



Innovative Medicines Initiative

Joint research for better medicines



Overview

- IMI:
 - What?
 - Objectives
 - Why?
- The Calls for proposals:
 - What?
 - Funding rules
 - IP policy
 - Why apply?
- IMI research projects
- IMI Knowledge Management
- Contacts



What is IMI?

- The biggest public-private funding scheme in biopharmaceutical research:
 - € 1 billion from the European Commission
 - € 1 billion in kind contribution by EFPIA,
- an innovative research programme,
- accelerating the R&D of safer and more effective drugs,
- by innovative partnerships between industry, academia, regulators, hospitals and patients organisations in Europe.



What is IMI?

- IMI launches a new Call for proposals every year
- Open Information Day (Q4):
IMI presents the research topics of the new Call
- Stakeholder Forum (Q2):
Presenting ongoing projects and strategic discussions



IMI objectives

- Making the pharmaceutical R&D process faster and more effective, rather than directly delivering new drugs
- Accelerating the development of safer and more effective medicines for patients in Europe
- Improving the environment for pharmaceutical R&D in Europe
- Boosting the biopharmaceutical sector in Europe

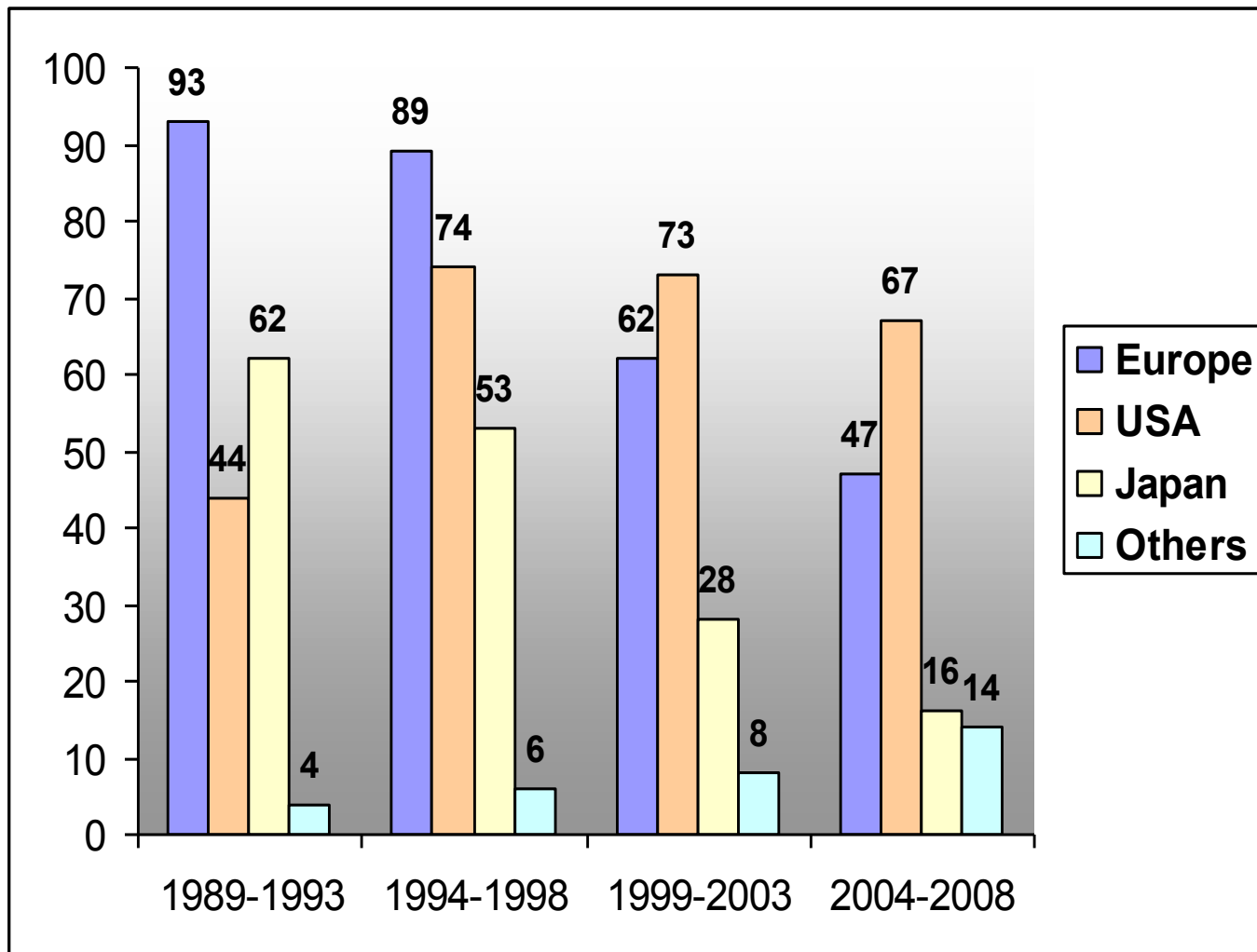


Why is IMI needed?

