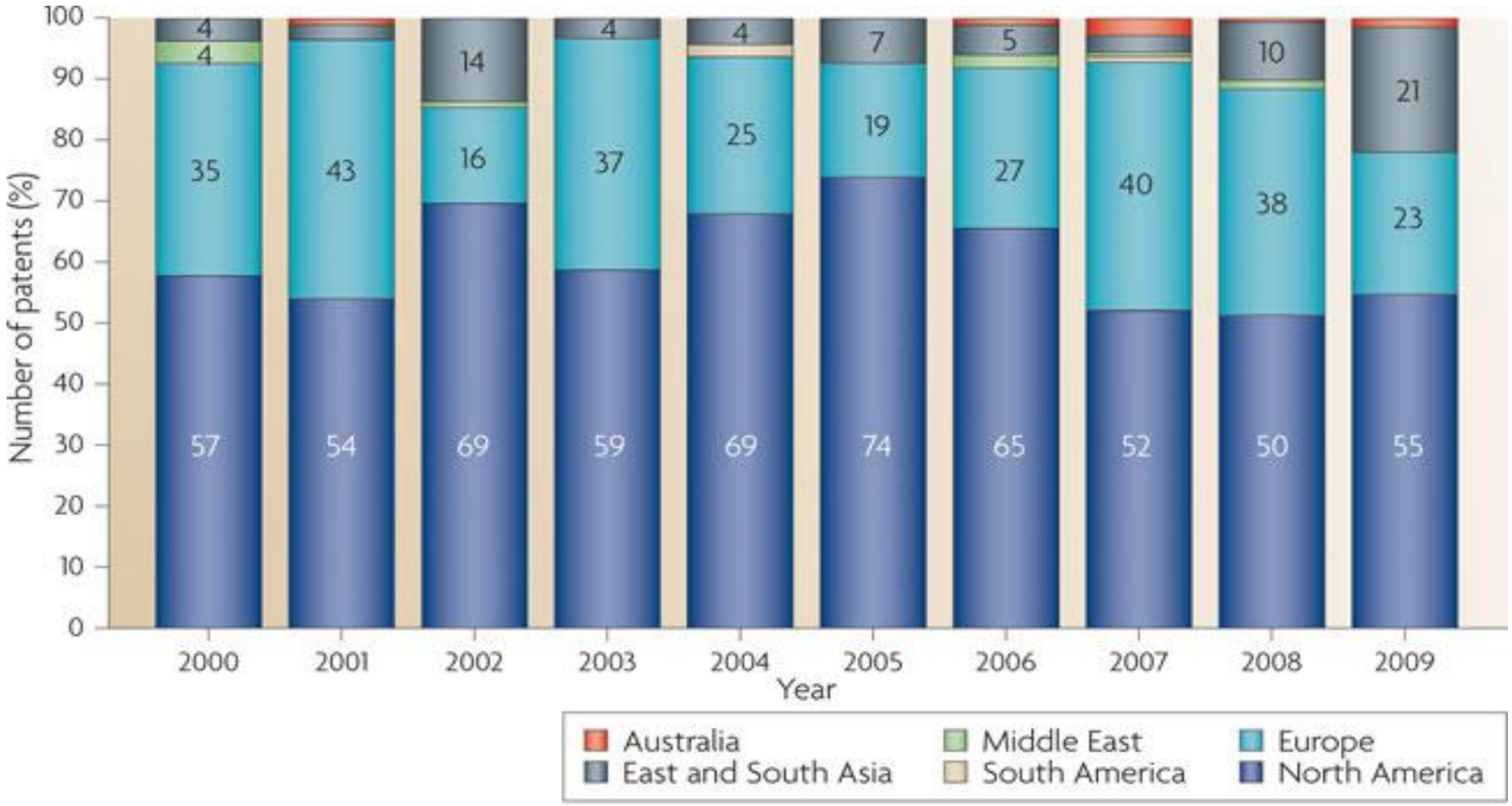
Reasons for Failure in Clinical Development



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 (absorbtion, 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.

