The Innovative Medicines Initiative (IMI)

Overview of IMI

efpia

- European Technology Platforms
- Joint Technology Initiatives
- Health research in FP7
- History of Innovative Medicines Initiative (IMI)
- Governance of IMI
- How IMI is proposed to work
- Added value
- Expected timeframe
- More information

European Technology Platforms

Rationale

- Contribute to Competitiveness - Lisbon objective
- Boost research performance - ERA, 3% target (1/3 public sector, 2/3 private sector)
- Positive impact on other Community policies
- Concentrate efforts and address fragmentation

Concept

- Provide framework to bring stakeholders together
- Develop common “vision” for a specific technology
- Mobilisation of critical mass of research and innovation effort
- Definition of a Strategic Research Agenda

European Technology Platforms

Stakeholders getting together to define a Strategic Research Agenda on a number of strategically important issues with high societal relevance where achieving Europe's future growth, competitiveness and sustainable objectives is dependent upon major research and technological advances in the medium to long term.

Stage 1: Stakeholders get together

Stage 2: Stakeholders define a Strategic Research Agenda

Stage 3: Stakeholders implement the Strategic Research Agenda

European Technology Platforms

- Implementation under the 7th European Framework Programme for Research 2007-2013 (FP7)

- Majority of European Technology Platforms

  ⇒ Supported using funding schemes under Cooperation Specific Programme (collaborative research)

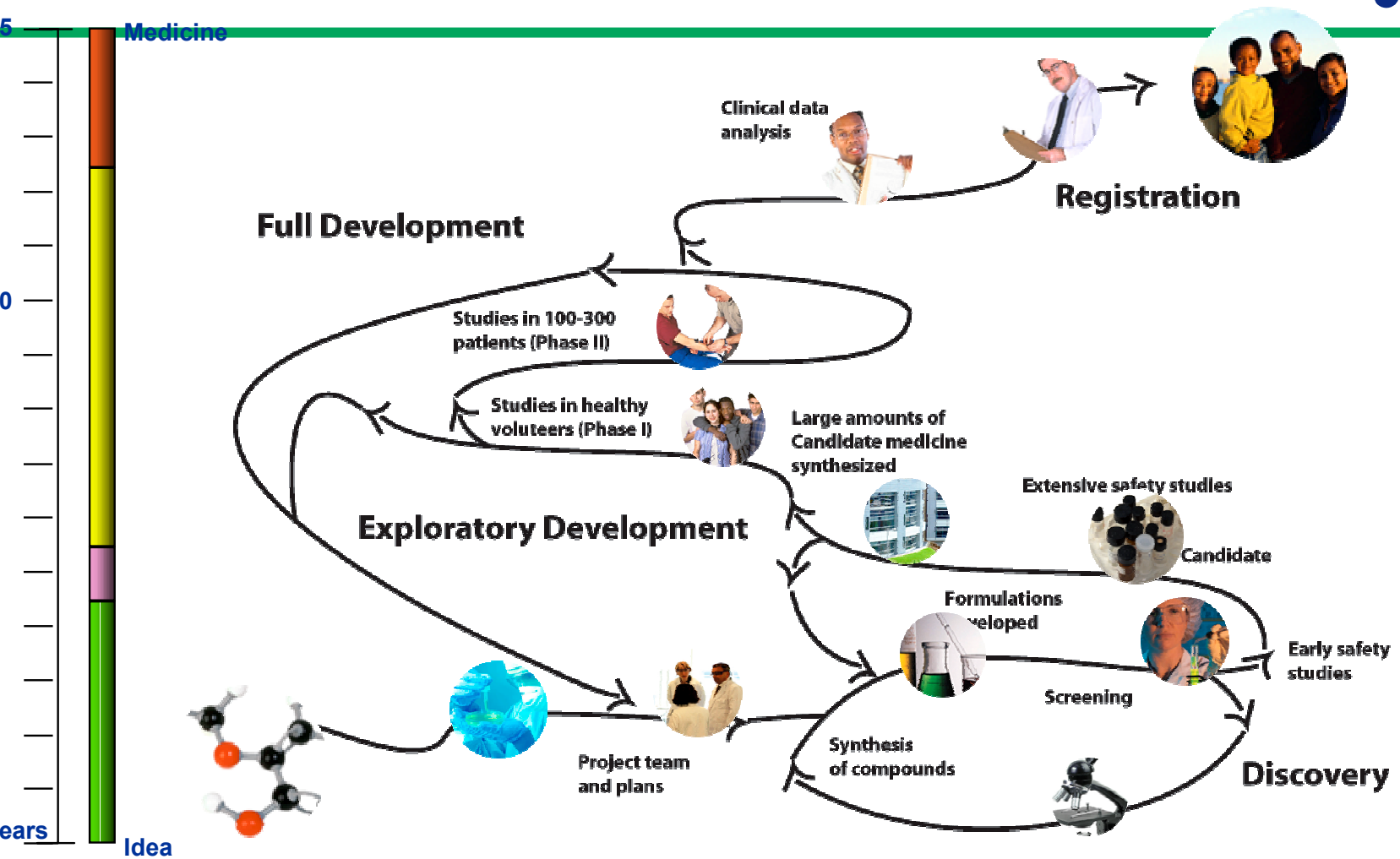
- Small Minority

  ⇒ Joint Technology Initiatives

Joint Technology Initiatives (JTIs)

- Establish long-term public-private partnerships in research at European level
- Co-ordinate research efforts and respond to industry needs
- Focus on fields of high industrial and policy relevance
- Build on European Technology Platforms
- To be implemented through new organisations established as Joint Undertakings under Article 171 under the EC Treaty
- Four proposals on the table of the EU Member States for decision
- IMI, Clean Sky, ARTEMIS, ENIAC

Challenges in the pharmaceutical sector



Creating new medicines is a high risk journey

EU Challenges for biopharmaceutical R&D

- Pharmaceutical R&D moving out of Europe
- Public spending on health R&D lower and stagnating compared to the US
- Private investments in sector (VCs, etc.) much lower than the US, and increasing risk adversity among investors
- Fragmentation of research efforts – basic, clinical and industry
- Escalating drug development costs, high failure rates

EU challenges for biopharmaceutical R&D Identifying research needs

EC challenged industry to identify the bottlenecks to pharmaceutical innovation and where R&D is the key.