- Drug R&D is become increasingly complex, expensive and time consuming
- The number of new drugs (new molecular entities) for patients is declining
- Europe is loosing ground in global pharmaceutical R&D

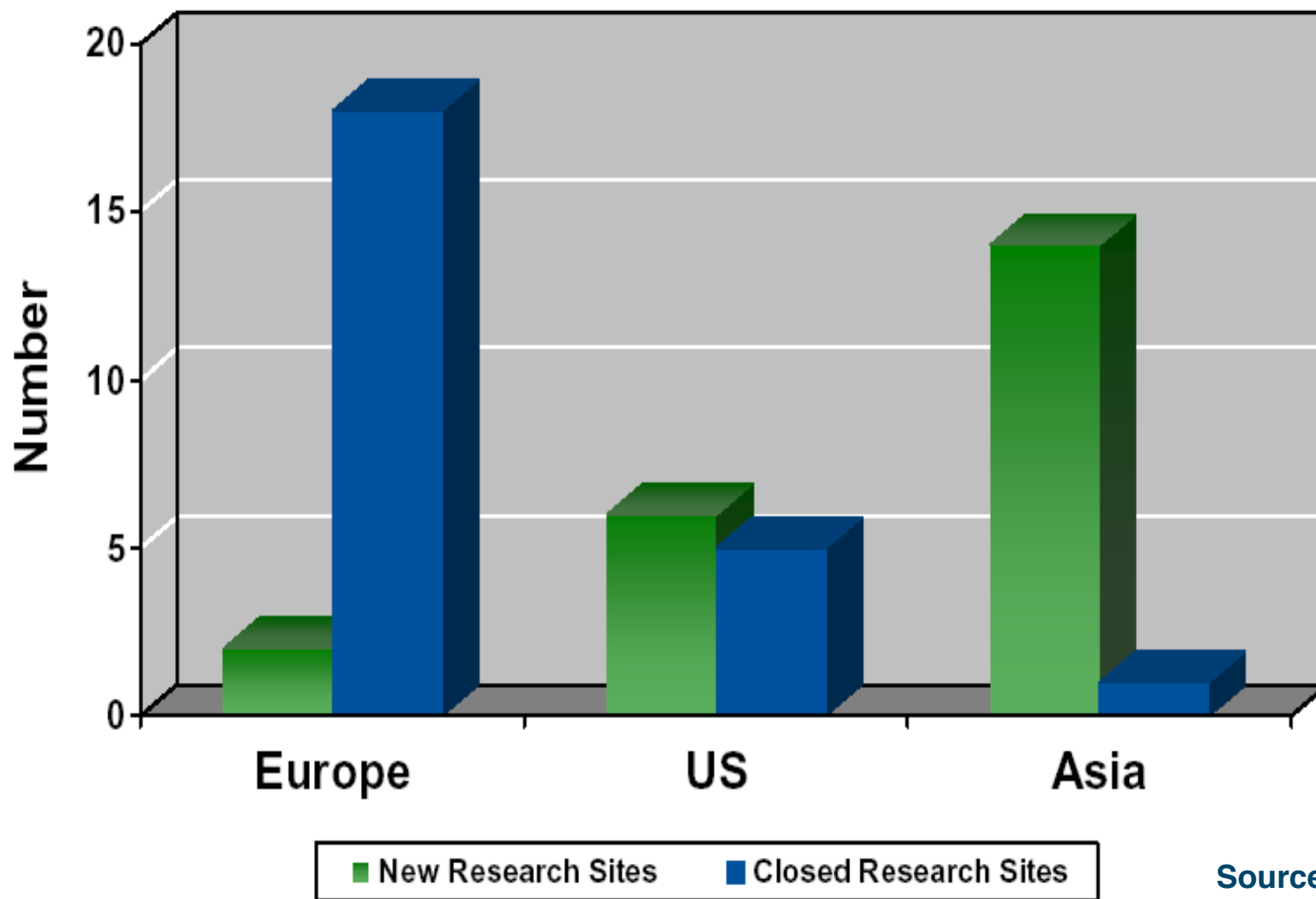


New Molecular Entities 1989-2008



Source:
SCRIP - EFPIA
calculations
(according to
nationality of mother
company)

