

What does the European Technology Platform “Innovative Medicines initiative” offer?

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Innovative Medicines Initiative (IMI)

- **WHAT** - - - - - does IMI mean?
- **WHY** - - - - - IMI is needed?
- **HOW** - - - - - IMI will operate?
- **WHO** - - - - - players and participants?
- **HOW MUCH** - funding principles?
- **IMPACT** - - - - - the expected outcomes of the joint effort?

WHAT?

Definition:

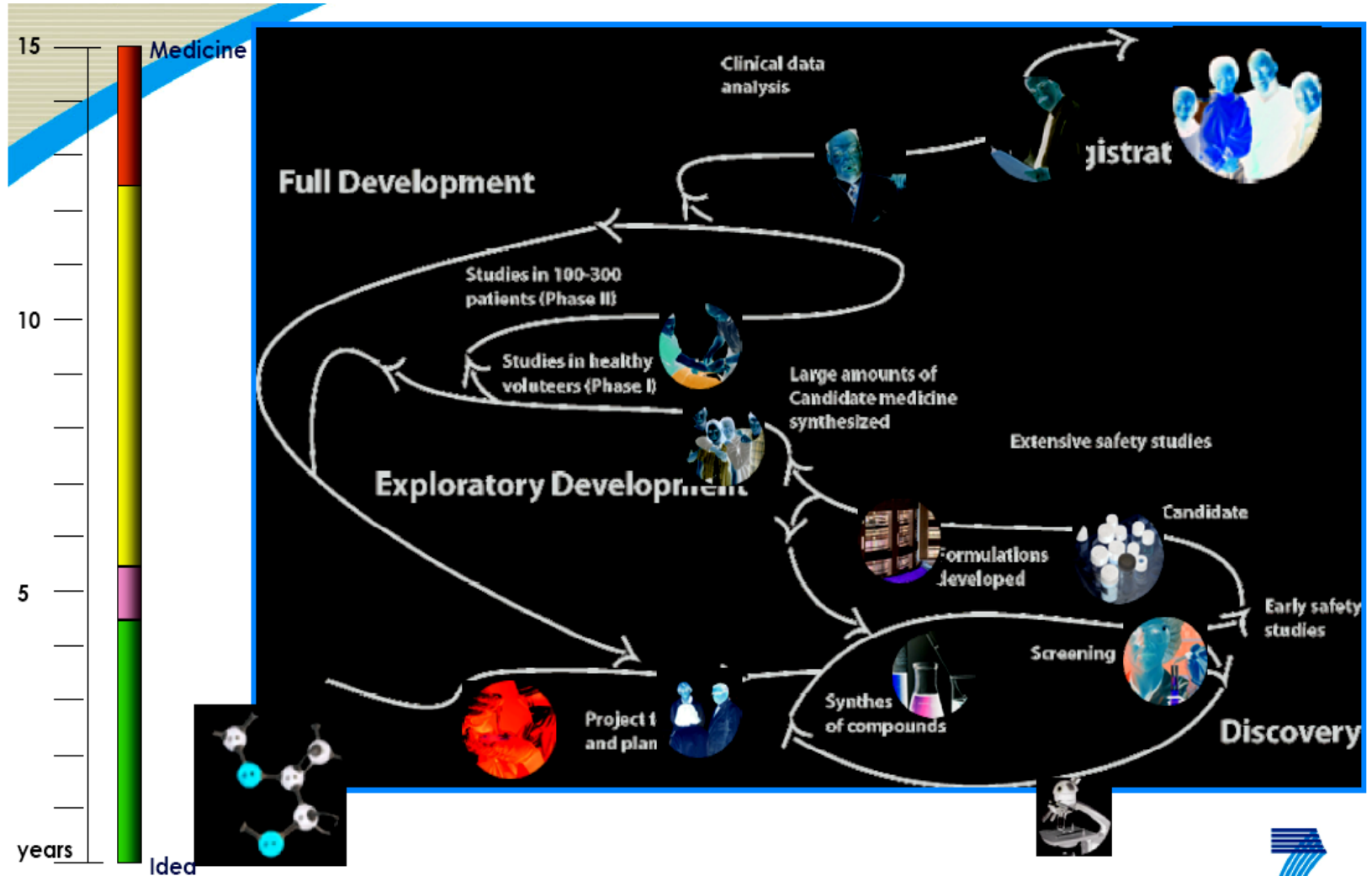
The Joint Technology Initiative on “Innovative Medicine (IMI JTI) – is a new research funding **instrument** characterized by a private/public partnership by European Commission and EFPIA (the European Federation of Pharmaceutical Industries and Association)

WHAT?