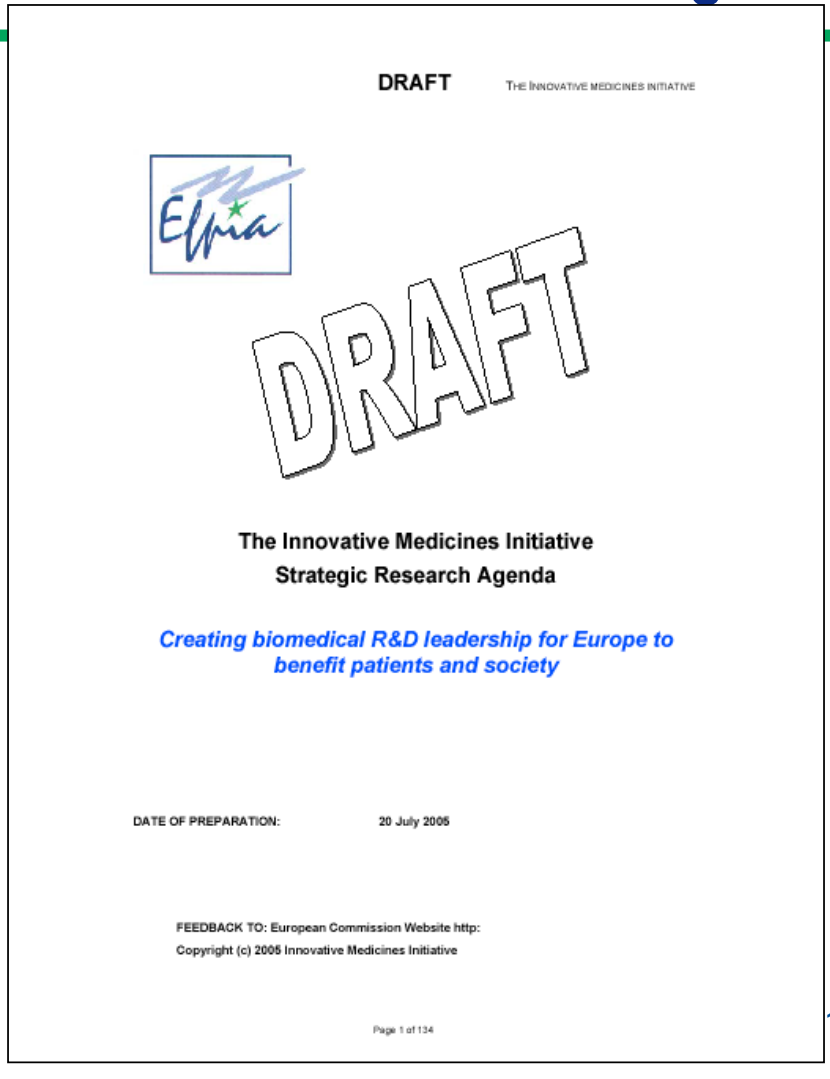
Industry via EFPIA's Research Directors Group responded by identifying 4 areas for R&D in agreement with key stakeholders (patients, regulators, clinical and academic researchers, etc.):

- Predictive safety
- Predictive efficacy
- Knowledge management
- Education and training

and the Innovative Medicines Initiative (IMI) was created

IMI: The Strategic Research Agenda

- A unique achievement based on:
- EFPIA's Vision paper (Nov 2004)
- Workshops engaging the key stakeholder groups in setting research priorities (Jan-May 2005)
- Draft SRA published (July 2005)
- Consultation with EU Member State contacts and EMEA's CHMP and COMP (autumn 2005)
- New version of the SRA (Sept 2006)
- The SRA is a 'living' document



DRAFT THE INNOVATIVE MEDICINES INITIATIVE

DRAFT

The Innovative Medicines Initiative
Strategic Research Agenda

Creating biomedical R&D leadership for Europe to benefit patients and society

DATE OF PREPARATION: 20 July 2005

FEEDBACK TO: European Commission Website http:

Aims and Objectives

Aim

- To remove major bottlenecks in drug development, acting where research is the key

