



REGIONE DEL VENETO



Innovative Medicines Initiative

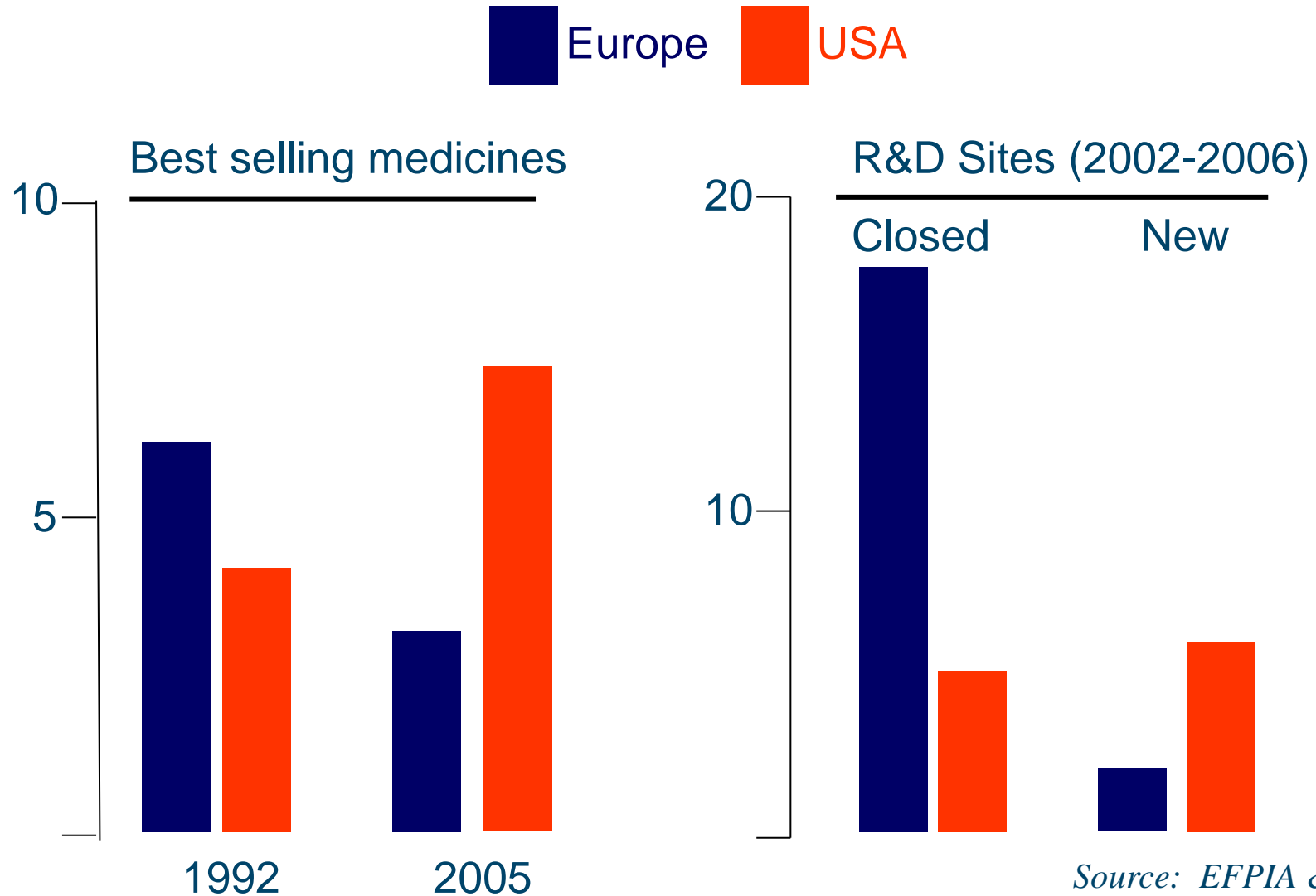
THE INNOVATIVE MEDICINES INITIATIVE JOINT UNDERTAKING

Background and Application procedures

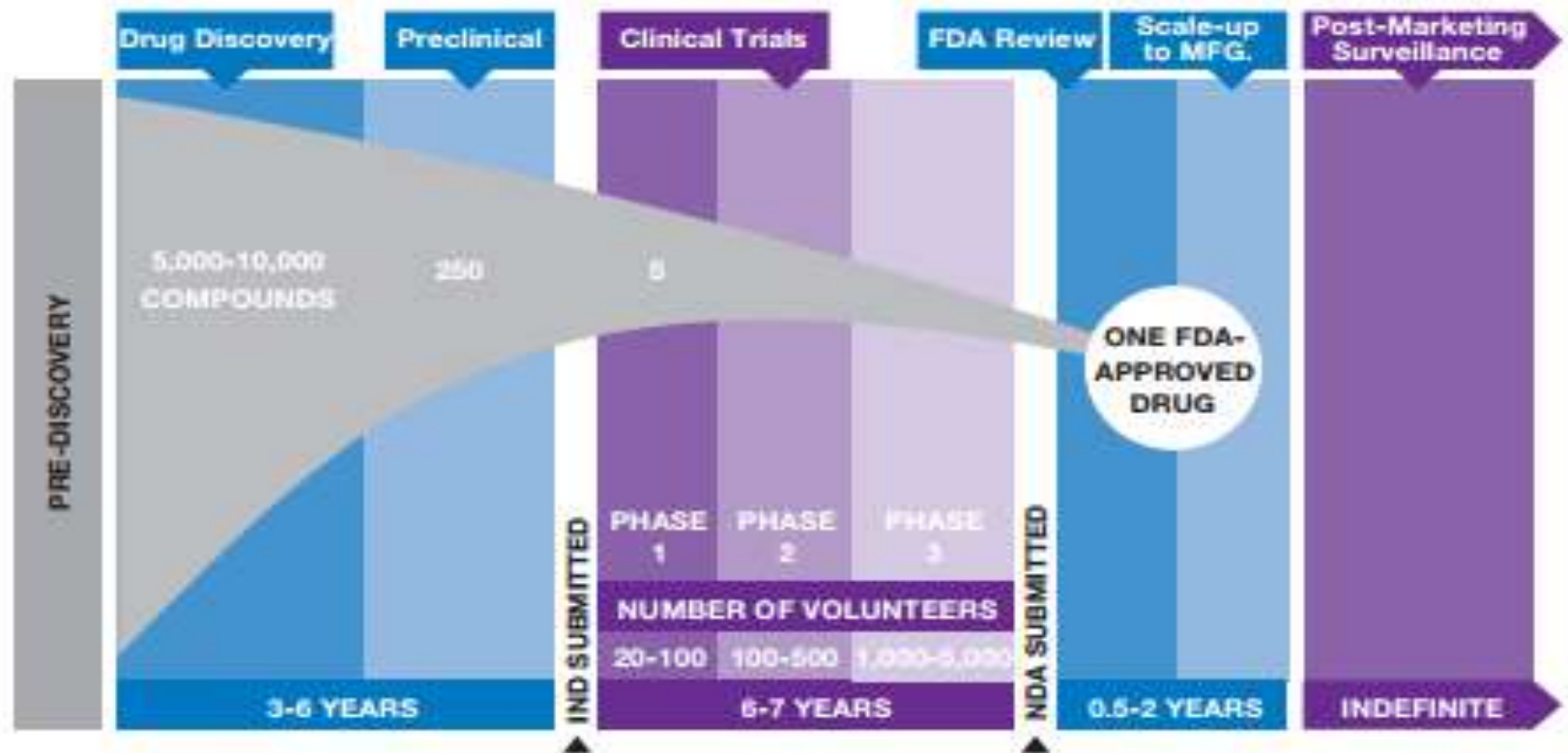