The main research objective of the Innovative Medicines Initiative will be development and validation of new and better techniques and methods to predict safety and efficacy of new medicines.

A key feature – research results will be compiled and made available to benefit the entire European pharmaceutical sector

WHY?



Creating new medicines is a high risk journey



WHY?

Challenges - European, Industry and Scientific (1)

- Escalating, unsustainable, drug development costs
- High failure rates during the development process
- Pharmaceutical R&D moving out of Europe
- Public spending on health R&D lower and stagnating compared to the US

WHY?

Challenges - European, Industry and Scientific (2)

- Private investments in sector (VCs, etc.) much lower than the US, and increasing risk adversity among investors
- Scientific breakthroughs has not given the expected results
- Fragmentation of research efforts – basic, clinical and industry

WHY?

The overall goal of the Innovative Medicines Initiative (IMI) is to re-invigorate the European bio pharmaceutical sector and to make Europe more attractive for private R&D investment in this sector. In the long term, IMI is also expected to provide faster access to better medicines for European citizens

Main policy drivers:

- **Contributes to the Growth and Job strategy**
- **Increasing competitiveness** of European health-related industries and businesses
- **Improving health** of European citizens

Health Theme in FP7, Collaborative research HOW?

The Health Theme in the 7th European Research Framework Programme (structure and content)

- – Biotechnology, generic tools and technologies for Health
- – Translating research for human health
- – Optimising the delivery of healthcare to citizens

Other actions across the theme

IMI JTI

Core activities and goals

HOW?

- 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 infrastructure 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!*

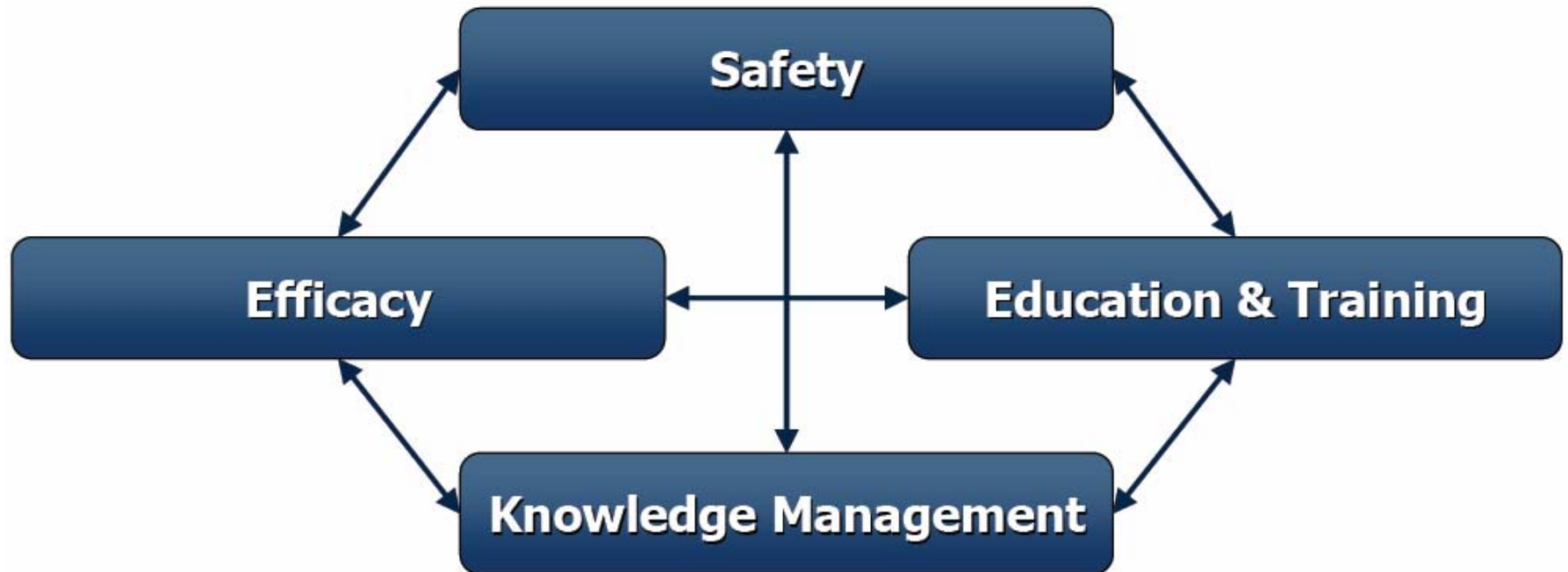
IMI JTI

Core activities and goals

HOW?