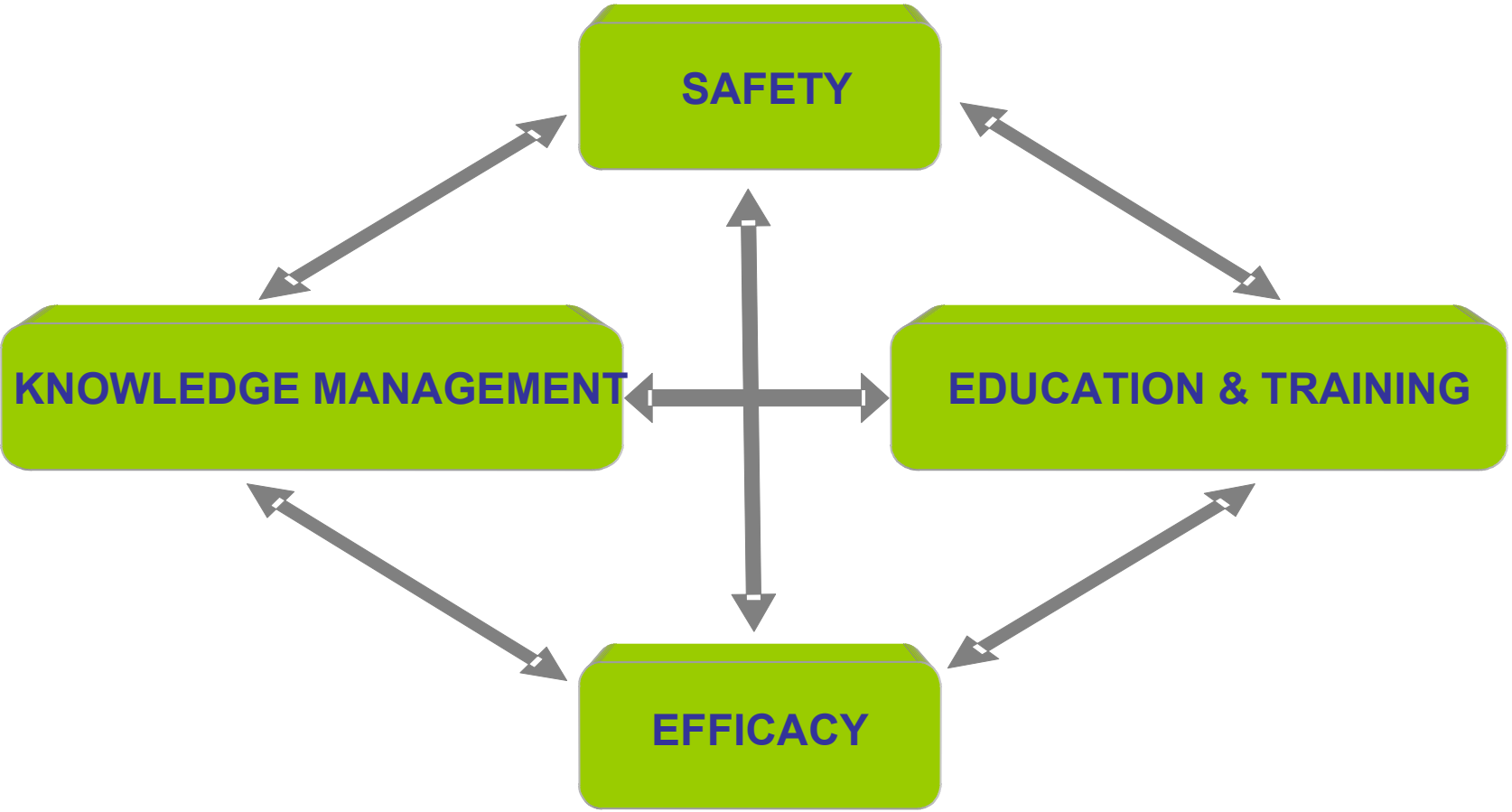
Long term objectives

- To increase competitiveness of European pharmaceutical sector and foster Europe as the most attractive place for pharmaceutical R&D, thereby enhancing access to innovative medicines for patients

Funds


2 Billion EURO
1 Billion Euro
1 Billion Euro
efpia
European Federation of Pharmaceutical Industries and Associations
Public
Private
Partnership

IMI Focus Research Areas



Source: EFPIA

IMI - Core activities and goals

- IMI will foster the development a new « toolbox » (toxicology tests, biomarkers, clinical trials protocols, etc.) for drug developers to reduce the risk of failure of new medicines in the drug development process (pre-clinical and clinical phases).
- IMI will provide the opportunity for validation of the new tools in view of rapid uptake into regulatory and industry practice.
- IMI will set up ‘knowledge platform’ pooling data from toxicology testing and biomarker validation will be set up and will be available to all researchers (industry and academic).
- IMI will not develop new medicines or new vaccines!

Governing structure

= Legal entity established upon decision of European Council to implement IMI

IMI Joint Undertaking (IMI JU)