efpia

The Decline of Pharmaceutical Industry in Europe



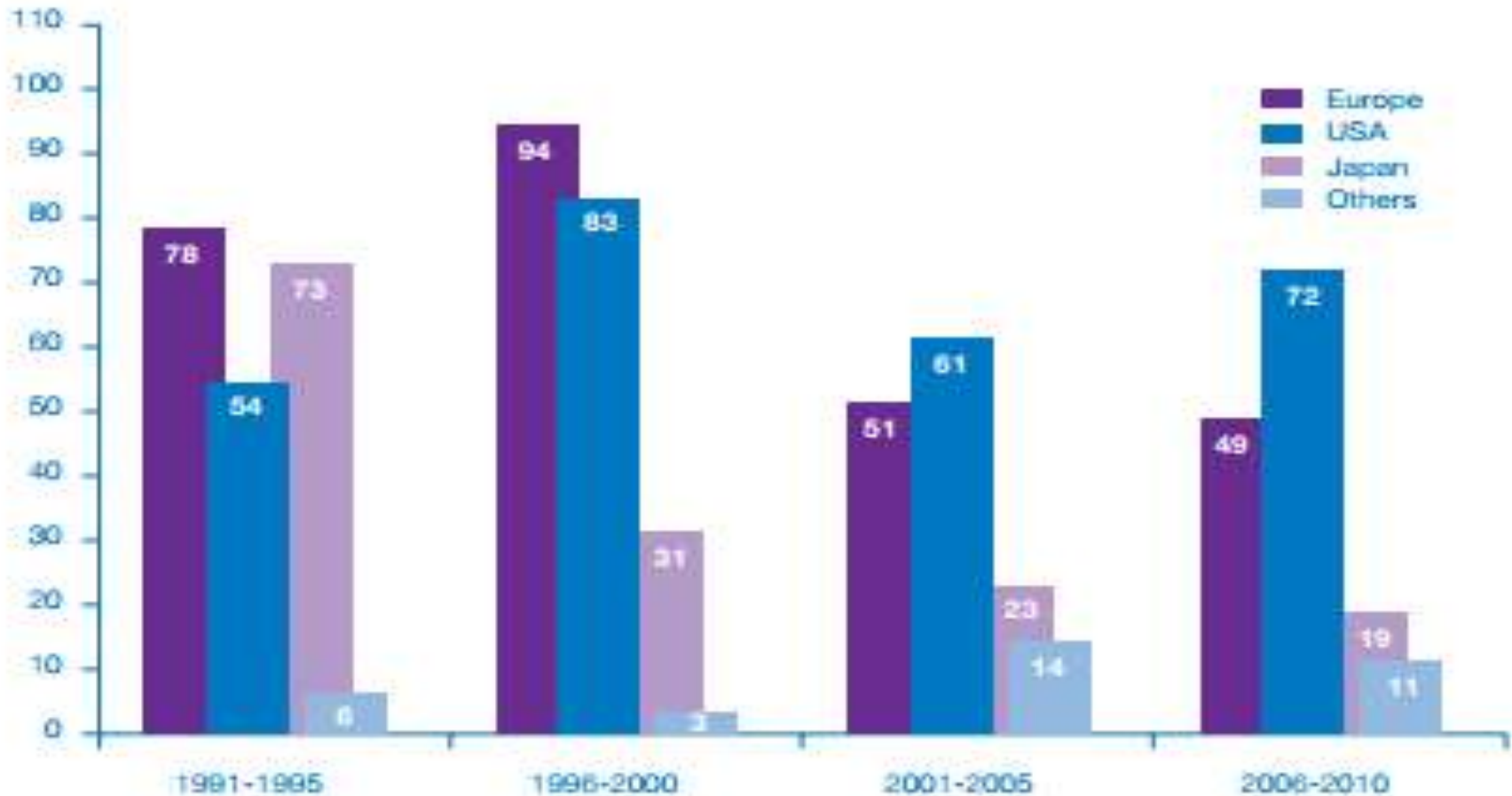
Pharma Research & Development process



Source: PhRMA 2011 profile, Pharmaceutical Industry. p. 12.