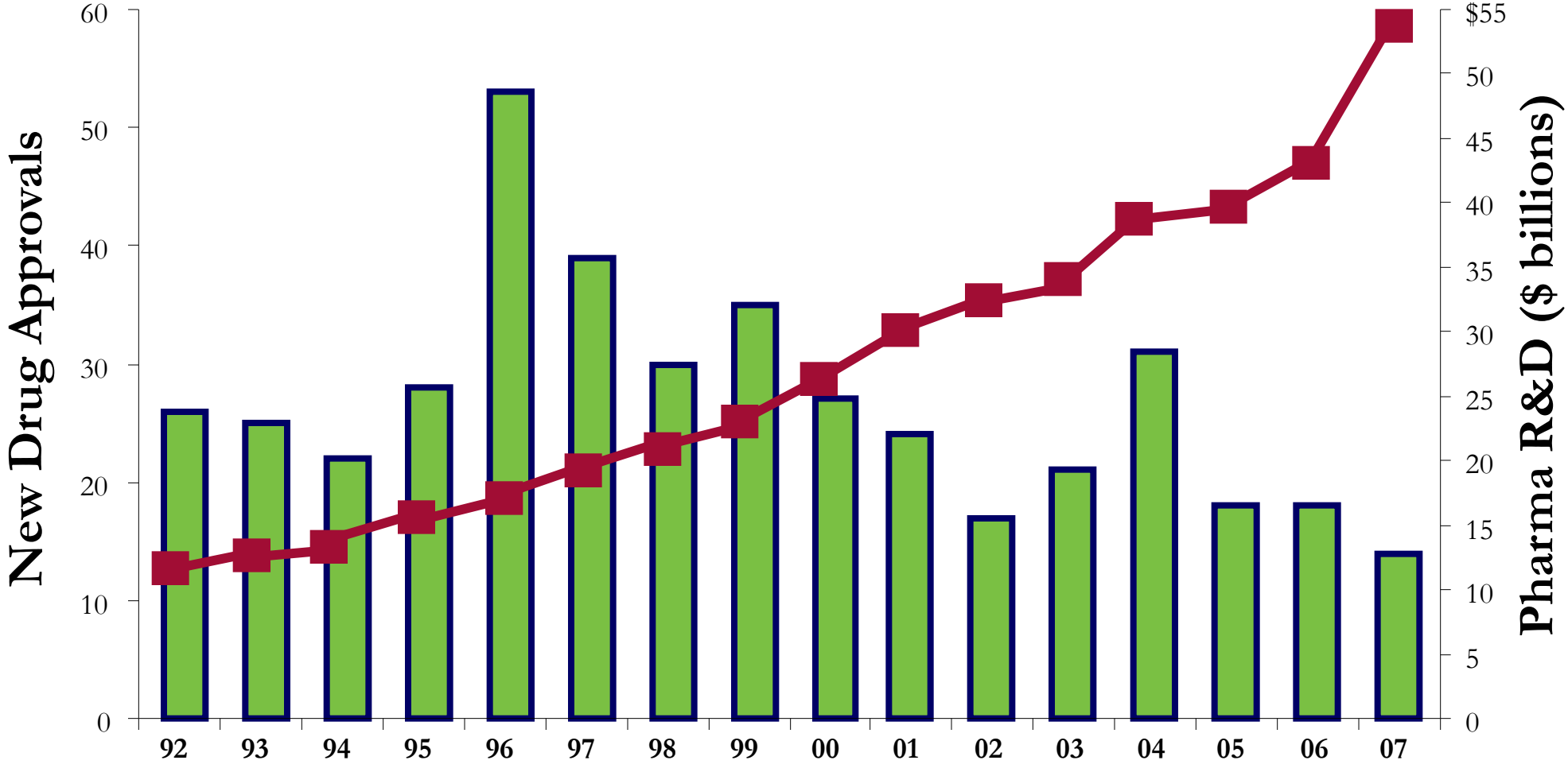
Origin of Patents in the Pharma Sector



Yali Friedman

Nature Reviews Drug Discovery **9**, 835-836 (November 2010)

The Productivity Gap in Pharma R&D



Source: Burrill & Company; US Food and Drug Administration.