Board

Executive Office

Scientific Committee

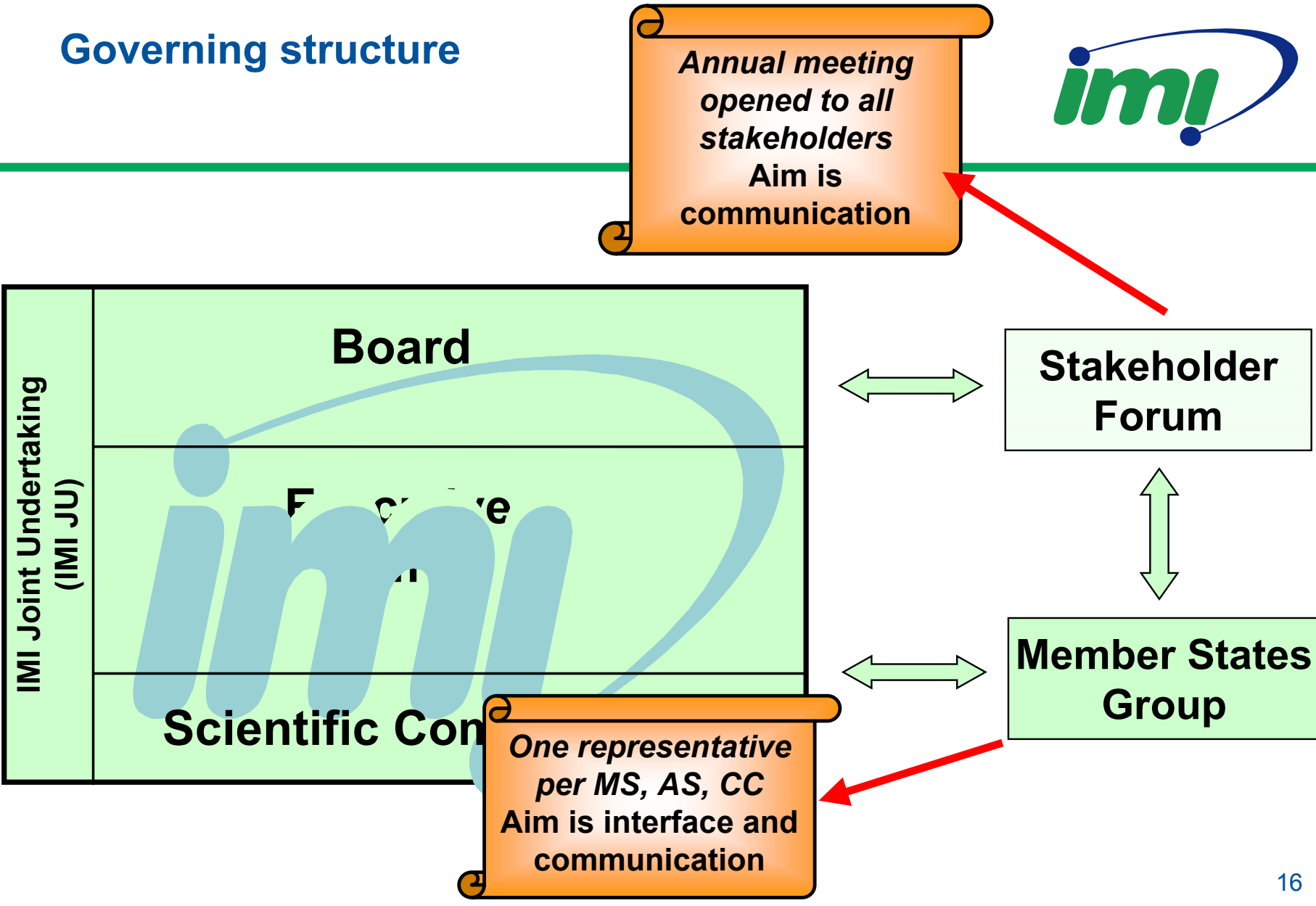
2 Founding Members

Has overall responsability for the operations of IMI

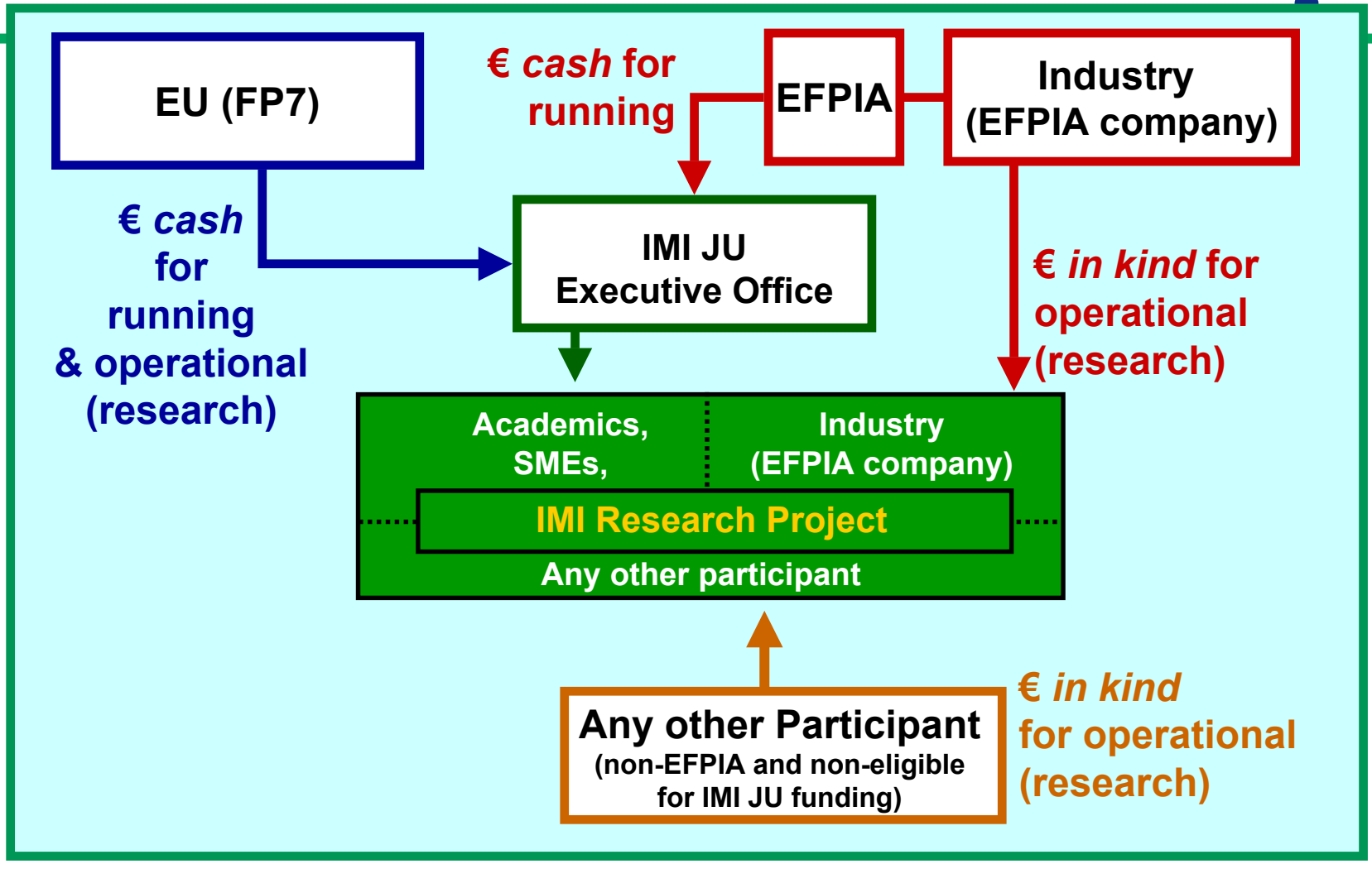
Executive Director + Staff
Responsible for day-to-day management