Available at: http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf

Nr of new chemical/biological entities launched on the world market



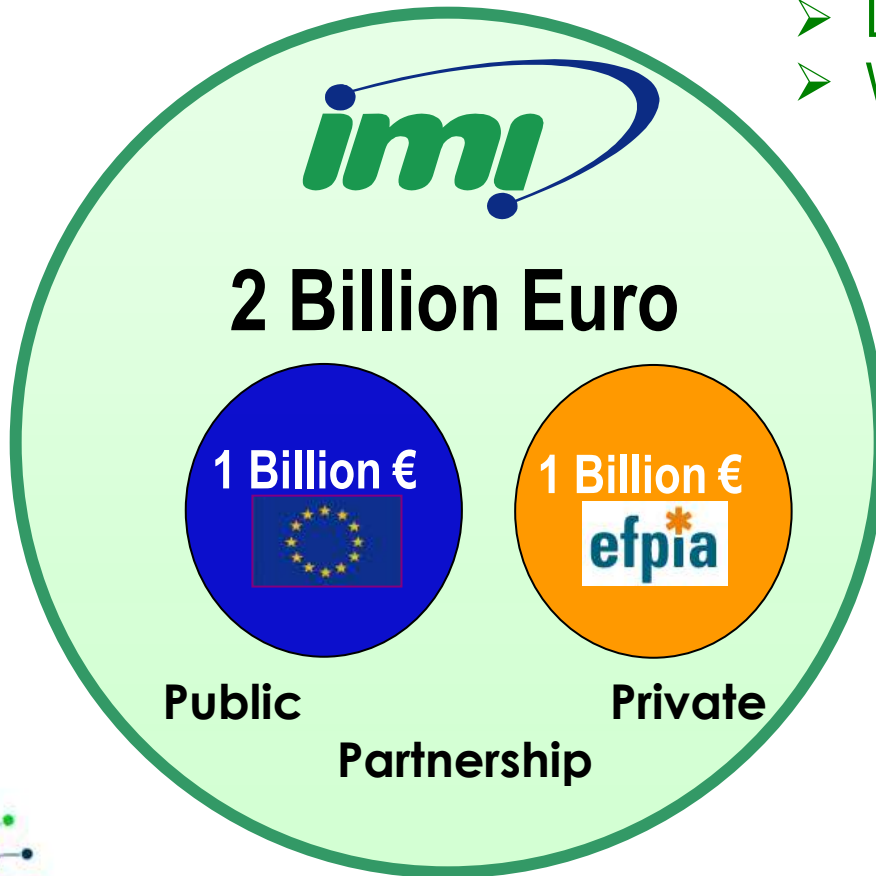
Source: EFPIA, 2010. *EFPIA industry in Figures 2010*, p. 10.

Available at: <http://www.efpia.eu/content/default.asp?PageID=559&DocID=11585>

Innovative Medicines Initiative: The Largest PPP in Life Sciences R&D



- Launched in 2008 for 10 years
- Will be increased under Horizon 2020



EFPIA = European Federation of Pharmaceutical Industries and Associations



IMI Main Objectives



- Accelerating the development of safer and more effective medicines for patients in Europe
- Boosting the biopharmaceutical sector in Europe
- Create a Open innovation model for cooperation for academia, industry, SMEs, regulators and patients (collaboration of public-private consortia, data sharing, wide dissemination of results)

IMI Governance



Funding research projects to remove the *bottlenecks* in drug development:

- Pre-competitive research for pharmaceutical industries
- Open innovation model (collaboration of public-private consortia, data sharing, wide dissemination of results)

