



EU Commission/EFPIA Public-Private Initiative to Support Innovation: The Innovative Medicines Initiative

- EFPIA RDG's point of view

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The Innovative Medicines Initiative

History and Future

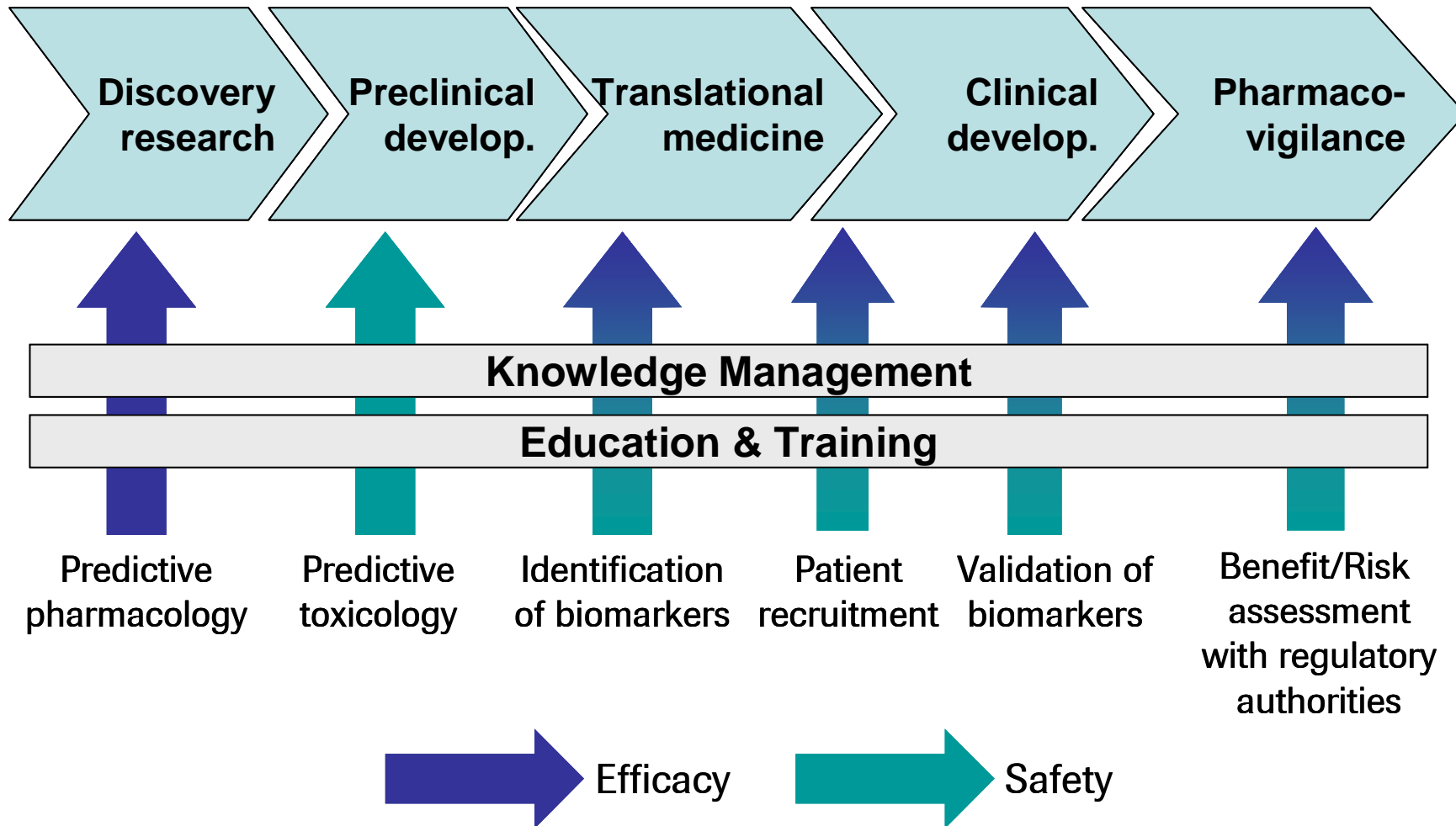


- Joint initiative between EFPIA and European Commission in 2004 – consultation with stakeholders throughout 04/05.
- Pilot proposal generated and now funded under Framework Programme 6: InnoMed
- Strategic Research Agenda: www.imi-europe.org
- IMI to be proposed as a Joint Technology Initiative under Framework Programme 7
- 2 billion euros over 7 years, shared equally between EFPIA members and the EC