IMI directly aiming at:

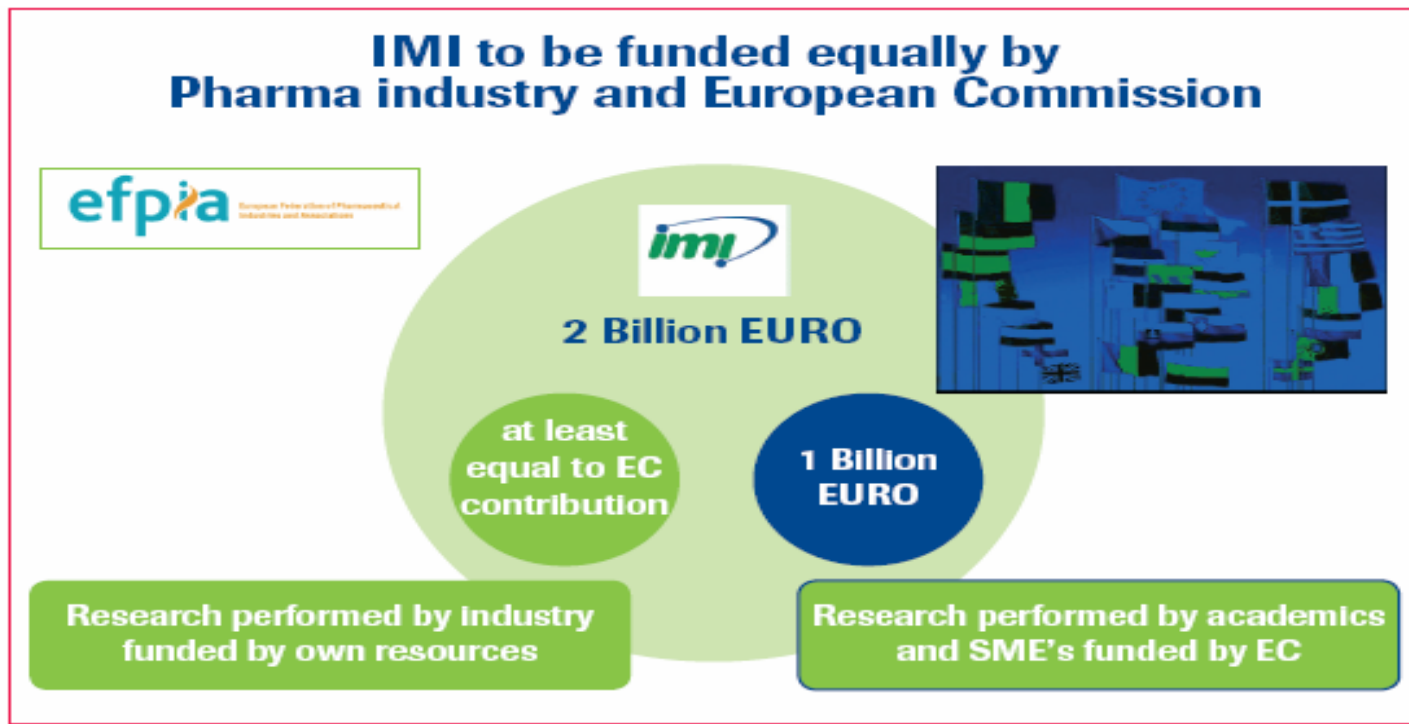
Removal of the major bottlenecks in drug development, to which research is the key" (safety, efficacy, knowledge management, education & training)