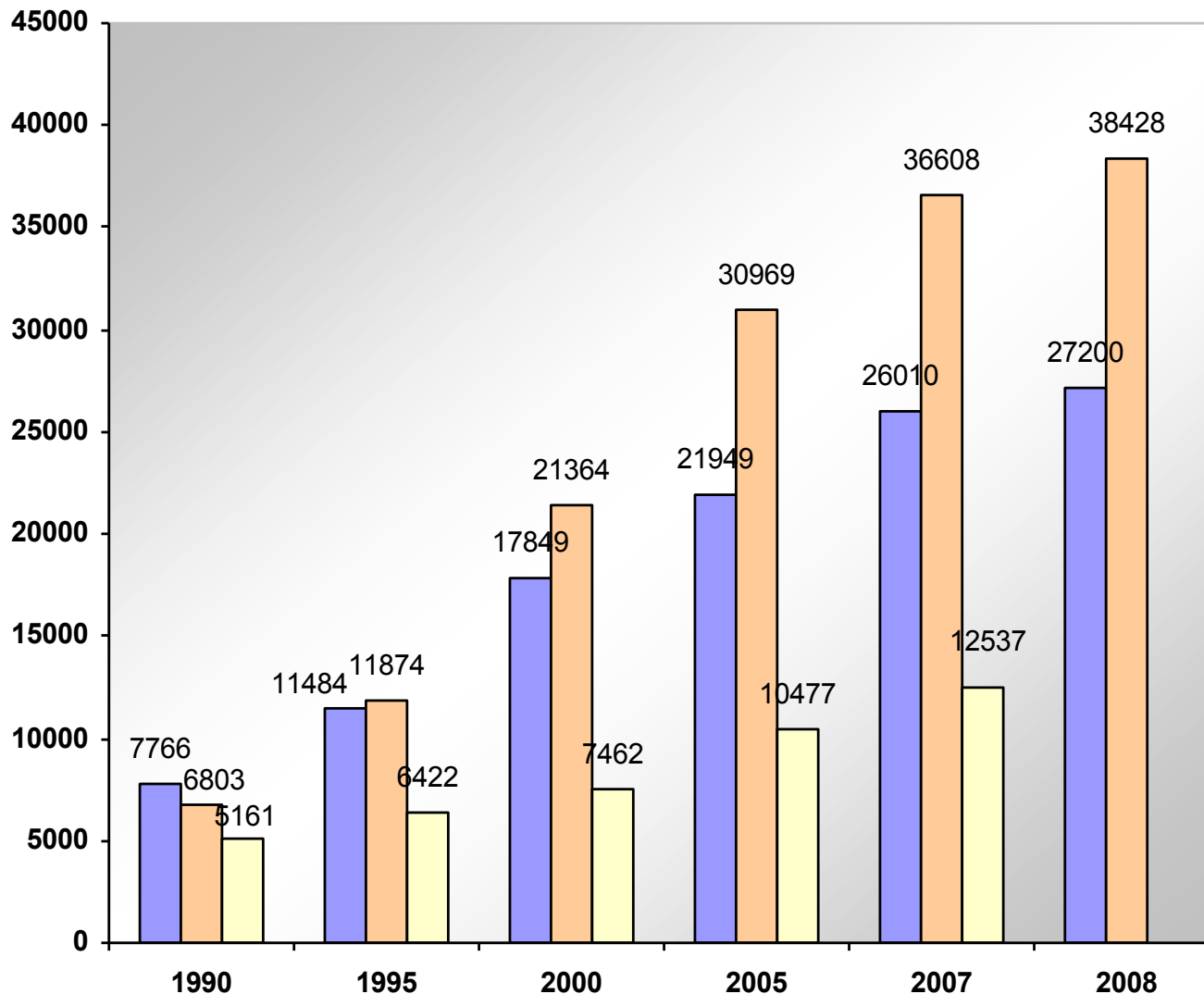
Changes in Research Sites* 2001-2006



*Data relate to 22 global companies

Source: IMI (EFPIA Research Directors Group & IFPMA)

Pharmaceutical R&D expenditure in Europe, USA and Japan, 1990-2008



In Million of National currency units:

Europe: € million;

USA: \$ million;

Japan: ¥ million x 100

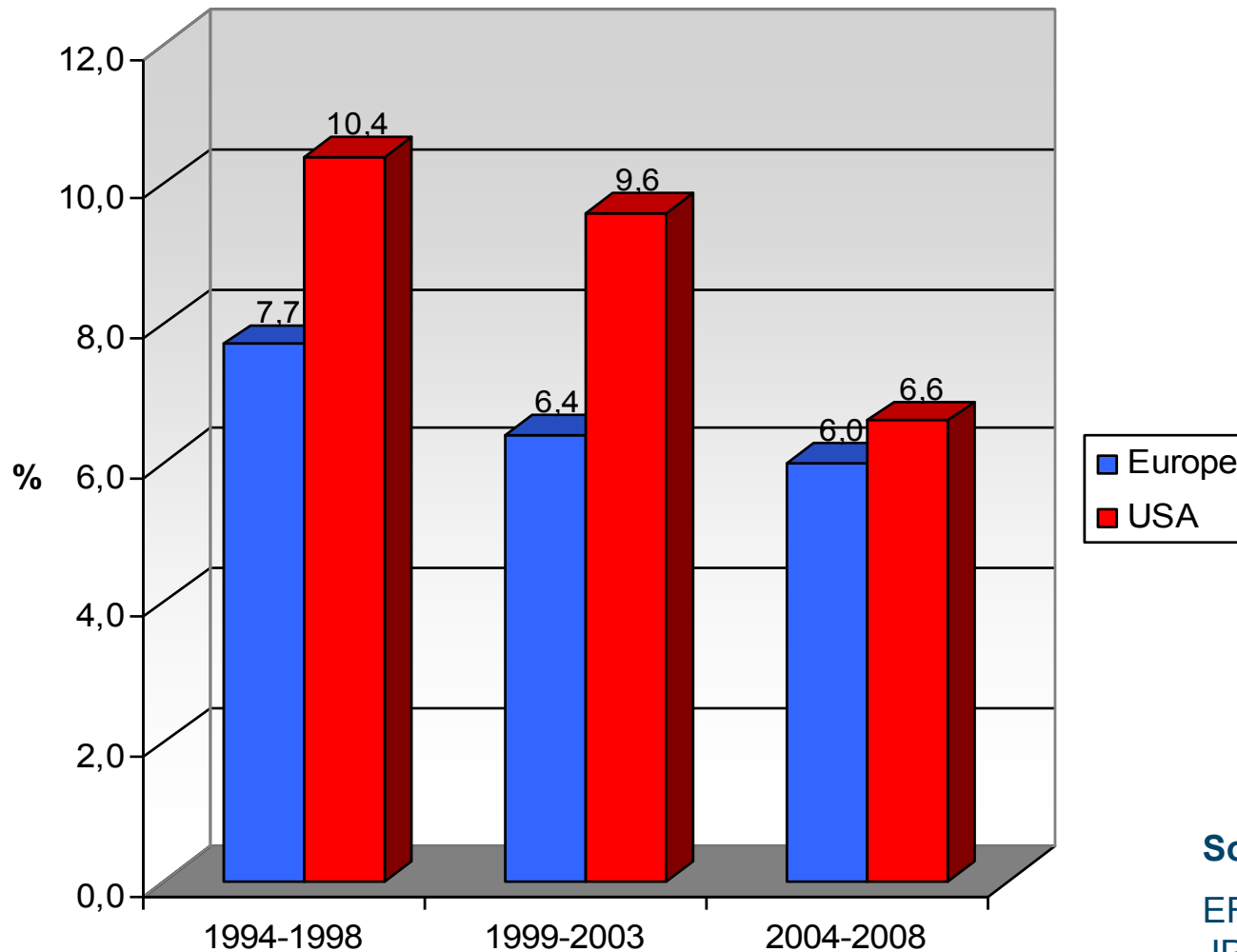
Data 2008: estimate
EFPIA & PhRMA

Source:

EFPIA member
associations,
PhRMA, JPMA

Pharmaceutical R&D Expenditure

Annual growth rate in % (Europe - USA)



Source:

EFPIA member associations, PhRMA, JPMA

Need for Public-Private Partnerships to boost the Health Sector



- Personalised innovative medicines require in-depth knowledge of disease pathways and molecular targets
- Anticipating potential side effects of new drugs becomes increasingly important
- The pharmaceutical industry requires new business models based on collaboration and transparency



Aim: Building on Strengths and Tackling Weaknesses in the EU



- Major pharma companies based in Europe
 - High-quality research and medical centres
 - Critical mass assembled through EU programmes
 - Biomedical clusters based on PPP across Europe
 - Insufficient global investment in R&D
 - Fragmented legal framework for IP rights
 - Insufficient incentives for bioentrepreneurs
 - Education programmes not adapted to industry needs
-



IMI: an Autonomous Body



Need for a neutral third-party

- To implement programmes and activities in the common interest of patients, industry and academia
- To monitor the combined use of public funds and industry investments
- To guarantee fair and reasonable conditions for optimal knowledge exploitation



A Public Private Partnership



* Research performed by
EFPIA member companies

= *in kind* contribution

IMI Research funding
for

Academia, SMEs, patients
organisations, Regulatory
Authorities, etc.