The Four Pillars of the Innovative Medicines Initiative

The Research Priorities in the revised IMI Scientific Research Agenda

New Research Priorities

Established Research Priorities

System approaches in drug research

API Technology Drug Compound development

iPS for toxicity and drug development screening

Rare Diseases and Stratified Therapies

Beyond HTS - pharmacological interactions at the molecular level

Pharmacogenetics and Taxonomy of Human Diseases

Safety

Biomarkers and biobanks

Coping with Regulatory and Legal Hurdles

Knowledge Management

Science Communication

Infectious and immunological diseases

Cancer

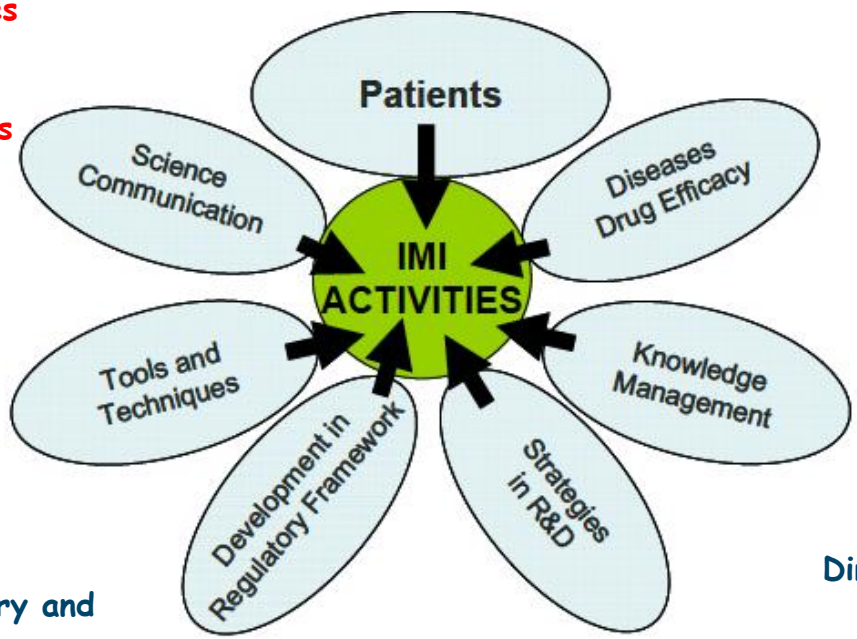
Neuro-psychiatric Dirsorder/Brain diseases