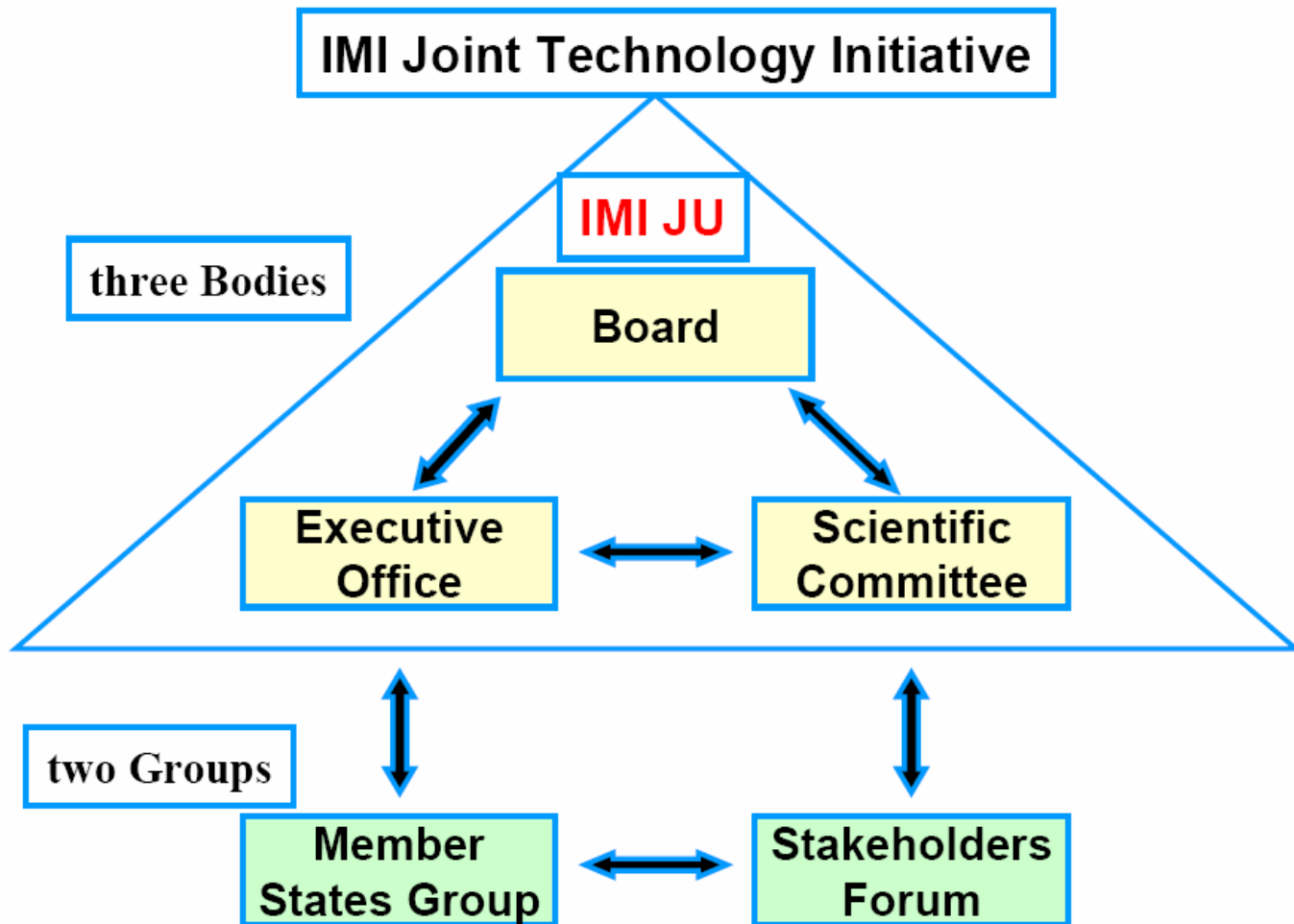
Main principles:

IMI proposal is based on the principle of co-financing between the EC and the pharmaceutical industry.

- The total budget of IMI – **2 billion EUR**, from which EC contribution to the Innovative Medicines Initiative is **1 billion EUR** for the period of the FP7



IMI JTI Governance Structure WHO?



September 13, 2007

SGM&M2B International & Training
Workshop

IMI Rules for participation:

- Any legal entity established in any country can participate in Projects, provided that their research activities related to the Project are performed in Europe
- Projects must include at least one legal entity who is member of the EFPIA company and one legal entity who is not a member of EFPIA and who is eligible to receive IMI funding
- Legal entities participating in the same Project must be independent of each other