IMI Research Projects



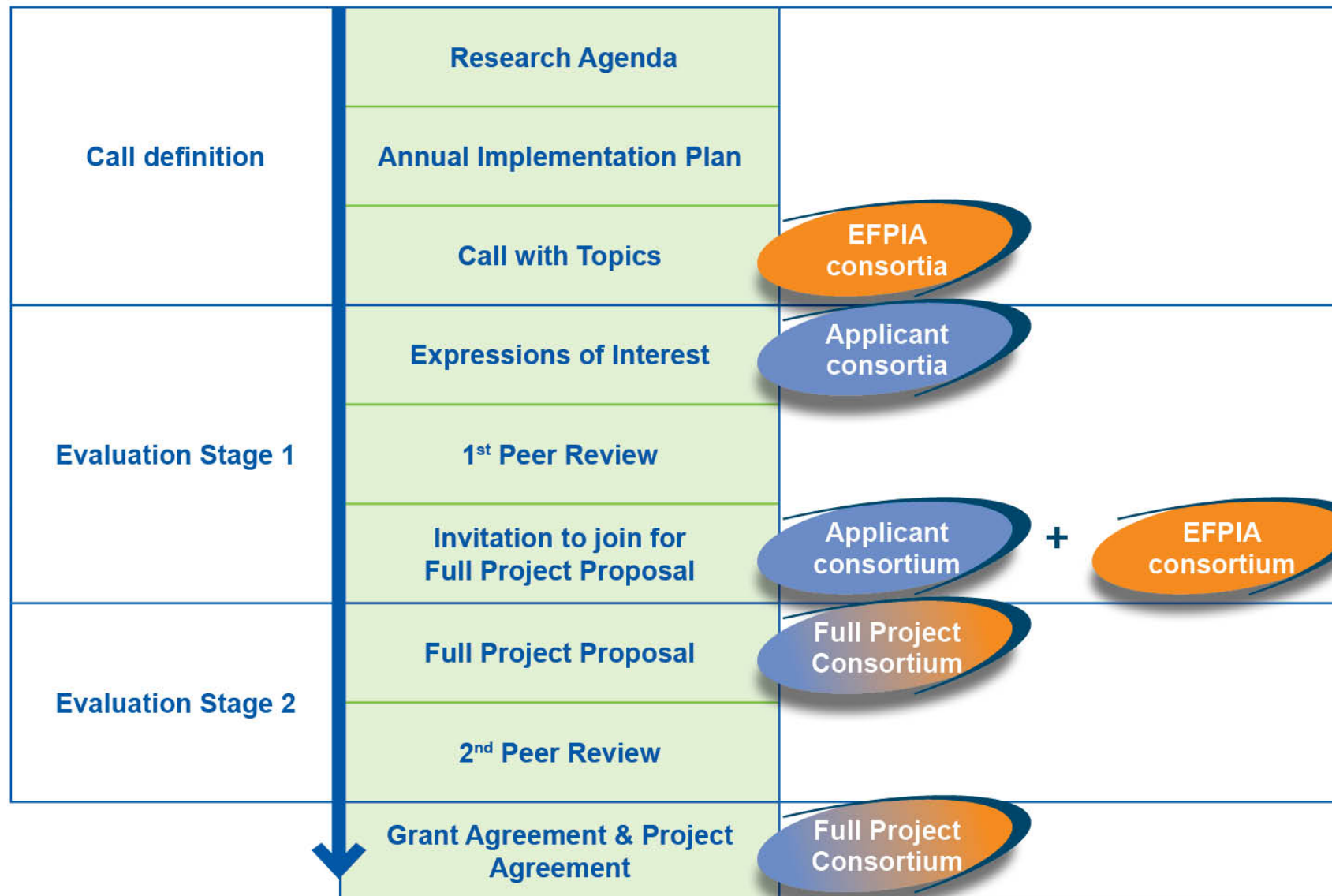
Innovative Medicines Initiative

IMI Research Projects

How to participate



IMI Call Process

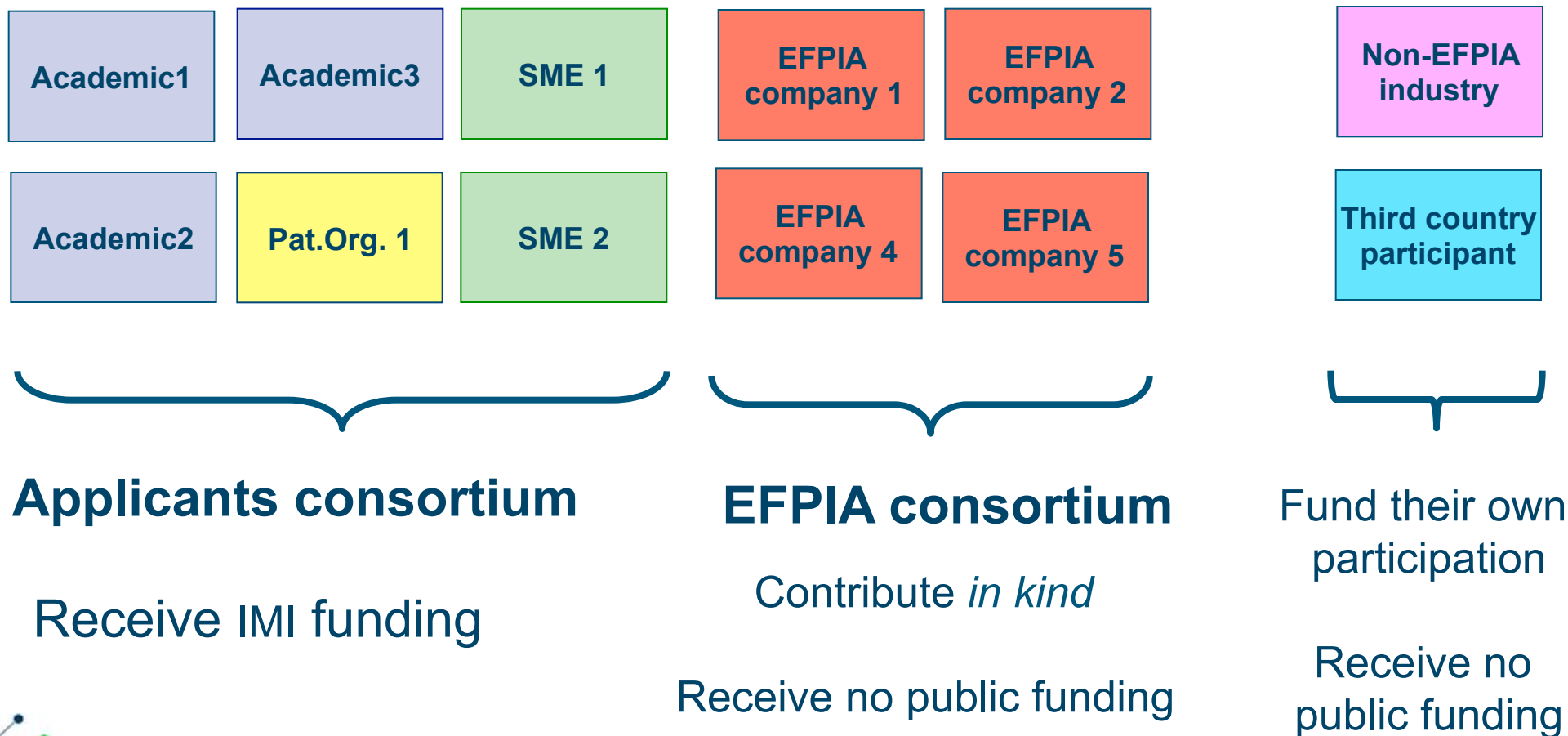


Calls for proposals

- Open and competitive Calls for proposals
- Winning proposals selected by independent experts (peer review)
- New Call every year
- Several topics (projects) in each Call, in varying disease areas
- Published on www.imi.europa.eu (Q3- Q4)



IMI Funding rules



IMI Funding Rules

Eligible for funding:

- Participants in **EU countries**
- Participants in **FP7-associated countries**:
Switzerland, Israel, Norway, Iceland, Liechtenstein, Turkey, Croatia, the Former Yugoslav Republic of Macedonia, Serbia, Albania, Montenegro, Bosnia & Herzegovina
(soon also: Faroe Islands)

Organisations in other third countries:

- are allowed to participate in IMI projects,
- are **not** eligible for IMI funding.



IMI Funding Rules

IMI funding: up to:	Contribution by EFPIA member companies:
75% of total eligible research costs + 100% of total eligible management and training costs + overhead: 20% of total direct eligible costs	in-kind* contributions, at least matching the IMI funding *consisting mainly of research activities

Details: Rules for Participation: www.imi.europa.eu



IMI Funding Rules

Direct eligible costs = actual costs, recorded in accounts			Indirect eligible costs = overhead, not to be proven by invoices
Research activities	Personnel	Up to 75 % funded by IMI	E.g. VAT, duties, taxes, exchange losses, interest owed ... ↓ IMI funds: Flat rate of 20% of direct eligible costs, excluding subcontracting or reimbursement of third party costs
	Equipment		
	Consumables & Materials		
	Subcontracting for services		
Other activities	Management activities	Up to 100 % funded by IMI	
	Training activities		
	Other		



Why apply?