Metabolic/Cardiovascular diseases

Training and Education

Integration imaging into drug research

Advanced formulations

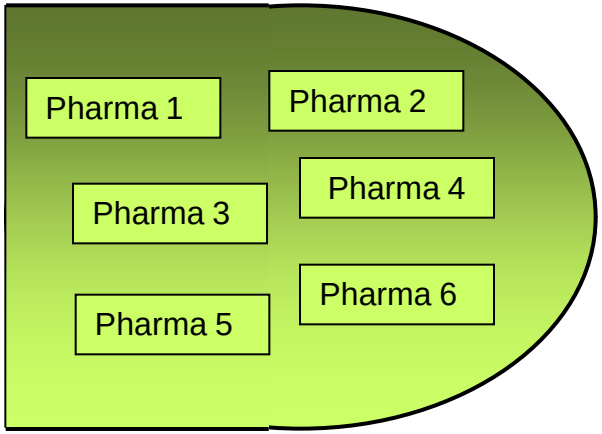


IMI Areas of Research Interest

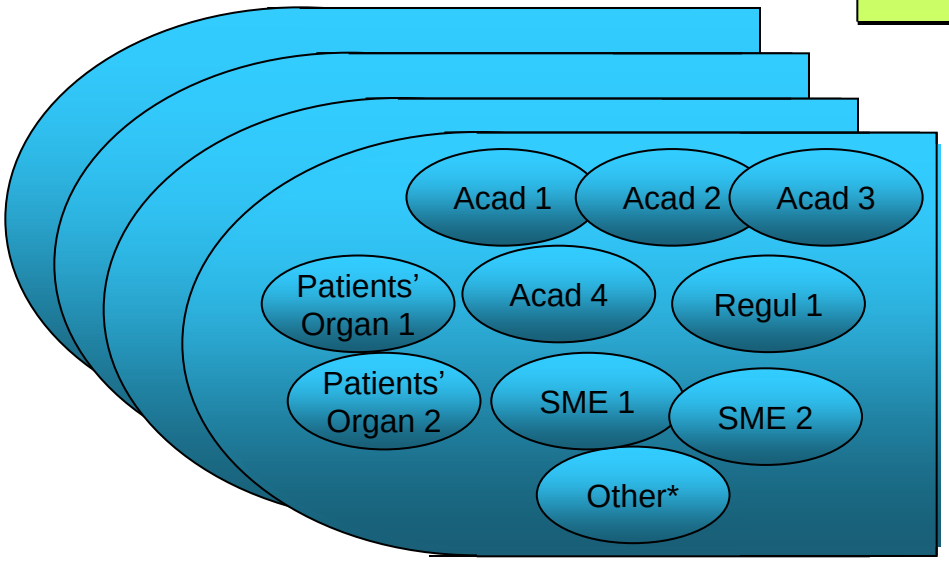
Key Bottlenecks in Pharma R&D

- Disease heterogeneity
- Lack of predictive biomarkers for drug efficacy/ safety
- Insufficient pharmacovigilance tools
- Unadapted clinical designs
- Lack of incentive for industry

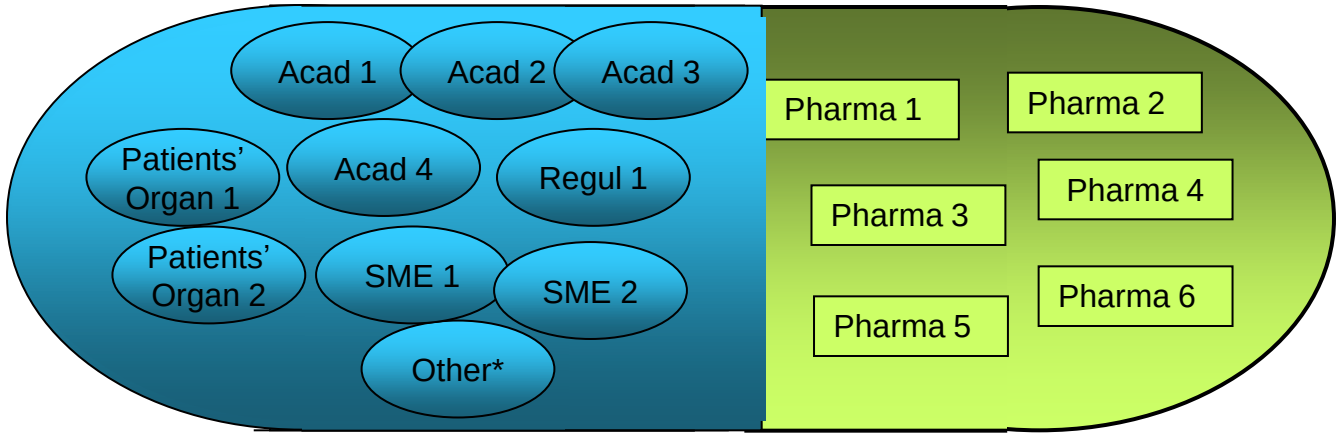
Building a IMI Consortium



Step 1:
A set of EFPIA companies define a topic on which they commit to collaborate