How IMI works

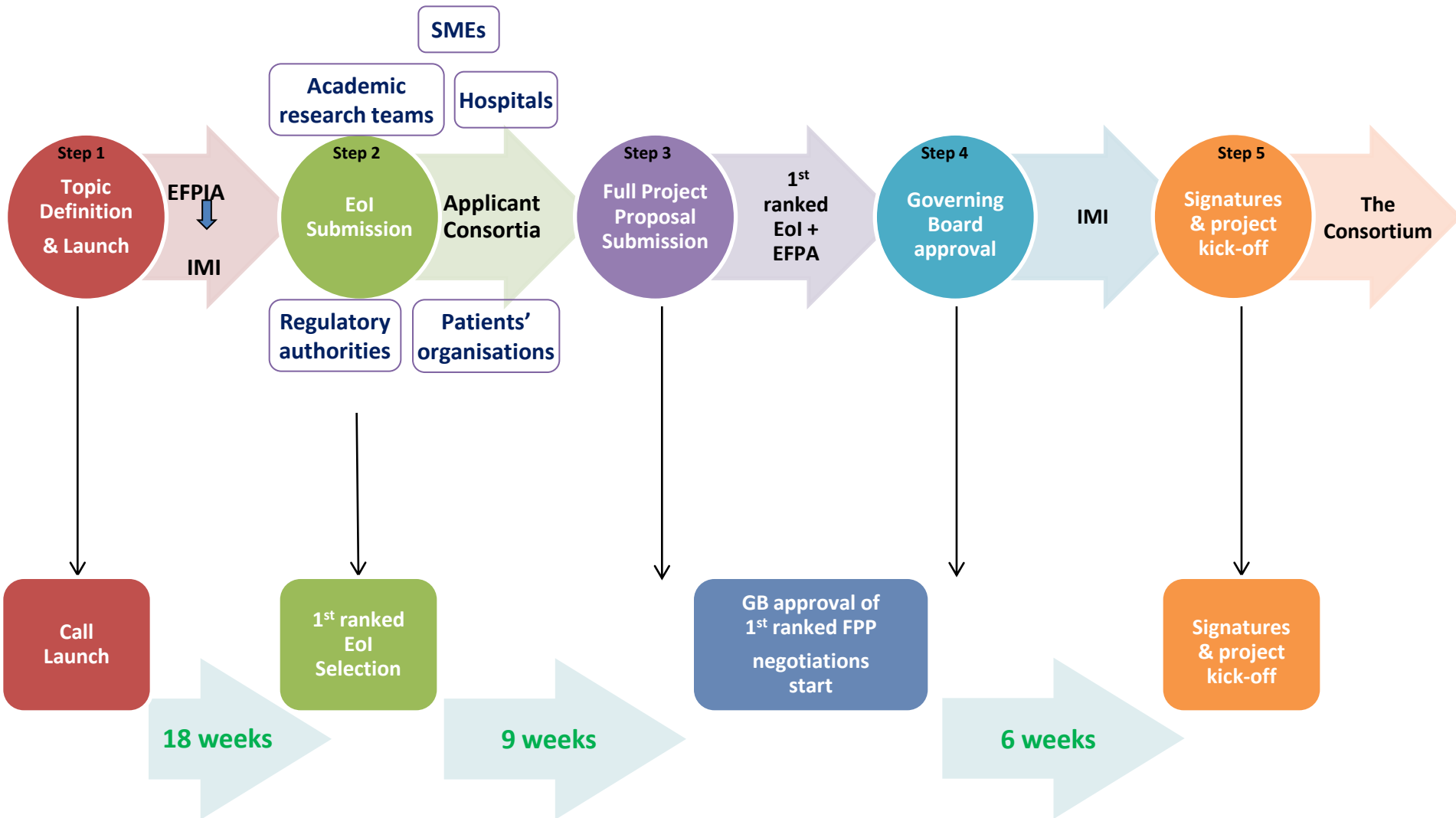
How does IMI work



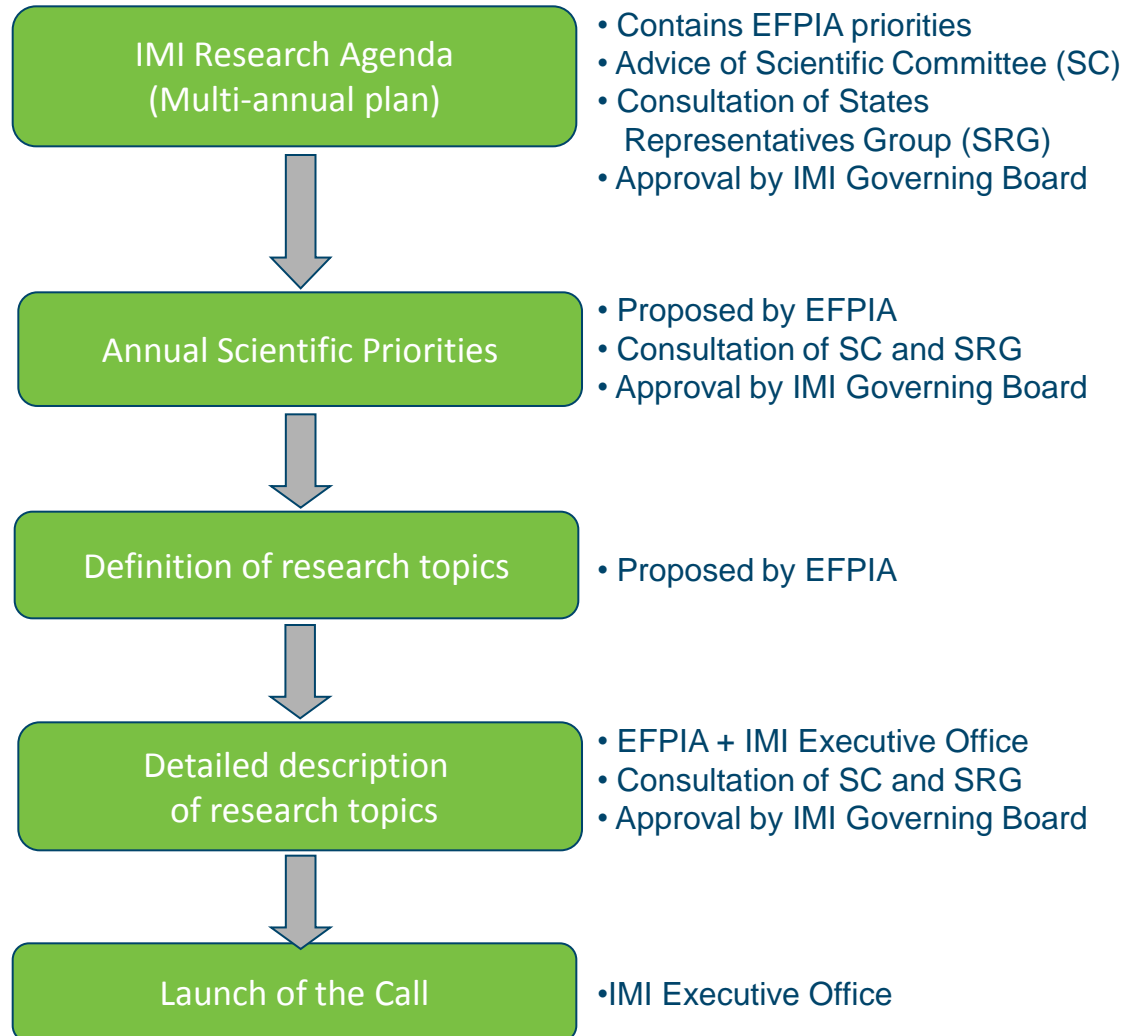
- IMI lunches calls for proposals on pre-competitive research-themes relevant for Pharma-Industry to remove bottlenecks in drug development
- Receives Expressions of Interest (EoI) from Academia, Regulators, SMEs & other Industries, Patients org.
- Selects the best EoI (peer review) and invites the applicant consortium to join the consortium of EFPIA Companies.
- A full Project is prepared, peer reviewed and eventually granted.



How IMI works – The Process



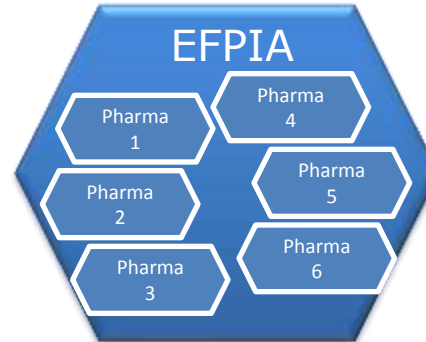
Preparatory Phase: Call definition & Launch



A Typical EFPIA Consortium



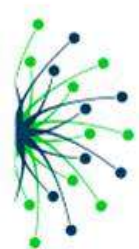
**Private
Investment
in kind
(€ 1 billion)**