The Innovative Medicines Initiative

Strategic Research Agenda focus on the “pre-competitive”
bottlenecks in the R&D Process



SAFETY: Making Medicines Safer



- Main recommendations:
 - Create a European Centre for Drug Safety Research
 - Establish a framework for biomarker development to study human relevance and regulatory utility
 - Develop computational methods for predicting toxicity
 - Pharmacovigilance: Develop novel methods of risk prediction and benefit-risk assessment
- Outcomes:
 - Reduced late stage failure
 - Better post-marketing risk-benefit analysis
 - Higher rate of approval based on improved risk management
 - Reduced burden of mandatory post-approval trials
 - Faster delivery to patients but with reduced risk

EFFICACY: Making Medicines More Effective



- Main recommendations:
 - Focus on areas of high scientific challenge
 - cancer, inflammatory disease, brain disorders, metabolic disease, infectious disease
 - Stimulate translational medicine
 - Create disease-specific imaging networks
 - Develop partnership with regulators for innovative clinical trial design and acceptance of biomarkers
- Outcomes:
 - Reduced failure rate at proof of concept and later
 - Greater efficacy of new medicines
 - Better more robust measures of efficacy addressing patient need
 - Reduced burden of clinical trials

KNOWLEDGE MANAGEMENT and EDUCATION & TRAINING Underpinning Infrastructures



KM

- Main recommendations:
 - Enhanced knowledge representation models and data exchange standards for complex systems
 - Core reference database of validated experimental data extracted from the literature
 - Expert tool to allow the federation of local databases in a secured environment

E&T

- Main recommendations:
 - Create a European Medicines Research Academy for education and training for professionals involved in biomedical R&D and regulation
 - Develop programmes for the critical areas of need
 - Foster mobility and understanding between academia and industry

Impacts in the R&D Process

What could change?