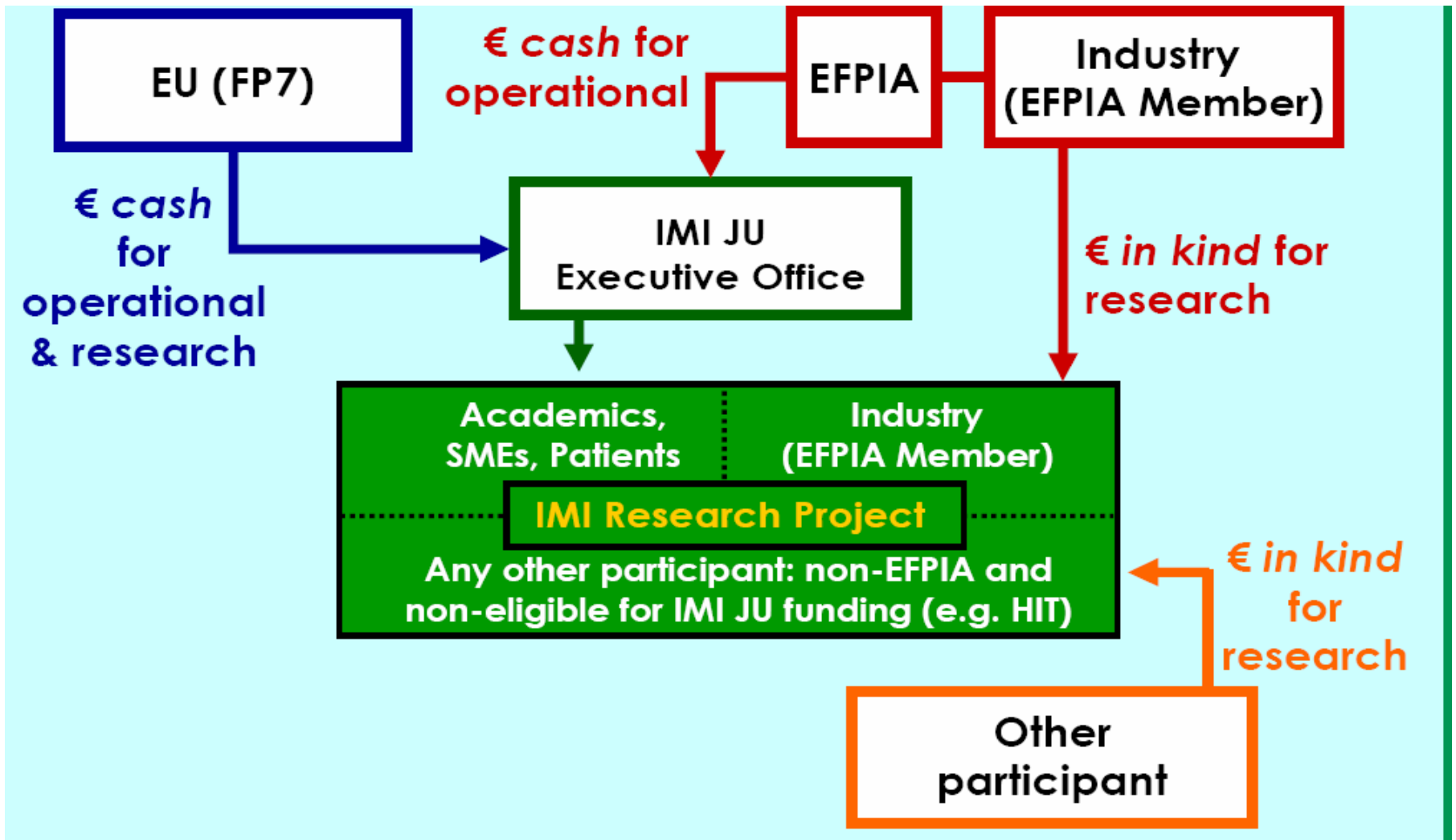
IMI JTI

HOW MUCH?

Calculation of IMI contribution for participants eligible for IMI funding

- Maximum of 75% of eligible direct and indirect costs for research activities
- Maximum of 100% of eligible direct and indirect costs for management and training activities

IMI JTI Funding Flow and Contributions HOW?



IMPACT - the expected outcomes of the joint effort

- Increased leverage of EC research funds – each € 1 from FP7 will generate research worth € 2
- Improved drug development process (better prediction of safety and efficacy, utilization of research results and data, rapid translation of scientific results into regulatory and industry practice, etc.)
- Better use of invested resources – both private and public
- Increased attractiveness to do (bio) pharmaceutical R&D in Europe

IMPACT - the expected outcomes of the joint effort

- Reduced risk of failure - Venture Capitalists more inclined to invest in SMEs in the sector
- Better availability of excellent competencies (via education and training, networking of centres of excellence, etc.)
- More dialogue and collaboration between all stakeholders (patients, regulatory, industry, academy, clinicians, etc.)
- Faster access to new therapies for patients

More information about IMI can be founded at web:

<http://www.imi-europe.org>

Thank you!

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