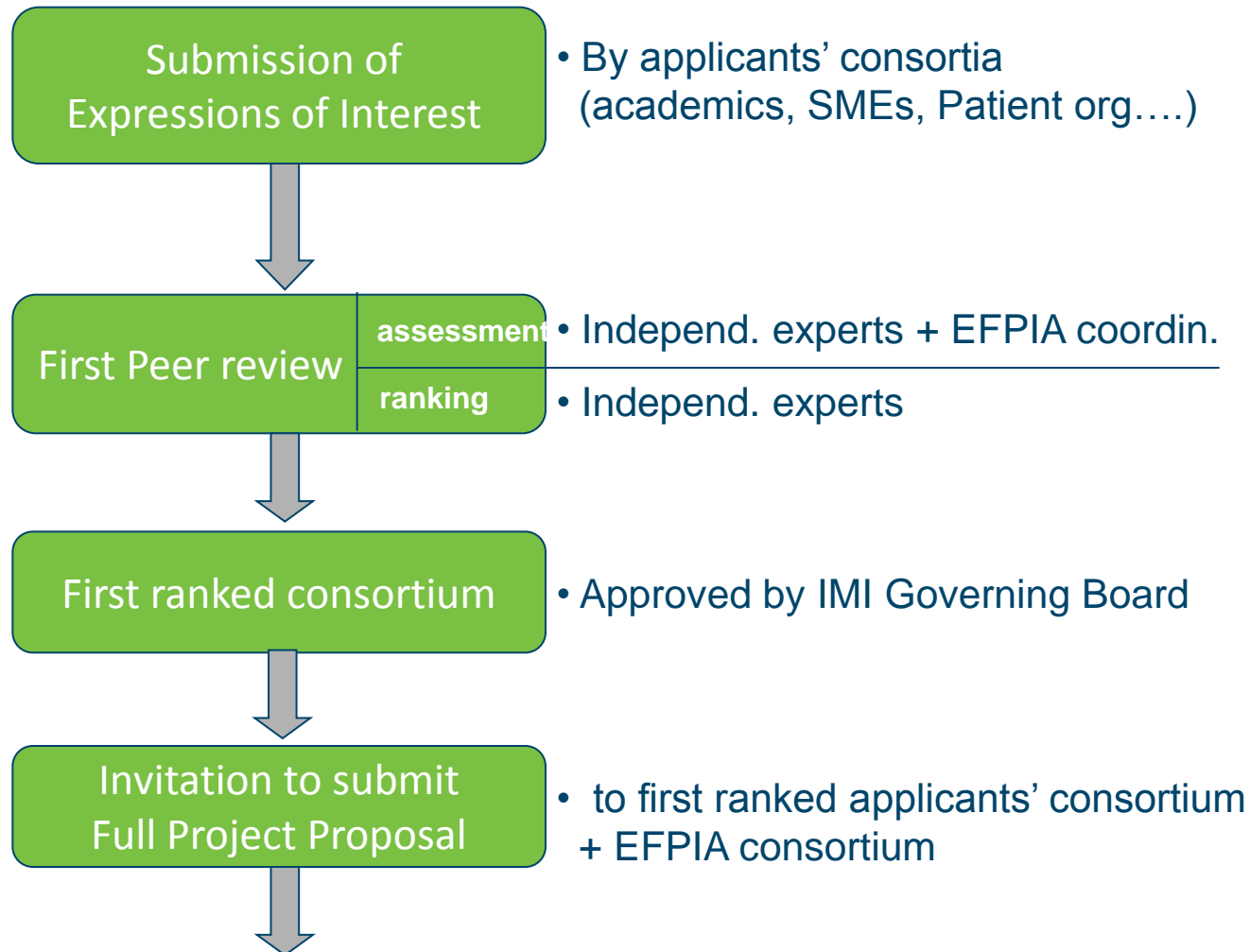
EFPIA Member Companies



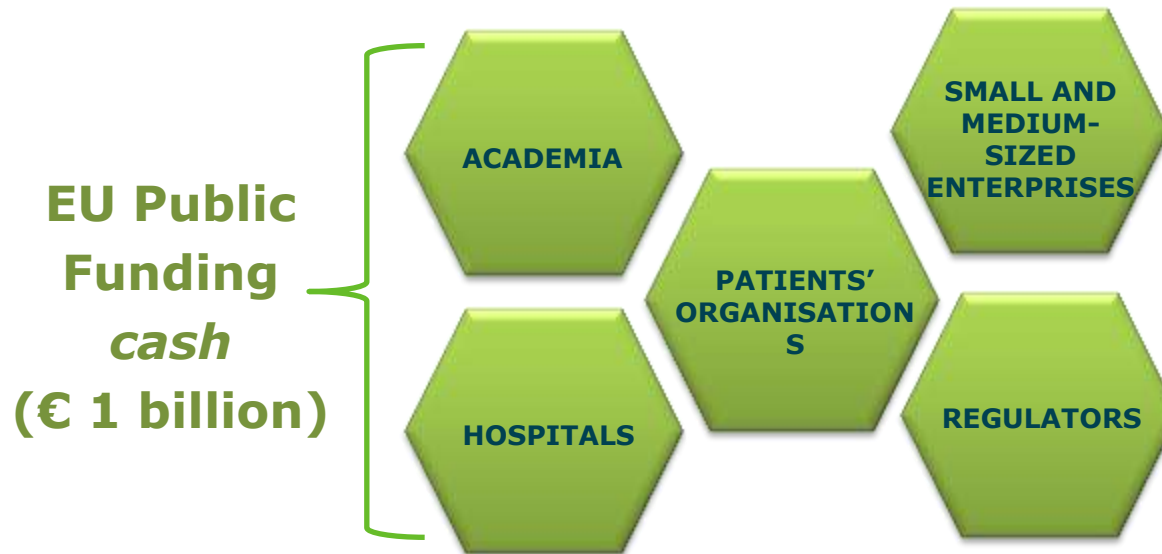
Participating companies (September 2010):