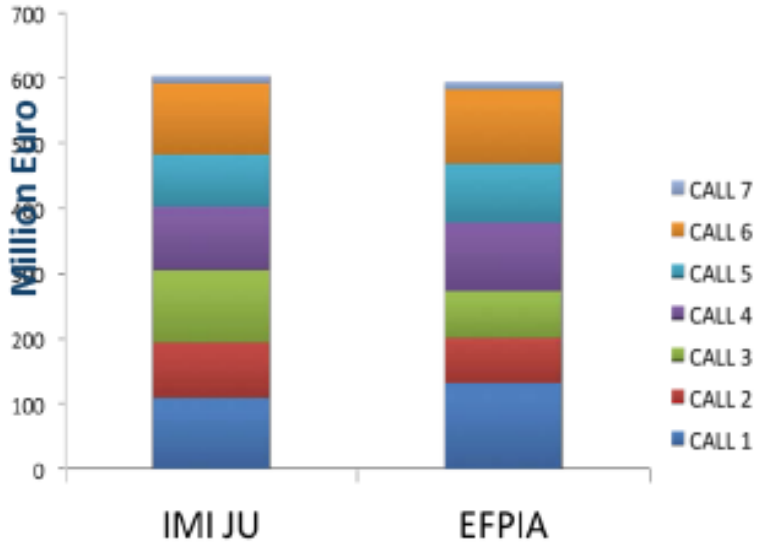
Step 2:
Consortia eligible for EU funding compete through expressions of interest which are ranked by independent experts



Step 3:
The top-ranked EU-fundable consortium join the EFPIA companies to form the final consortium which develops the full proposal, subject to peer-review before final approval

Implementing IMI

- 7 calls so far
- First projects run for ~3 years but generate already exciting results, way beyond state of the art

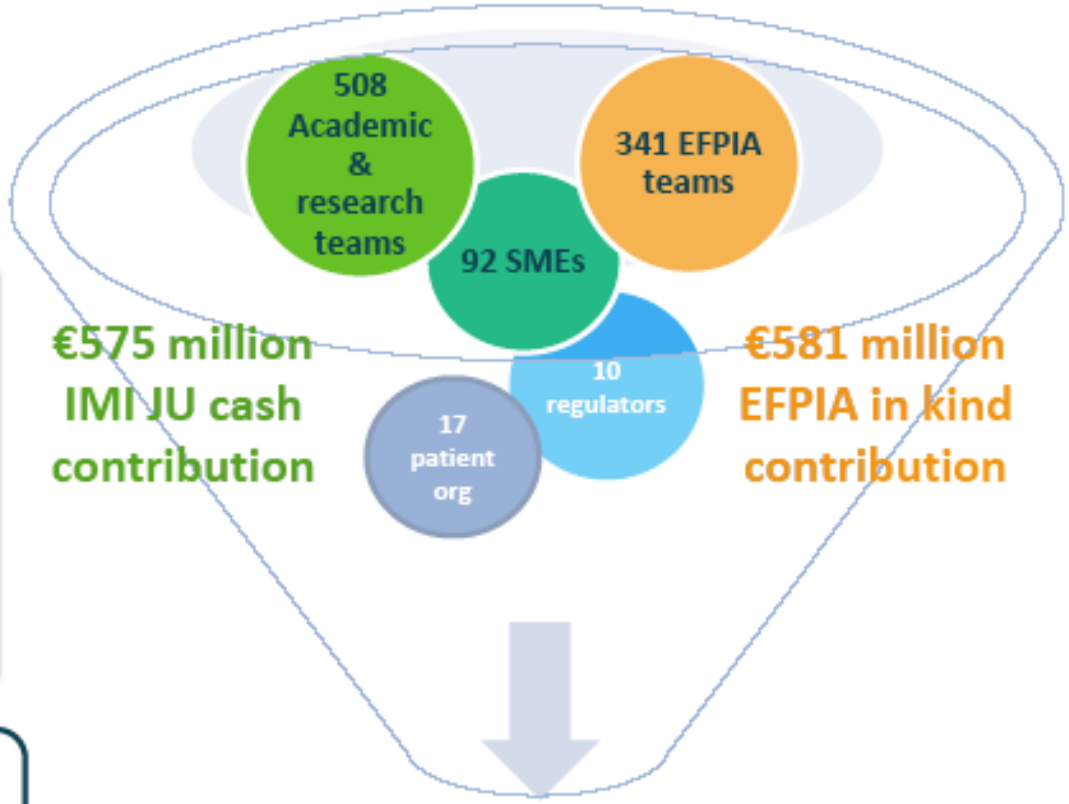


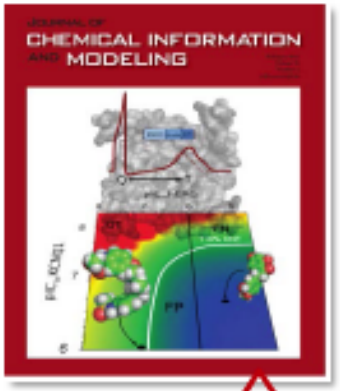
- 8th call to be launched shortly, will bring contributions from IMI Joint Undertaking and EFPIA to ~€750 million each