Doing what we do now but better and/or faster

- Predictive toxicology
- Predictive pharmacology
- Pharmacovigilance

Doing things differently

- Patient databases
- Patient recruitment
- Clinical trial design
- Approval

IMI Rules for Participation



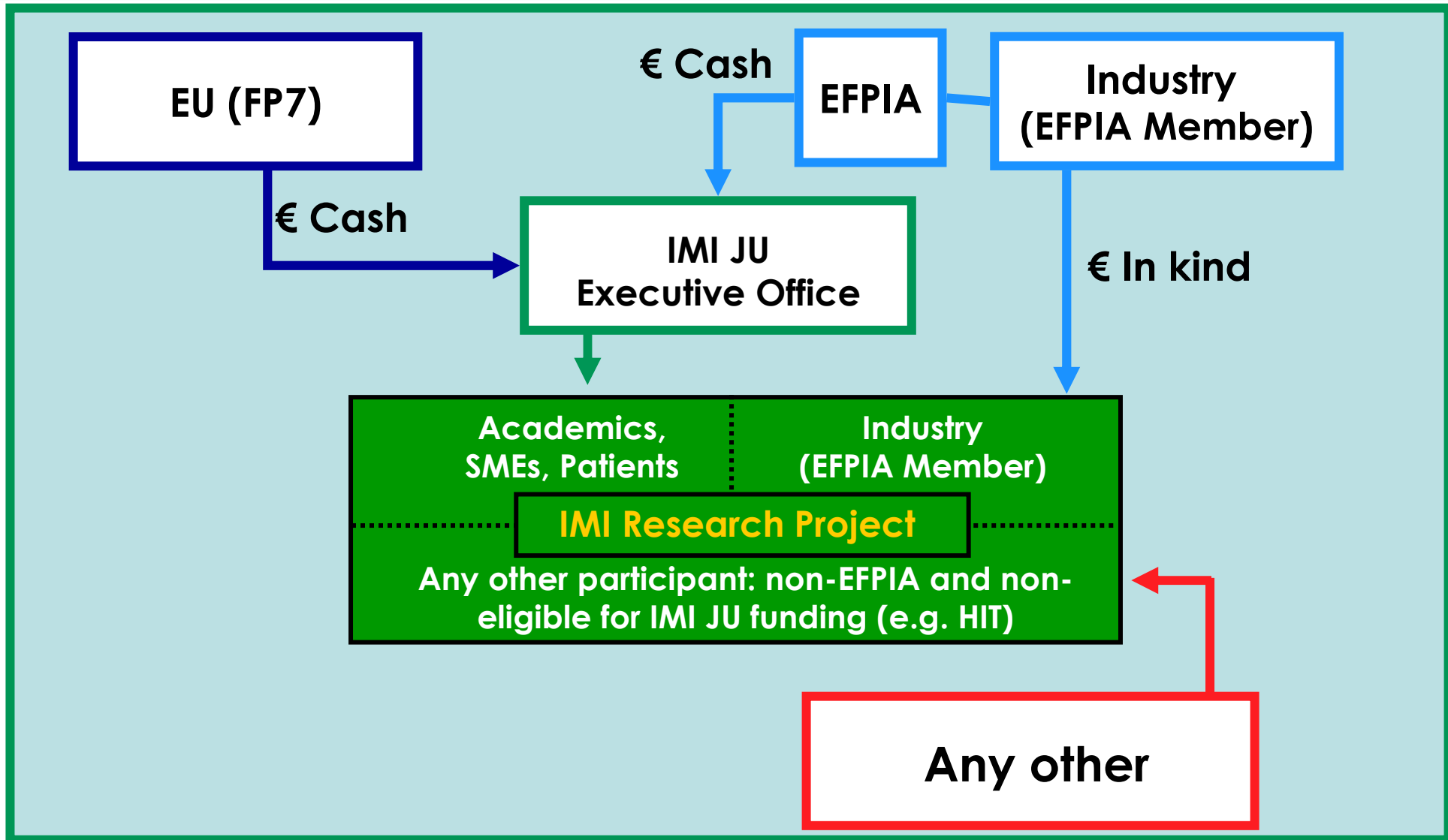
- Participants in a Project shall carry out the work themselves
- Any legal entity established in any country can participate in Projects, provided that the relevant research is performed in Europe
- Projects must include at least one legal entity who is member of EFPIA and one legal entity who is not a member of EFPIA
- Legal entities participating in the same Project must be independent of each other