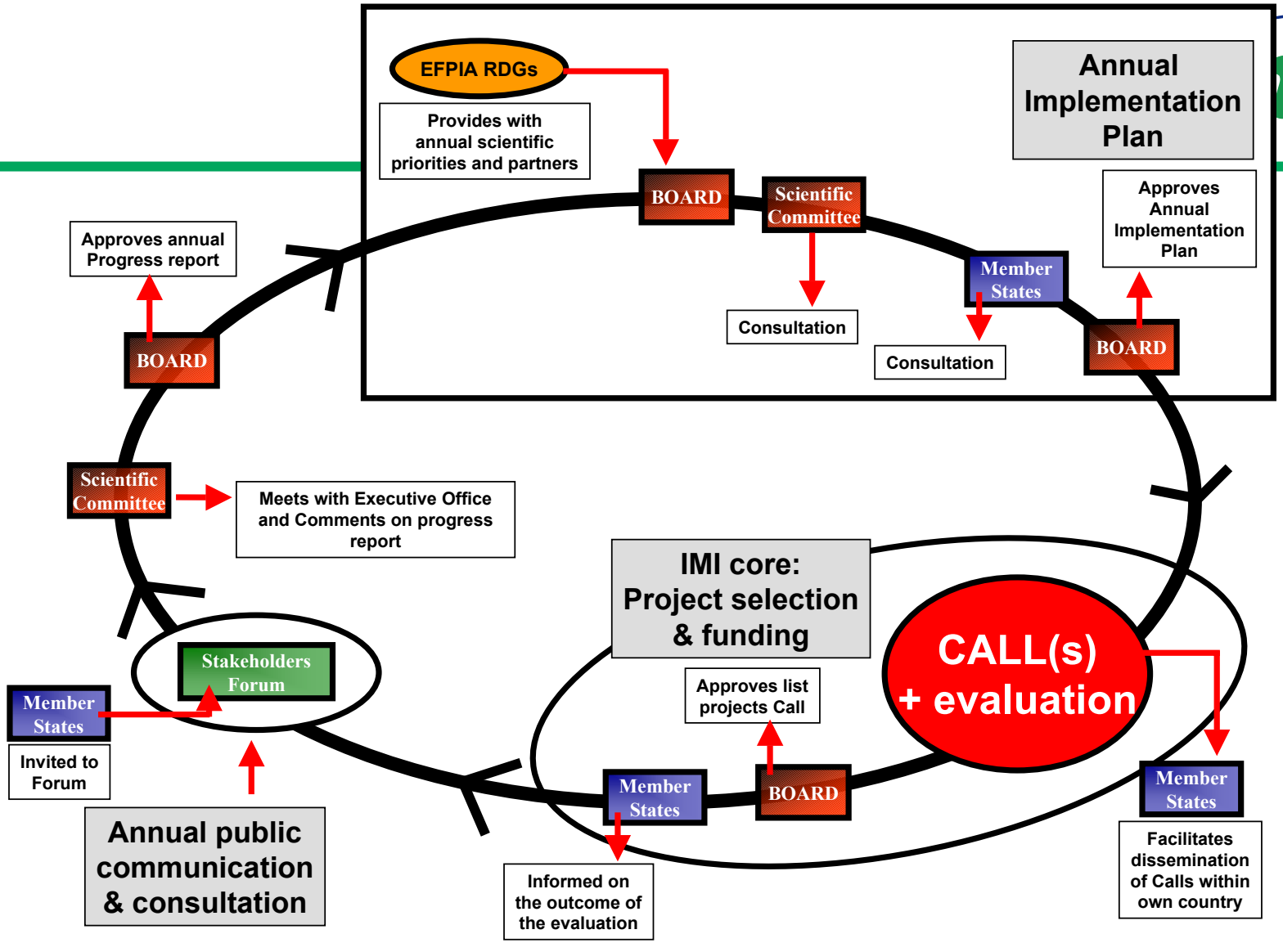
15 representatives
Advising the Board and Executive Office