Research and Innovation

37 ongoing projects - key figures

EU-AIMS contribution to autism





eTOX contribution to cardiotoxicity

ABIRISK — Anti-Biopharmaceutical Immunization: prediction and analysis of clinical relevance to minimize the RISK

37 Partners:
- Istituto Giannina Gaslini –GE
- Uni Firenze

19 Partners:
- Novartis Vaccines and Diagnostics Siena
- Uni Siena

Be the Cure FOR RHEUMATOID ARTHRITIS

33 partners from 15 Countries
- Fondazione Humanitas per la Ricerca, Università degli Studi di Milano, FHR

Drug Disease Model Resources
ddmore
Home

25 Partners:
- CNR e Uni Pisa
- Uni Pavia

DIRECT
DIABETES RESEARCH ON PATIENT STRATIFICATION

25 Partners:
- CNR-ISIB Padova

PharmaCog
Advancing science and treatment of Alzheimer's Disease

30 Partners:
- Uni Verona
- Ordine Ospedaliero San Giovanni di Dio – Fatebenefratelli, Milano
- Uni Foggia
- Istituto di Ricerche Farmacologiche Mario Negri, Milano

SUMMIT

26 Partners:
- Istituto di Ricerche Farmacologiche Mario Negri, Milano
- Uni Pavia
- Uni Padova
- Uni Firenze
- Uni Pisa
- Uni Cattolica Sacro Cuore, Milano
- Chiesi Farmaceutici Spa, Parma in kind

efpia

EU-AIMS
Autism Research in Europe

25 partners:
- **Uni Campus Bio Medico di Roma**

Eu2P
EUROPEAN PROGRAMME IN
PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

24 partners:
- **Uni Verona**

imidia
European combined excellence in diabetes research

21 partners:
- **Uni Pisa**

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

51 Partners
- **Uni Cattolica Sacro Cuore, Milano**

U-BIOPRED

39 Partners:
- **Uni Catania**
- **Uni Roma Tor Vergata**
- **Uni Cattolica del Sacro Cuore di Milano**
- **Lega Italiana Anti Fumo – Onlus Catania**

PROTECT

30 partners:
- **Istituto di Ricerche Farmacologiche Mario Negri, Milano**

Key Deliverables of Non-Competitive Research

- Establishment of common databases
- New tools for identification of drug targets
- Standardization and harmonization of models and assays for drug efficacy and safety (*biomarkers*)
- Patient reported outcomes
- Classification of diseases

A closer look at neurosciences

Expected output	newmeds	PharmaCog	EU-AIMS Autism Research in Europe	EuroPain
Mechanistic knowledge	✓	✓	✓	✓
Patient stratification	✓	✓	✓	✓
Standardized model - in vitro -			✓	
Standardized model - in vivo -	✓	✓	✓	✓
Predictive biomarkers - genetic -	✓	✓	✓	
Predictive biomarkers - "omics" -	✓	✓	✓	✓
Predictive biomarkers - "imaging" -	✓	✓	✓	✓
Early involvement of regulators		✓	✓	