Interest in:

- Speeding up drug development by pooling public-private expertise
- Translation of basic knowledge into medical advances
- Open innovation in the health sector through partnership with pharmaceutical companies



IMI Intellectual Property Policy

- The IMI Intellectual Property (IP) Policy is defined in:
 - IMI IP Policy (www.imi.europa.eu) and Grant Agreement
 - Project Agreement
- Aligned with IMI objectives, i.e.
 - to promote knowledge creation, together with its disclosure and exploitation, to achieve fair allocation of rights, to reward innovation,
 - to achieve a broad participation of private and public entities in IMI projects
- Intends to provide some scope of flexibility for participants to establish the most appropriate agreements serving the project objectives (-> Project Agreement)



IMI Intellectual Property Policy



- **‘Background’**: IP brought into and needed for the project:
 - ownership not affected
- **‘Foreground’**: IP generated in the IMI project, excluding Sideground:
 - belongs to the participant who generates it,
 - must be disseminated no later than 1 year after termination of the project
- **‘Sideground’**: IP generated during the project, but outside project objectives and not needed for completing the project or for research use of Foreground:
 - belongs to the participant who generates it
- **‘Research Use’**: use of Foreground or Background necessary to use Foreground for all purposes other than for completing the Project or for Direct Exploitation



IMI Intellectual Property Policy

- **Access rights to participants to implement the project:**
Background and Foreground: non-exclusive, and free of charge.
- **Access Rights to participants/affiliates for Research Use during and after project:**
Foreground, and Background required for use of Foreground:
non-exclusive, and free of charge or under fair and reasonable terms as determined in the Project Agreement.
- **Access Rights to third parties for Research Use:**
Foreground, and Background required for use of Foreground:
non-exclusive, and under fair and reasonable terms as determined in the Project Agreement.



How apply?



A two-step process:

Stage 1:

Expressions of Interest (Eoi)

by applicant consortia:

- academic institutions
- non-profit organizations
- SMEs
- regulators
- patient organisations
- other entities (not belonging to EFPIA)



How apply?



Evaluation (peer review)



Stage 2:

For each Call topic:

1st ranked consortium merges with the consortium of EFPIA companies connected to the topic.



Joint preparation of **full project proposal**.



Peer Review Stage 1



- **Evaluation Panels**

- Independent Experts & EFPIA coordinators
- Criteria:
science/technology, partnership, work plan

- **Outcome**

- Ranking and selection of the best Expression of Interest (EFPIA coordinators do not contribute to the final ranking)



Expression of Interest (Stage 1)



CONTENT:

- Scientific/technological case (*3 pages*)
- Partnership case (*1 page + ½ page per participant*)
- Summary of workplan (*2 pages incl. indicative budget plan*)
- Ethical issues (*½ page*)

**Prepared by Stage 1 consortium
(without involvement of EFPIA companies)**



Expression of Interest (Stage 1)

Application forms,
Rules for participation,
Rules for submission



Available at www.imi.europa.eu
when the Call is open



Interested in joining the evaluation panels?



**Register as an expert
via the link on
www.imi.europa.eu**



Search for Partners



LifeCompetence:
www.lifecompetence.eu

CORDIS:
www.cordis.europa.eu/fp7/partners_en.html

SMEs go health:
www.smesgohealth.org/common/home.asp

German Federal Ministry of Education and Research:
www.imi-partnering.eu





Innovative Medicines Initiative

IMI Research Projects



IMI Research: 4 pillars



- Predicting safety
 - Predicting efficacy
 - Knowledge Management
 - Education & Training
- Call topics focus on specific disease areas within a pillar



Calls

	1st Call 2008	2nd Call 2009	3rd Call 2010
IMI funding + EFPIA contribution	€ 110 million + € 136 million = € 246 million	€ 76.8 million + € 79.6 million = € 156.4 million	€ 96 million +
Call topics	18	9	
Expressions of Interest	134	124	
Participants	1294	1118	



Projects

- Average project size: €20 million, of which €7,5 million funded by IMI
- Average size of a full consortium participating in proposals after the 1st call are in the range of:
 - 4-16 pharmaceutical companies
 - 7-35 academic, SME, regulatory, patient organizations



An example of a Consortium



Participation in Projects

	MAR	eTO	SAFI	PRO	IMID	SUM	EUR	NEW	PHA	U-BI	PRO	EMT	SAFI	PHA	EU2P	
Amgen			x	x										x	x	
AstraZeneca		x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Bayer	x	x	x	x								x	x	x	x	
Boehringer Ingelheim	x	x	x		x	x	x		x	x	x	x	x		x	
Chiesi Pharmaceuticals										x	x					
Eli Lilly			x		x	x	x	x	x				x		x	
Esteve		x					x					x		x		
Genzyme				x								x				
GSK		x	x	x					x	x	x	x	x	x	x	
J&J		x						x	x	(x)		x		x	x	
Laboratoires Almirall			x							x	x	x	x	x	x	
Lundbeck	x	x		x				x	x			x	x		x	
Merck Group				x					x				x	x		
Novartis	x	x	x	x	x			x	x	x	x	x	x	x	x	
Novo Nordisk				x	x							x	x	x	x	
Orion								x				x	x	x	x	
Pfizer		x	x	x			x	x		x	x	x	x	x		
Roche		x	x	x	x	x		x	x	x		x	x	x	x	
Sanofi Aventis		(x)	x	x	x		x					x	x	x	x	
Servier		(x)			x			x	x							
Sigma-Tau																
UCB	x	x					x		x	x	x	x	x	x	x	
* snapshot in time																