Stage 1: Competition between Applicants' Consortia



A Typical Applicant Consortium



How to find/become partner



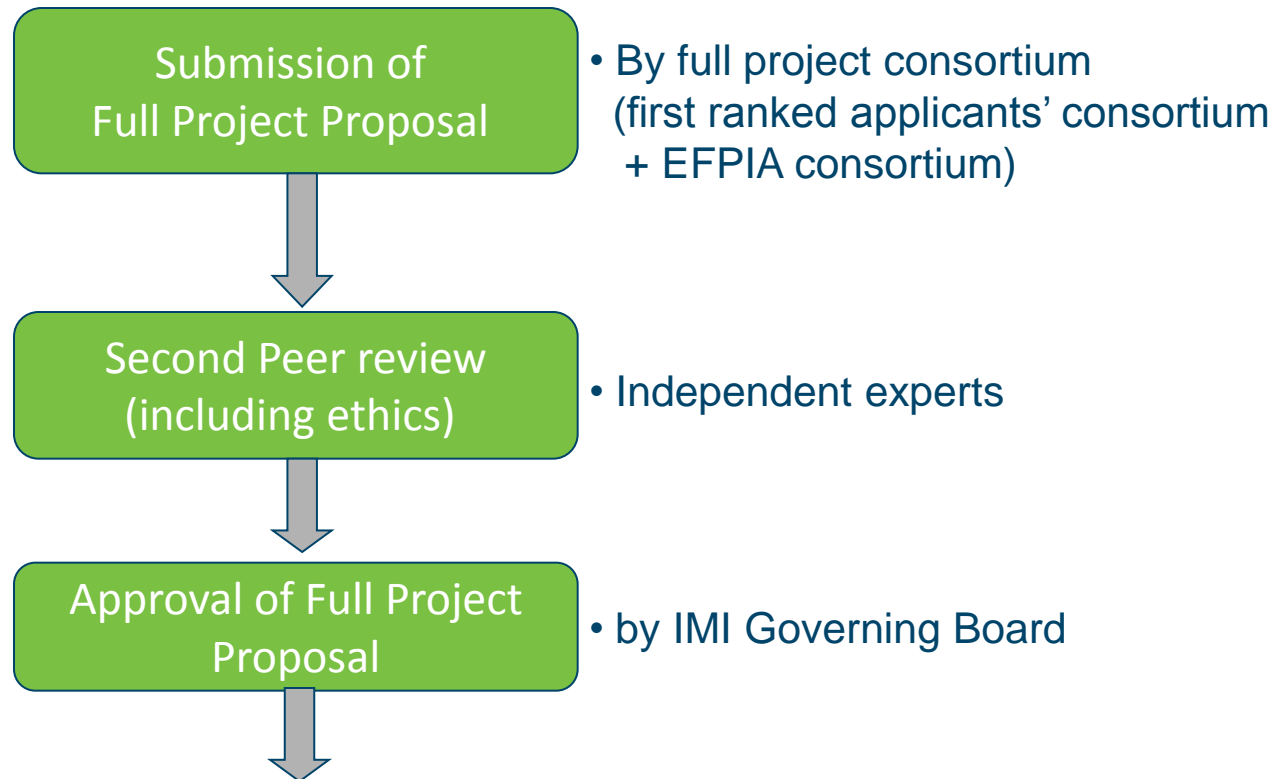
IMI Partner Search Tool



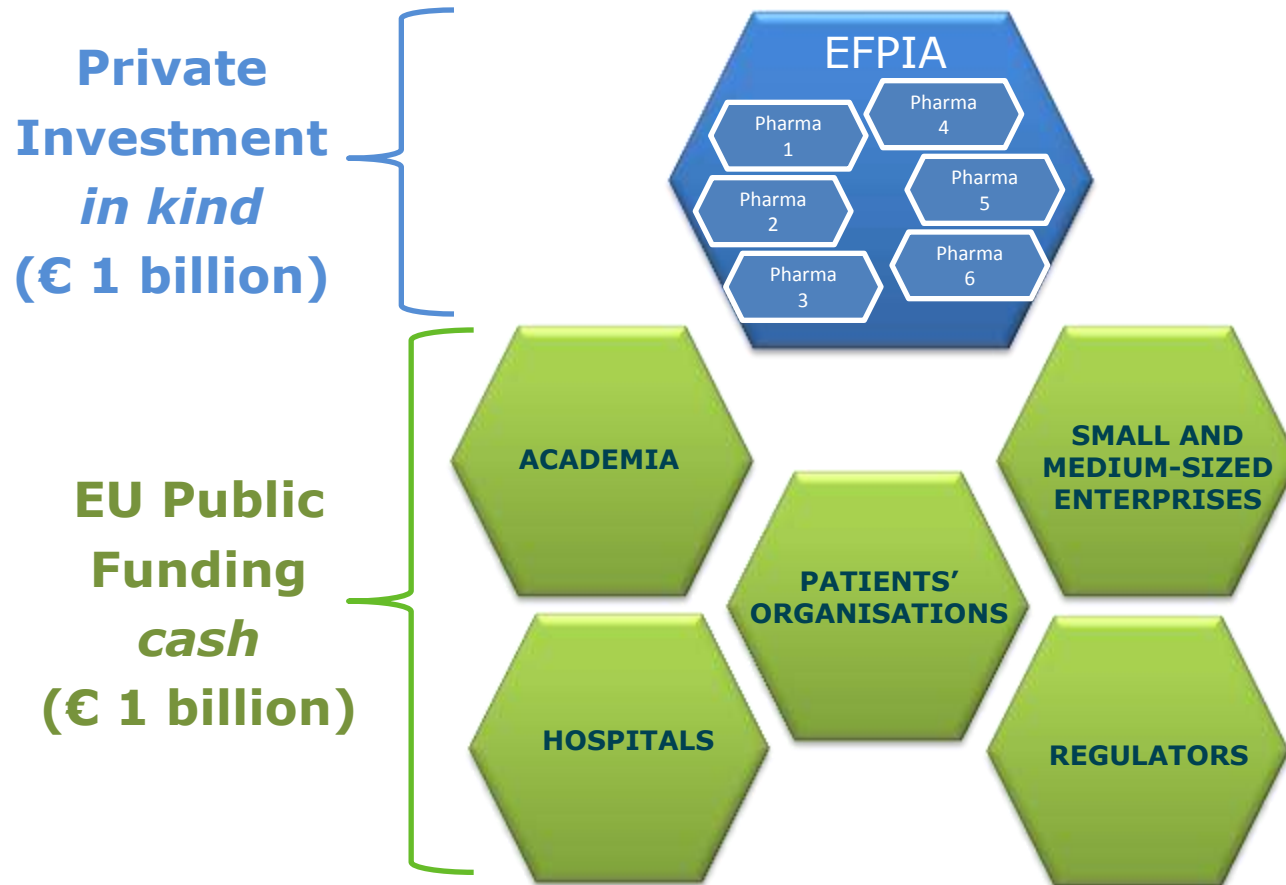
The screenshot shows a web browser window displaying the IMI Partner Search Tool. The browser's address bar shows the URL: `http://localhost:4514/content/imi-pst/en/secure/partnersea`. The page features the IMI logo and the text 'Innovative Medicines Initiative' at the top. A navigation menu on the left includes links for 'Home', 'My Data', 'Participant Search' (which is highlighted), and 'Log Out'. Below the menu, there is a section for 'IMI Members' with logos for the European Union and 'efpia'. The main content area displays a welcome message for 'Michel Goldman' and a 'Participant Search' section. This section includes a dropdown menu with the selected option 'I'm looking for partners having experience with...'. Under this, the 'Medical Information Framework (EMIF)' is expanded, showing a list of search criteria with checkboxes:

- ☐ Patient level health data providers
- ☐ Patient level health data users
- ☐ Paediatric data providers
- ☐ IT knowledge and architecture expertise
- ☐ Systems Biology models
- ☐ Health data management
- ☐ Health data analysis
- ☐ Interoperability and data standards
- ☐ Expertise in obesity and metabolic complications
- ☐ Expertise in Alzheimer disease and its predictive factors
- ☐ Paediatric expertise
- ☐ Extreme phenotype research approach
- ☐ Expertise in -omics
- ☐ Epidemiology
- ☐ Data governance -privacy/ethics

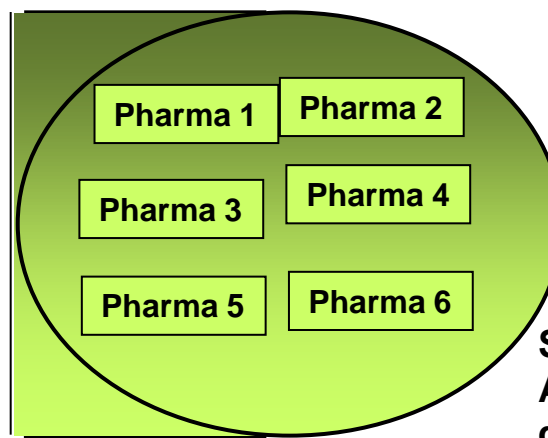
Stage 2: Joint Preparation of a Full Project Proposal