IMI Funding Principles

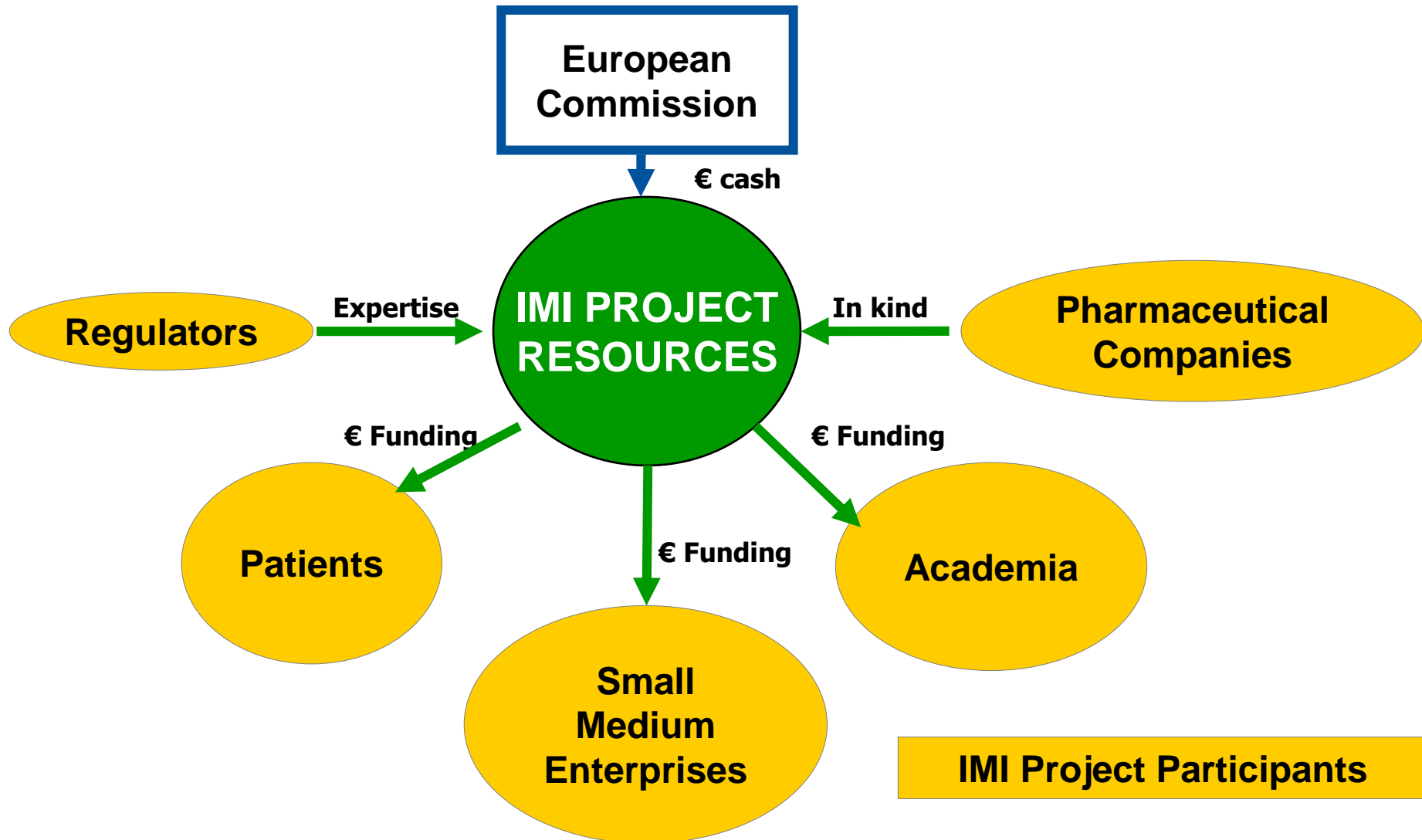


- SMEs, public bodies, secondary and higher education establishments, and research organisations will be eligible for funding by IMI
- All for-profit legal entities outside these categories shall carry their own costs for participating in an IMI Project
- Unless otherwise specified in the call, project budgets will aim at a 50:50 ratio between *in cash* financial contribution from IMI JU and *in kind* contributions from EFPIA members.