EFPIA member companies participating



Amgen
AstraZeneca
Bayer
Boehringer Ingelheim
Chiesi Pharmaceuticals
Eli Lilly
Esteve
Genzyme
GSK
J&J
Laboratoires Almirall
Lundbeck
Merck Group
Novartis
Novo Nordisk
Orion
Pfizer
Roche
Sanofi Aventis
Servier
Sigma-Tau
UCB



1st Call approved projects 2008



<http://www.imi.europa.eu/content/research-projects-0>

SAFETY:

1. **MARCAR**: Non-genotoxic Carcinogenesis
2. **eTOX**: Expert Systems for in silico Toxicity Prediction
3. **SAFE-T**: Qualification of Translational Safety Biomarkers
4. **PROTECT**: Strengthening the Monitoring of Benefit/Risk

EFFICACY:

5. **IMIDIA**: Islet Cell Research
6. **SUMMIT**: Surrogate Markers for Vascular Endpoints
7. **EUROPAIN**: Pain Research
8. **NEWMEDS**: New Tools for the Development of Novel Therapies in Psychiatric Disorders
9. **PHARMACOG**: Neurodegenerative Disorders
10. **U-BIOPRED**: Understanding Severe Asthma
11. **PROACTIVE**: COPD Patient Reported Outcomes

TRAINING:

12. **EMTRAIN**: European Medicines Research Training Network
 13. **SAFESCIMET**: Safety Sciences for Medicines Training Programme
 14. **PHARMATRAN**: Pharmaceutical Medicine Training Programme
 15. **EU2P**: Pharmacovigilance Training Programme
-



2nd Call topics 2009



EFFICACY: ONCOLOGY:

1. Target Validation
2. Molecular Biomarkers
3. Imaging Biomarkers

INFECTION:

4. Diagnostic tools

INFLAMMATION:

5. Aberrant Adaptive Immunity
6. Translational Research

KNOWLEDGE MANAGEMENT:

7. Drug/Disease Modelling
 8. Open Pharmacological Space
 9. Electronic Health Records
-



Drug Disease Modelling: Library and Framework



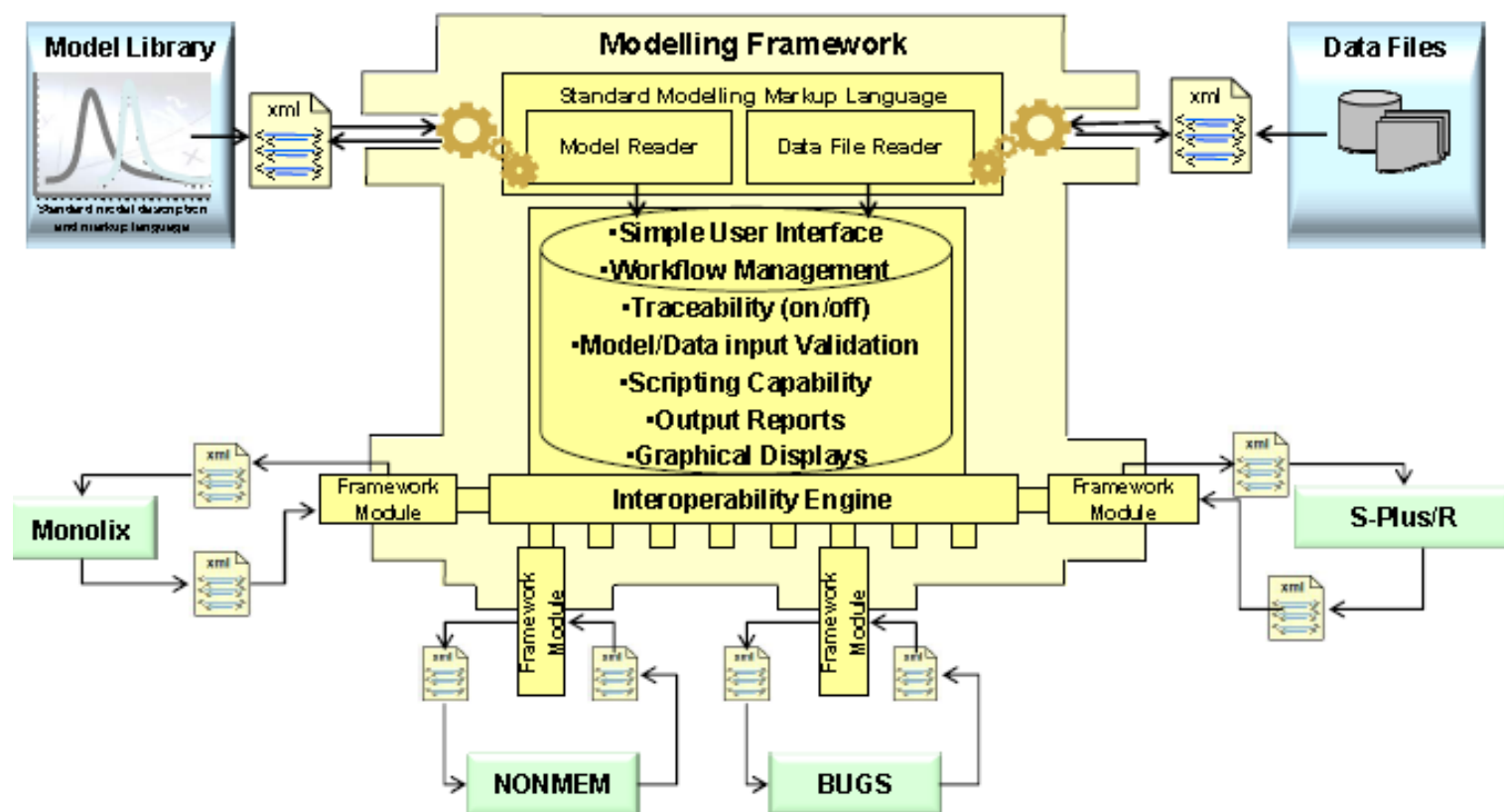
- Improve **Modelling & Simulation (M&S)** activities for model based drug discovery and development
- Create common **ontology** to describe **pharmacometric & mechanistic modelling**
- Develop **library** for pharmacometric, statistical and systems biology **models**
- Create **software interoperability** framework