Governing structure

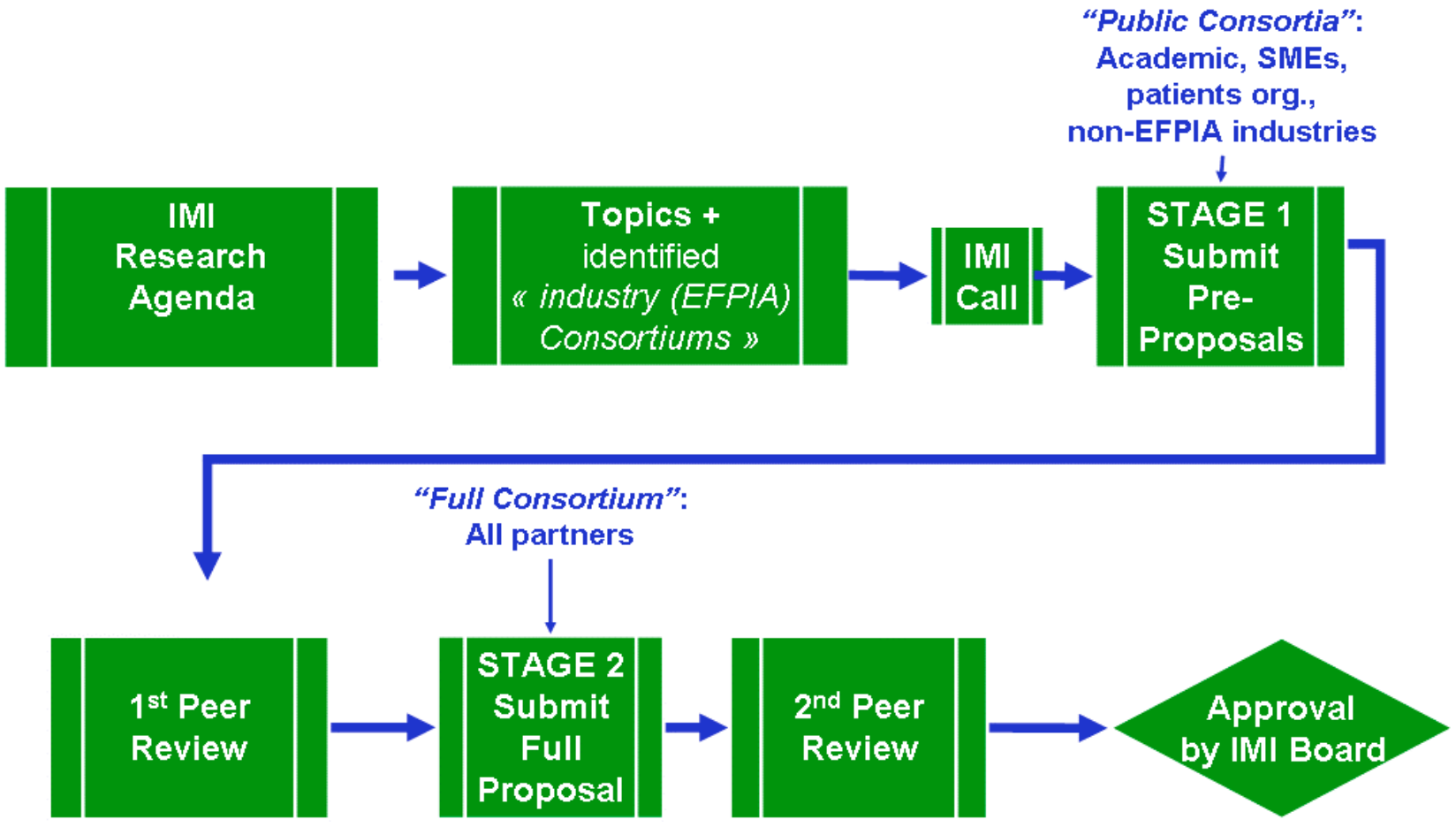


IMI Funding Flow and Contributions

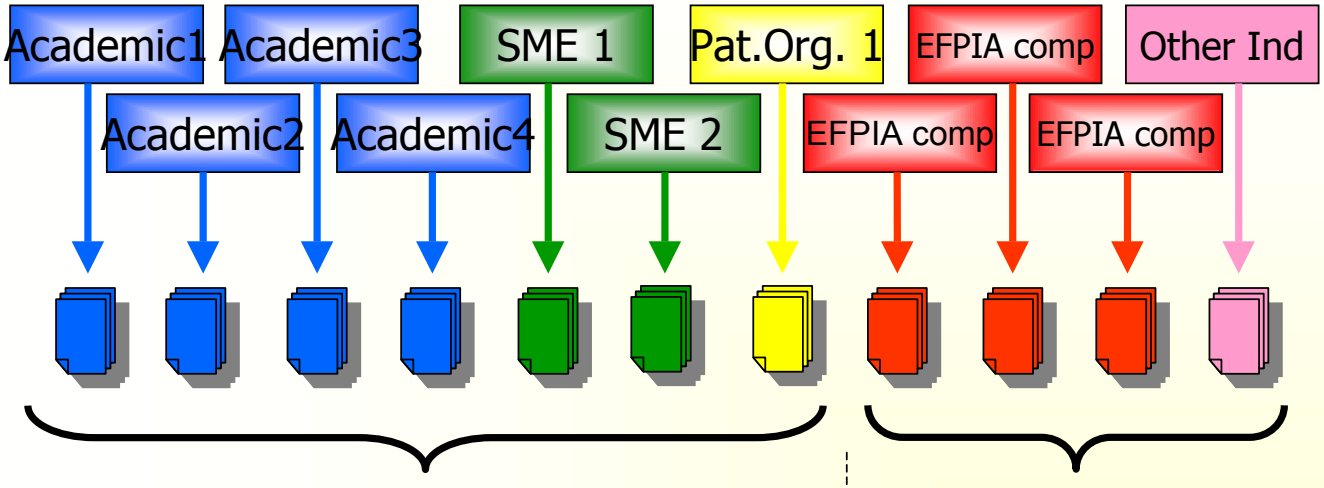



EFPIA RDGs
Provides with annual scientific priorities and partners
BOARD
Scientific Committee
Consultation
Member States
Consultation
BOARD
Annual Implementation Plan
Approves Annual Implementation Plan
Approves annual Progress report
BOARD
Scientific Committee
Meets with Executive Office and Comments on progress report
IMI core: Project selection & funding
CALL(s) + evaluation
Approves list projects Call
BOARD
Member States
Informed on the outcome of the evaluation
Member States
Facilitates dissemination of Calls within own country
Stakeholders Forum
Member States
Invited to Forum
Annual public communication & consultation

IMI Call for proposals



Financial reporting for participants in an IMI project & *in kind* contribution from industry



Composition of a typical IMI project

Financial reports
- Cost statement
- Audit certificate

IMI JU contributes up to:
- 75% for RTD costs
- 100% for management and training costs

Contribution counted as « EC contribution »

IMI JU contributes up to:
- 0% for any costs

Only EFPIA member companies costs counted as « EFPIA *in kind* » contribution

IMI JU Research expenditure

IMI - Funding Principles

- As a general principle, the participants in a Project shall have the capacity to carry out the work themselves
- Any legal entity established in any country can participate in Projects, provided that their research activities related to the Project are performed in EU Member States our in countries associated to FP7
- Projects must include at least two legal entities who are members of the EFPIA and two legal entities who are not a members of EFPIA and who is eligible to receive IMI funding
- 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, not falling within EU's definition of Small and Medium Enterprises (SMEs), of public bodies, of secondary and higher education establishments, and of research organisations, shall carry their own costs for participating in an IMI Project.

- Project budgets shall aim at a 50:50 ratio (unless otherwise specified in the call) between in in kind contributions from EFPIA Members and the financial contribution from IMI

Costs categories for any participant of an IMI project (industry, academic, SMEs, …)

Direct eligible Costs			Indirect eligible Costs
Activities	**Category**	**Details**	
Research activities	Personnel	FTEs in hours	Flat rate of 20% of Direct eligible costs, excluding subcontracting
	Equipment	Option 1 Purchase of equipment Option 2 Depreciation of equipment Option 3 Leasing of equipment	
	Protection of knowledge		
	Consumables & Materials		
	Other	E.g. Subcontracting for services	
Management activities	Personnel	FTEs in hours	
	Travel and subsistence	Meetings, workshops	
Training activities	Courses	FTEs in hours for teachers, fees for participants, travel and subsistence for participants, facilities, equipments. Salary costs of those being trained are not eligible	

Principles of the

IMI IPR policy

The IMI IPR Policy Must Align with the Objectives of IMI

- **IMI aims to remove the bottlenecks in R&D by conducting pre-competitive collaborative research in Europe utilising public (EU) and pharmaceutical industry resources**

  → IMI findings (Foreground) must be widely and readily available for research into the discovery and development of medicines

  → Information that Participants bring into a Project (Background) that is necessary for the research use of IMI findings (Foreground) must be widely and readily available for research into the discovery and development of medicines

- **IMI is a <u>public-private partnership</u>**

  → IMI (including its IPR policy) should <u>provide incentives for all actors</u> (academic, large pharmaceutical industry, SMEs) to participate in IMI projects