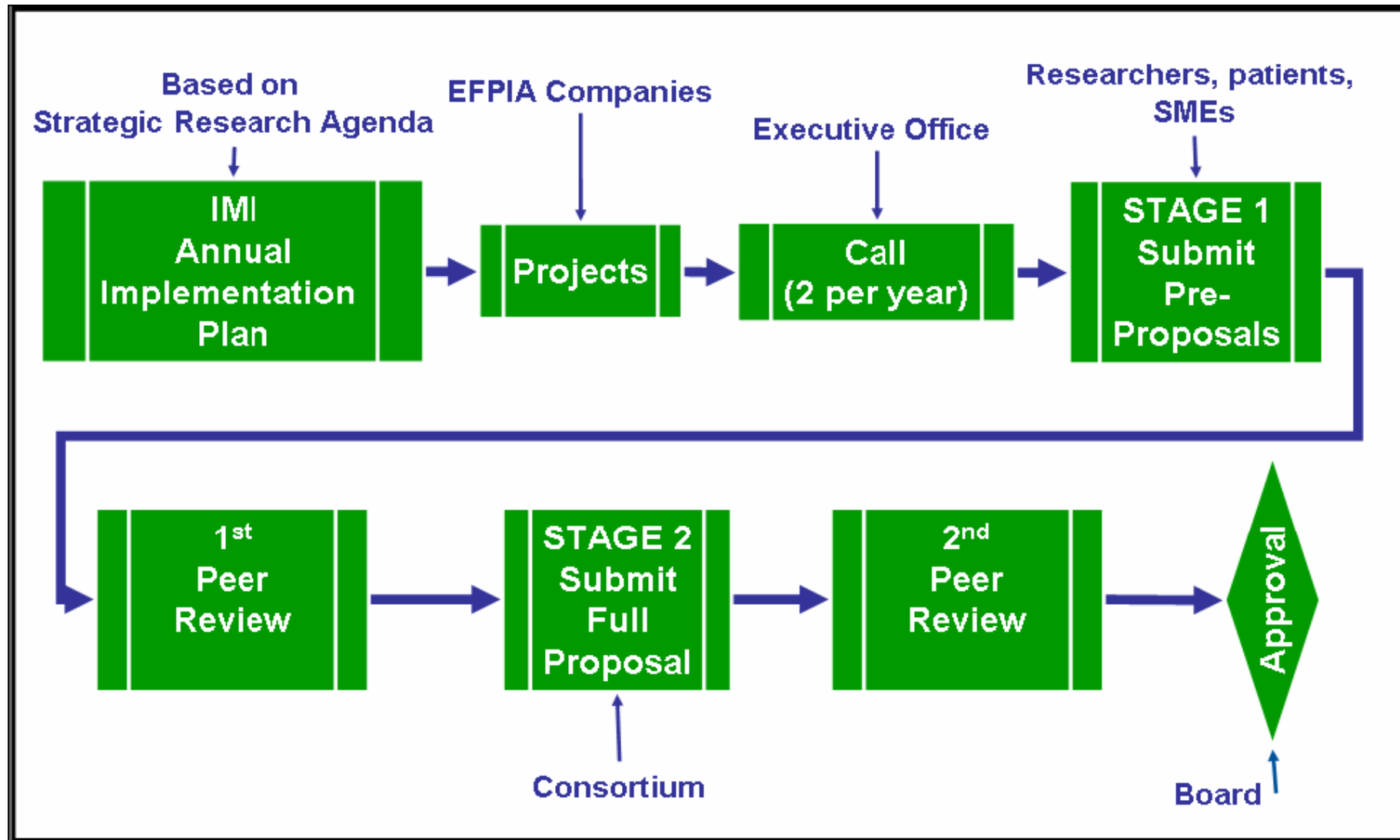
IMI Funding Flow and Contributions



Project Participants & their Contribution



IMI Call Process



Peer Review



Peer Review Committees:

- Standing Peer Review Committees to be established
- One for each of the Four Pillars of the Strategic Research Agenda
- Assisted by ad hoc experts relevant to the call topics (including EFPIA participants in 1st round)

Responsibility:

- To evaluate science of Pre-Proposals
- To evaluate Full Proposals based on science and feasibility

Composition:

- Members reflecting a balance of public-private research expertise
- Policy to prevent Conflict of Interest

Decision Making:

- By consensus between all experts

Intellectual Property Rights Policy *Objectives*



- Promote knowledge creation and dissemination
- Promote knowledge exploitation
- Promote participation in IMI Projects of:
 - Academic institutions
 - Small biopharmaceutical companies
 - Large biopharmaceutical companies

How do we get started?



- Need to put out a call as soon as IMI is approved by the Competitiveness Council
- Interim structure (EFPIA/EC) to manage first call prior to establishment of Executive Office
- EFPIA RDG currently selecting topics
 - Priorities for RDG members
 - Preclinical safety, pharmacovigilance, brain disease, diabetes, E&T
 - KM support
 - Workshops/consultation
 - Alignment with other initiatives (eg Critical Path, EMEA)
 - Quick wins and long term
 - Notional budget of 250m euros
 - 50/50 contribution

Why is IMI a good thing?



- Industry led
- Scope and duration
- Organisational structure gives flexibility and coordination
- Public money matching private resource is a great incentive to join
- Encouragement of openness
- Willingness on all sides to succeed
- Enthusiastic cooperation of regulatory authorities
- Boost to SME business development
- Long term effect on healthcare provision