→ Improved M&S infrastructure for public/private institutions

→ Releases data, models & framework in public domain



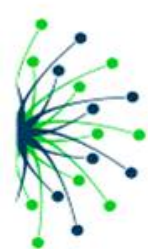
Drug Disease Modelling: Library and Framework



Open Pharmacological Space

- Data, tools and workflows for drug discovery i.e. drug targets and drugs for public/private institutions
- Data from public/private institutions shared openly with secure and stable service models
- Biological and chemical structure data relevant to early drug discovery
- Open source data infrastructure, free for the scientific community

→ Improved capabilities for drug discovery for public and private institutions



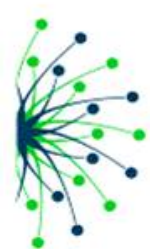
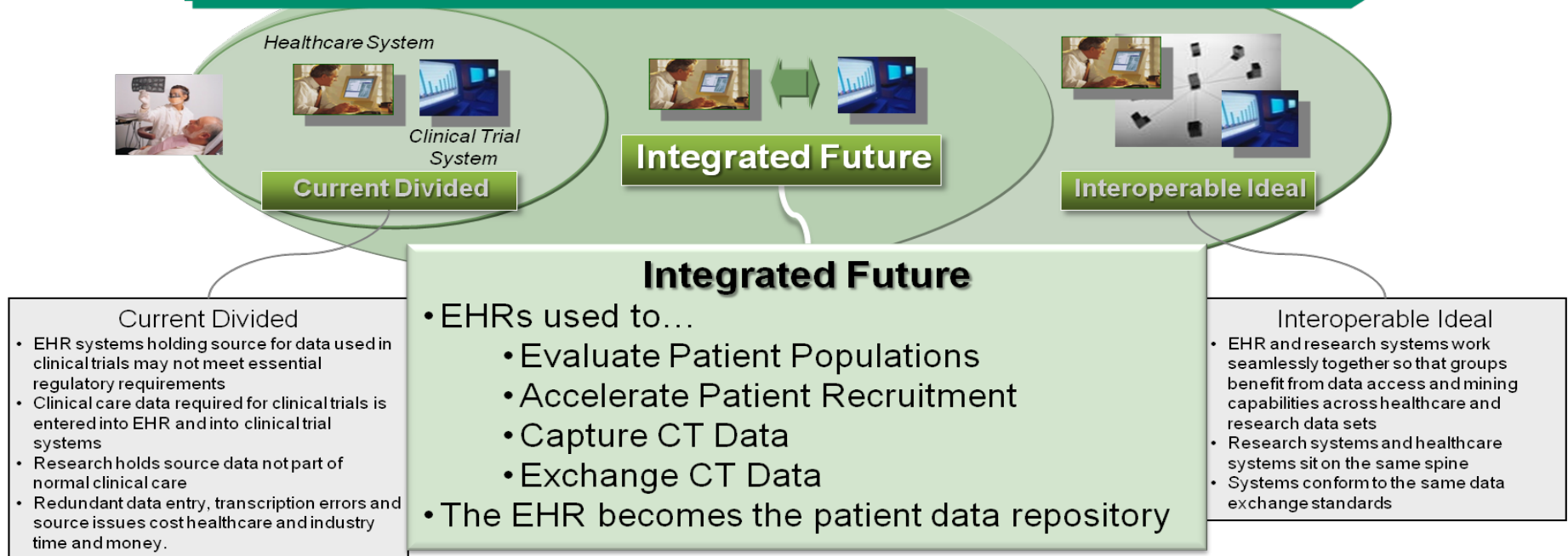
Electronic Health Records

- Sustainable framework for interoperability and secondary use EHR data
 - Focus on clinical trial protocol feasibility, patient recruitment, drug safety, and cost effectiveness
 - Clear value demonstration through execution of pilot projects
 - demonstrate integrity, security, performance & scalability
 - across European regions and/or countries
 - in an ethical and safe way complying with legal requirements
 - designed to protect patient confidentiality
 - Provide forum for emerging EHR initiatives across Europe through consistent adoption of best practices
- Improved infrastructure for clinical research, convergence clinical care and research



Project objective

Emerging and Future EHR-Research Connectivity and Complexity



Implications

- Challenges in terms data
 - management including different implementations of CDISC
 - pooling
 - analysis
 - governance
- Impact in statistical programming and other informatics disciplines
 - enrichment of data models, standards
 - implementation and development ontologies
 - further standardization of data structures
 - implementations and alignment CDISC implementations
 - alignment with HL7 and other standards



3rd Call 2010

- Topics and Call to be published in 2nd half 2010



Open Info Day

Brussels, 22 October 2010

- Practical info on how to participate in IMI projects
- 3rd Call topics presented by project leaders



Further Information



www.imi.europa.eu

IMI on YouTube: www.youtube.com/user/imichannel

IMI newsletter subscription:

<http://www.imi.europa.eu/content/subscribe-imi-newsletter>

Follow us on Twitter: https://twitter.com/IMI_JU

Questions by email: Infodesk@imi.europa.eu