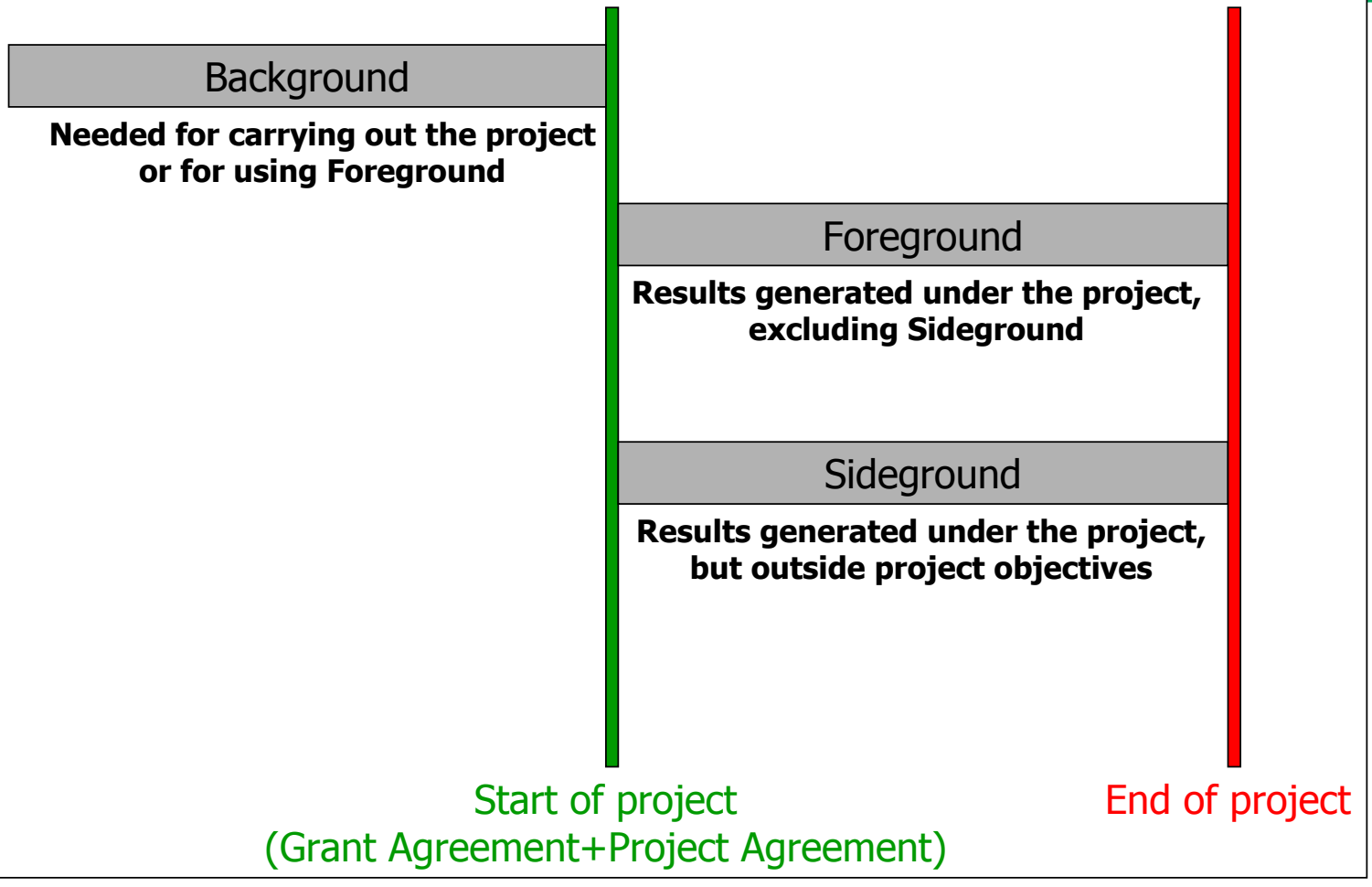
The IMI IPR Policy Must Align with the Objectives of IMI

⇒ Split of FP7 “Use” into IMI “ Research use” and “Direct exploitation”

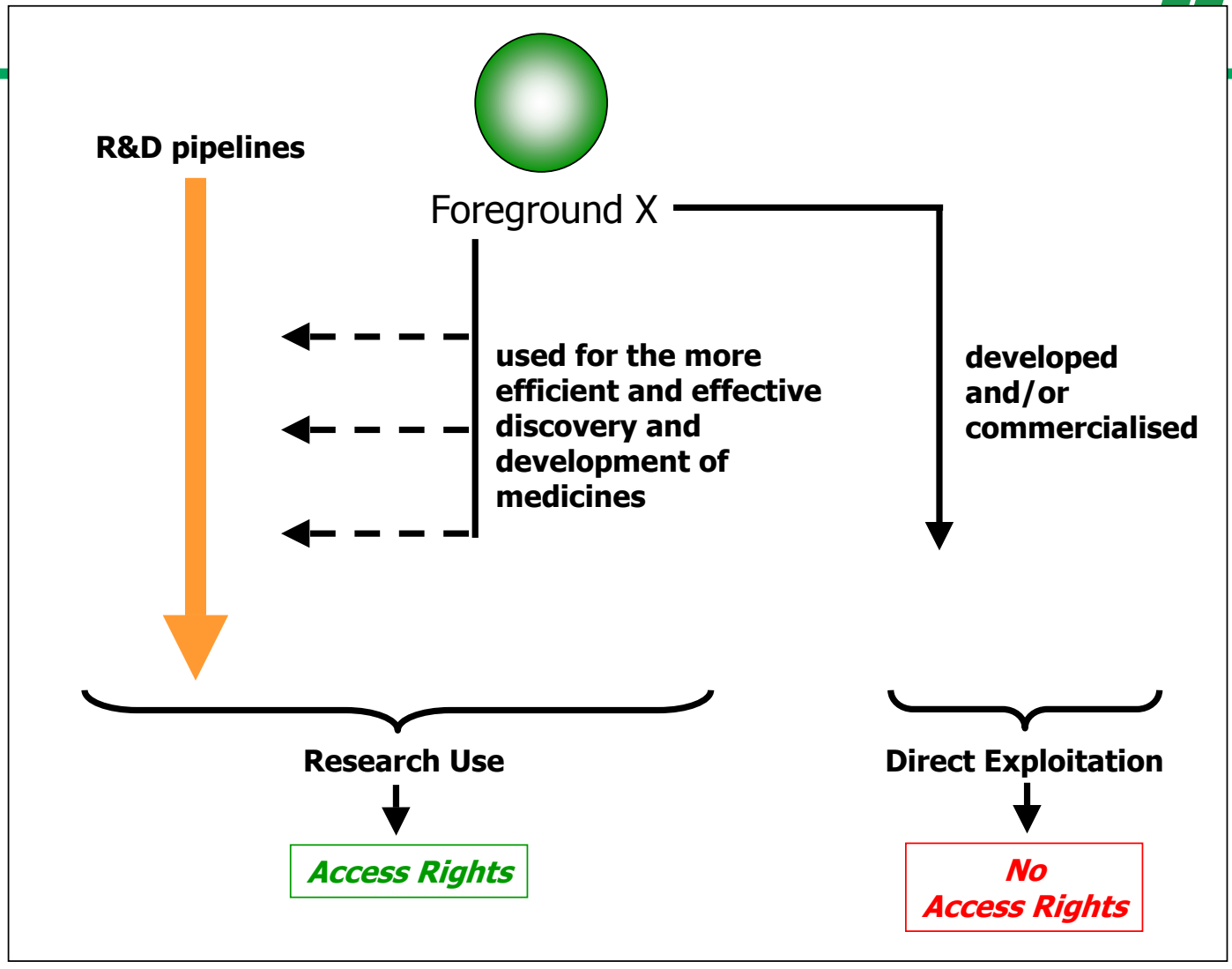
⇒ Compared to FP7, IMI would provide broader access to Foreground, but for a more restricted use (= only for “research use”):
(i) during and after completion of the project for participants;
(ii) after completion of the project for third parties