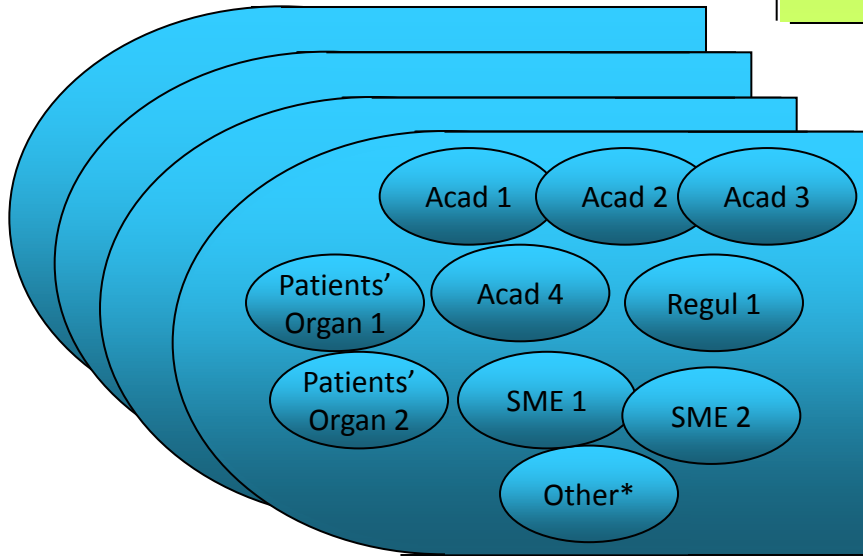
A Typical IMI Consortium



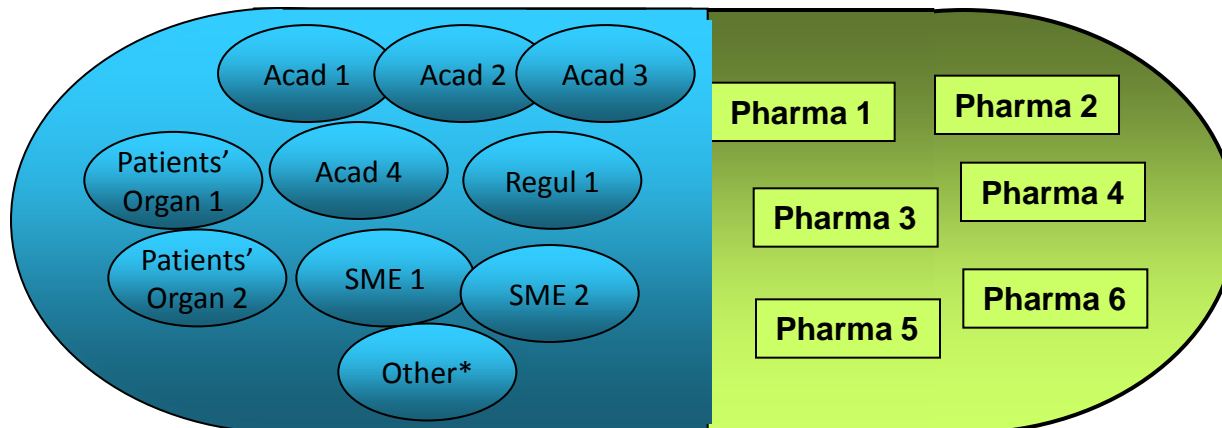
Building an IMI Consortium



Step 1:
A set of EFPIA companies
define a topic of common interest

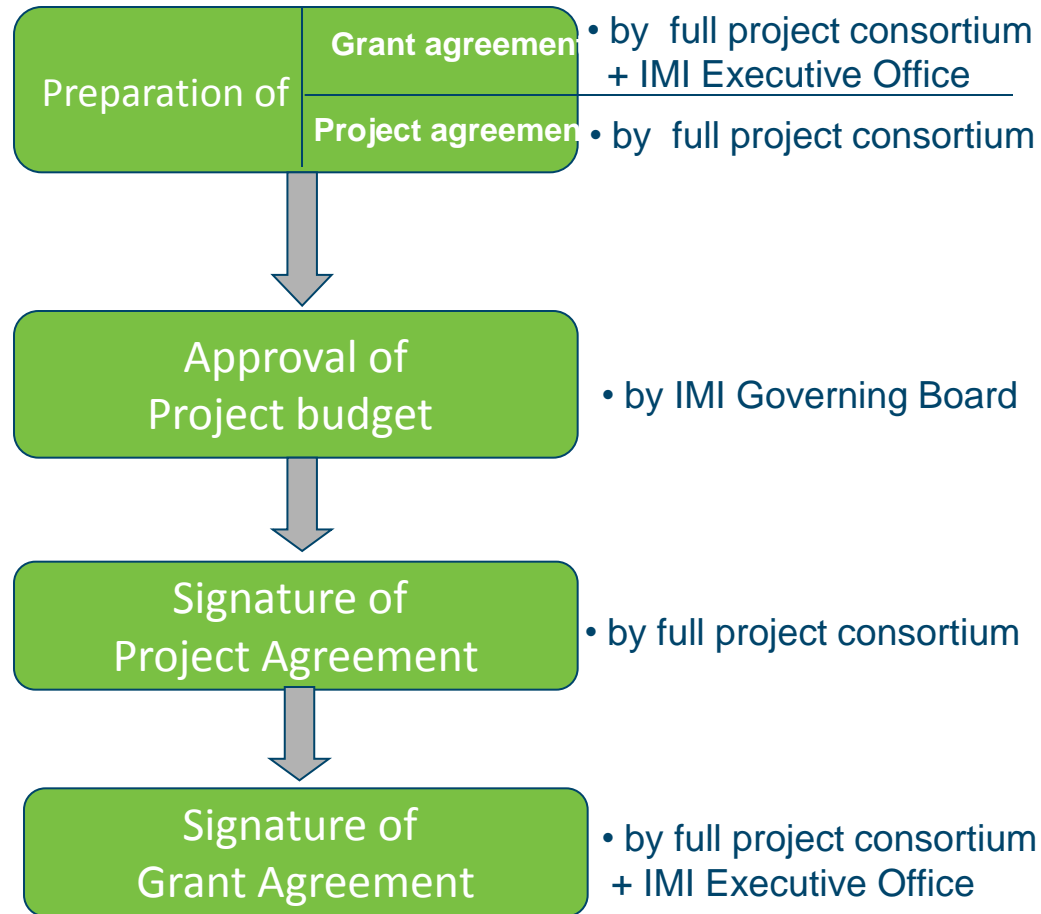


Step 2:
Consortia eligible for EU funding
compete through expressions of interest
which are ranked by independent experts



Step 3:
The top-ranked consortium joins
the EFPIA companies to develop
a full project proposal, subject to
peer-review.

Contract Negotiation & Grant award



Basic principles on IMI funding



Funding in IMI



Who is eligible to receive IMI funding (public funding):

- Academia
- SMEs
- Patient Organisations
- Non-profit research organisations
- Intergovernmental organisations

Contribution in-kind (samples, expertise, personnel):

- EFPIA companies
- Companies not falling within the EU definition of SMEs
- Others

- **Direct costs** (personnel, consumables, equipment,...)
- **Indirect costs = overheads**
 - Flat-rate of 20% of direct eligible costs
 - or**
 - Actual indirect costs
- **Funding rates**
 - **Research activities**
 - 75% of total eligible costs
 - **Other activities**, including management and training activities
 - 100% of total eligible costs

Intellectual Property: Guiding principles



Aligned with IMI objectives -> PPP, specific research needs and challenges:

- To achieve a broad participation
- To promote knowledge creation, disclosure and exploitation
- To achieve fair allocation of rights and reward innovation
- To provide flexibility for participants to establish the most appropriate agreements serving the project objectives -> Project Agreement



- **Background** remains the exclusive property of each participant
- **Foreground** (Project results) are owned by the generator(s)
- Possibility to **freely license, assign or otherwise dispose** of its ownership rights provided access rights to other partners are respected
- **Possible transfer** of ownership

IP: Access Rights basic principles



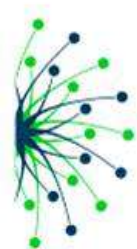
- Granted on **written request**, unless otherwise agreed
- **Non-exclusive** basis approach
- **No sub-licences**, unless otherwise agreed
- Not affected by the termination of participation
- Guiding framework for participants, affiliates and third parties
- Terms: royalty-free basis / fair and reasonable / to be negotiated

The Project Agreement



- Contractual arrangement **between all participants** to set out their rights and obligations, especially governance, liability and IPR
- Shall comply with the IMI model Grant Agreement
- Mandatory before the signature of the grant agreement with the Executive Office
- **To be adapted to the specific needs of each IMI project!**

- Dedicated point of contact: Hugh.Lavery@imi.europa.eu
- Improving communication with SMEs
 - European Biopharmaceutical Enterprises
 - EuropaBio
 - European Biotechnology Network
 - National and regional organizations
 - Enterprise Europe Network
 - SMCpharma
- Working closely with Commission and EFPIA
- Reducing the administrative burden



Some best practices:

- **IMIDIA**
 - Endocells Sàrl, France
- **NEWMEDS / BioVaSafe / EU-AIMS / STEMBANCC**
 - Islensk Erfdagreining Ehf (deCODE), Iceland
- **eTOX**
 - Molecular Networks GmbH, Germany
- **PharmaCog**
 - Innovative Health Diagnostics, France



What is in the future of IMI?



A future PPP under Horizon 2020

Moving forward with a PPP in Innovative Health Research

- Will be based on experience from IMI

Criteria to be fulfilled:

- Added value of action at the Union level
- Scale of impact on industrial competitiveness, sustainable growth and socio-economic issues
- Long-term commitment from all partners based on a shared vision and clearly defined objectives
- Scale of the resources involved and the ability to leverage additional investments in research and innovation
- Clear definition of the roles for each of the partners and agreed key performance indicators over the period chosen
- Continued partnership with EFPIA
- Plan to enlarging partnership to include vaccine, medical imaging and medical information technology industries

Keep up to date

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- Join the IMI group on [LinkedIn](#)
- Visit www.imi.europa.eu





Innovative Medicines Initiative

Thank you for your attention!



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