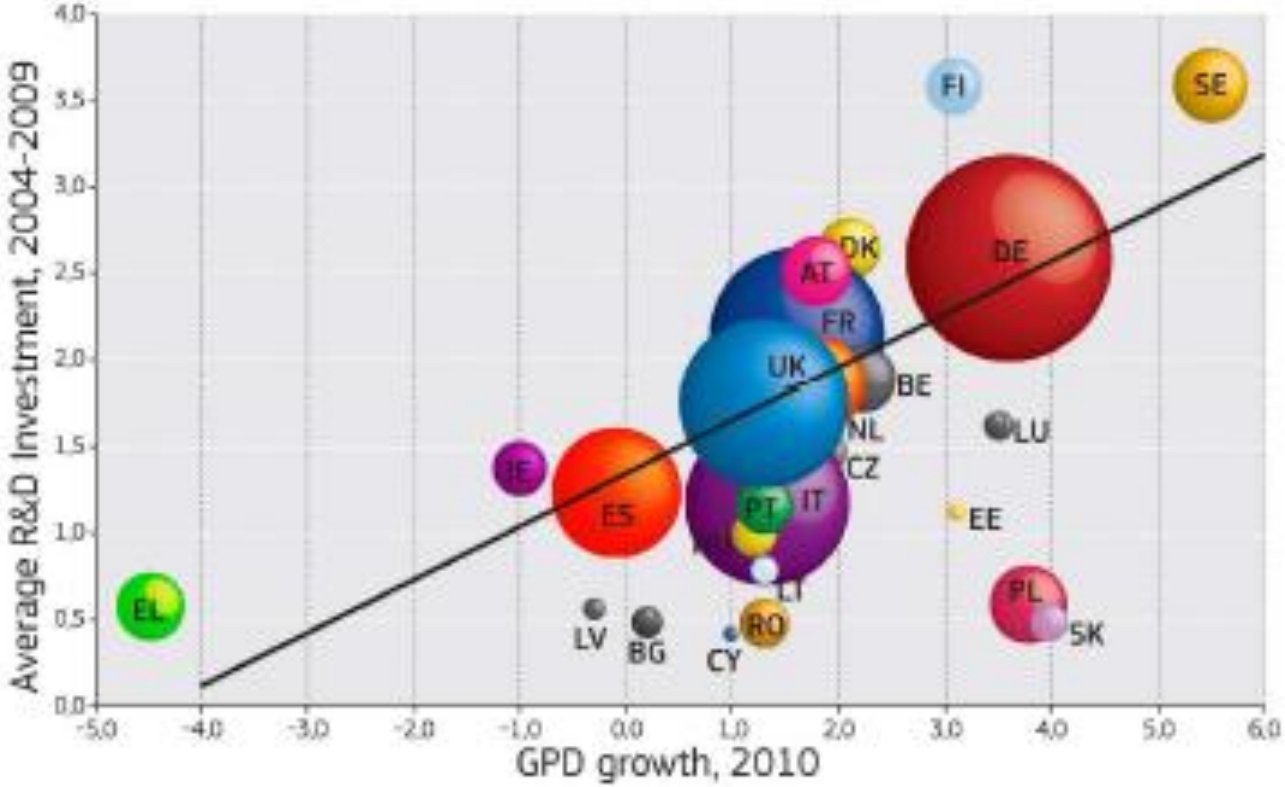
European Commission

Horizon 2020

The EU Framework Programme for Research and Innovation

2014-2020

Investment in R&D is part of the solution to exit from the economic crises



Public Private Partnerships

Article 19 Public-private partnerships

Horizon 2020 may be implemented through public-private partnerships where all the partners concerned commit to support the development and implementation of research and innovation activities of strategic importance to the Union's competitiveness and industrial leadership or to address specific societal challenges.

Research and Innovation

Public Private Partnerships

Article 19 Public-private partnerships (cont)

Involvement of the Union in those partnerships may take one of the following forms:

- *financial contributions from the Union to joint undertakings under the Seventh Framework Programme;*
- *to new public-private partnerships set up on the basis of Article 187 of the Treaty;*
- *entering a contractual agreement between the partners which specifies the objectives and conditions of the partnership.*

Three priorities:

1. Excellent science
2. Industrial leadership
3. Societal challenges

Scientific Contents – key principles

Innovative Medicines Initiative

- **Societal bottlenecks**: move from scientific and technological challenges in the industry only to addressing industry bottlenecks and resolving healthcare and societal challenges.

- **Holistic view on disease burden** (not just primary care focus)

- **Starting point**: health priorities, e.g. priority medicines and diseases as outlined in the 2004 WHO report (under revision)

Innovative Medicines Initiative

http://www.imi.europa.eu/

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