- **Background, Foreground, Sideground of a Participant**

  Relates to data, know how, information and intellectual property rights



2. Research Use and Direct Exploitation



General principles for ownership and access rights

	Background	Foreground	Sideground
Ownership	Each participant remains exclusive owner of its Background	The participant who generated it. If several participants: joint ownership. Possible to agree otherwise in Project Agreement	The participant who generated it. Possible to agree otherwise in Project Agreement
Right for a participant to transfer its ownership	Free to transfer ownership, subject to rights and obligations of the Grant/Project Agreement (i.e. buyer accepts the same legal position in relation to project). Notify the other participants after transfer	Only transfer if OK in Grant Agreement, Project Agreement or all participant agreed. Only deny to agree if affected. OK to affiliate.	
Right for a participant to license, use and exploit independently of the other participants	Right to independently non-exclusive license and otherwise use	Right to independently non-exclusive license and otherwise use	
Access rights for participants for the purposes of completing the project	Royalty free and non exclusive license for Background needed for carrying out the project	Royalty free and non exclusive license	
Access rights for participants (and affiliates) for Research Use during the project or after completion of the project	Non exclusive license on fair and reasonable terms or royalty free for Background needed for using Foreground, as determined in the Project agreement	Non exclusive license on fair and reasonable terms or royalty free, as determined in the Project agreement	
Access rights for Third Parties for Research Use after completion of the project	Non exclusive license on fair and reasonable terms for Background needed for using Foreground, as determined in the Project agreement	Non exclusive license on fair and reasonable terms, as determined in the Project agreement	
Rights for participants (and affiliates) or Third Parties for Direct Exploitation after completion of the project	No access rights. Subject for commercial negotiation	No access rights. Subject for commercial negotiation	

Transparency

clarity of rules,
open communication

European Commission

EC will present regularly reports about status and activities on the IMI JU

Council

Parliament

IMI - Added value

Closing the gap in the innovation system

- The JTI will fill a gap in the European Innovation system by providing mechanisms and networks for rapid valorisation and translation of research results into methods and technologies for industry and regulatory practice.
- The research results to be taken up can stem from research done at national/EC/international level and from academia as well as industry.
- IMI is changing the focus of industry collaboration from “competitive” research collaborations (to develop products) to “pre-competitive” collaborative research on scientific challenges

IMI - Added value

Stakeholders are looking for leadership and structure

- The JTI will provide “neutral ground” for the necessary collaboration between all stakeholders thereby removing the suspicions of “biased collaborations” that undermines collaborations today.
- Aiming at structuring the strongly fragmented European research base (both national and sector fragmentation will be addressed) -> ERA
- The necessary R&D cannot be done by any of the stakeholders group alone – collaboration is necessary

IMI - Added value

Industry commitment and collaboration

- The role of the EC has been, and will be, instrumental for the increased collaboration between companies.
- The EC and Industry will facilitate the participation of all stakeholder groups in the research following open calls and peer review. Research can be done by “anybody” as long as it is carried out in Europe.
- Similar activities has started in the US and Japan. Without a strong European initiative industry will increasingly move its research elsewhere.

IMI implementation expected timelines

The Commissions Proposal for a Council Regulation to set up the Innovative Medicines Initiative Joint Undertaking under Article 171 of the EC treaty was presented to the Competiveness Council 22 May 2007

Foreseen to agreed by Council following the opinion of the European Parliament and the Economic and Social Committee 2007/2008

IMI implementation expected timelines

November 2007

- Indication of First Call Topics

December 2007/January 2008

- Debate in the plenary assembly of the European Parliament
- Decision by the Council of the EU
- Publication of First Call Topics

End 2008

- Start of Research Projects

January 2009

- Publication of Second Call Topics

Links and Material available

http://www.imi-europe.org/Publications.asp

- Strategic Research Agenda
- IMI Intellectual Property Policy
- IMI Frequently Asked Questions
- IMI Keys for Success – Industry input
- IMI Two-pager
- IMI Key Messages for Member States
- IMI Flyer
- IMI Glossary

http://ec.europa.eu/research/health/imi/index_en.html

http://cordis.europa.eu/fp7/cooperation/health_en.html

http://ec.europa.eu/research/health/imi/member-states-group_en.html

- Proposal for a COUNCIL REGULATION setting up the Innovative Medicines Initiative Joint Undertaking
- Assessment of Economical and Societal Effects of IMI
- FP7 Health brochure
- Health Research in FP7 Flyer
- Innovative Medicines Initiative Flyer
- Joint Technology Initiatives Brochure