The Innovative Medicines Initiative

Creating Biomedical R&D Leadership for Europe to Benefit Patients and Society

EMEA-EFPIA INFO DAY, February 5th, 2007

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Agenda

- What is IMI?
- Why is IMI important to the EFPIA?
- What could be the role of the EMEA in IMI?

The Drivers for a New R&D Model Based on Public-Private Partnership

- The need to enhance European's competitiveness;
- Timelines and cost of drug development;
- Wealth of novel opportunities from new science and technologies;
- The potential of increased cooperation between stakeholders.

➔ European Commission and EFPIA will propose in 2007 the creation of the IMI Joint Technology Initiative.

The IMI Strategic Research Agenda

http://www.imi-europe.org

The Innovative Medicines Initiative (IMI)
Strategic Research Agenda

Creating Biomedical R&D Leadership for Europe to Benefit Patients and Society

DATE OF PREPARATION: 15 September 2006 (Version 2.0)

http://www.efpia.org/4_pos/SRA.pdf

- Identifies pre-competitive bottlenecks in the R&D process
- Proposes recommendations to address these bottlenecks
- Proposes a new model of Public-Private collaborations to implement these recommendations

How to Provide More Effective, Safer Medicines Faster?

- IMI is about R&D processes including registration;
- IMI is about tools and understanding of diseases, not about medicinal products;
- 'Patient Centred Projects' will address the principal causes of delay in the biomedical R&D process;
- IMI is a unique public and private sector collaboration in biopharmaceutical research.

For EFPIA, IMI is the top R&D Priority for 2007

Why is IMI a Top Priority for EFPIA?

- Faster interpretation of safety findings through sharing pre-competitive toxicology data;
- Reduction of animal use in safety evaluation;
- Validation of new assessment methods e.g. biomarkers;
- Fewer patients needed in pivotal trials;
- Faster approvals through better collaboration with EMEA;
- Fewer post-marketing withdrawals;
- More skilled professionals.

➔More cost-efficient R&D

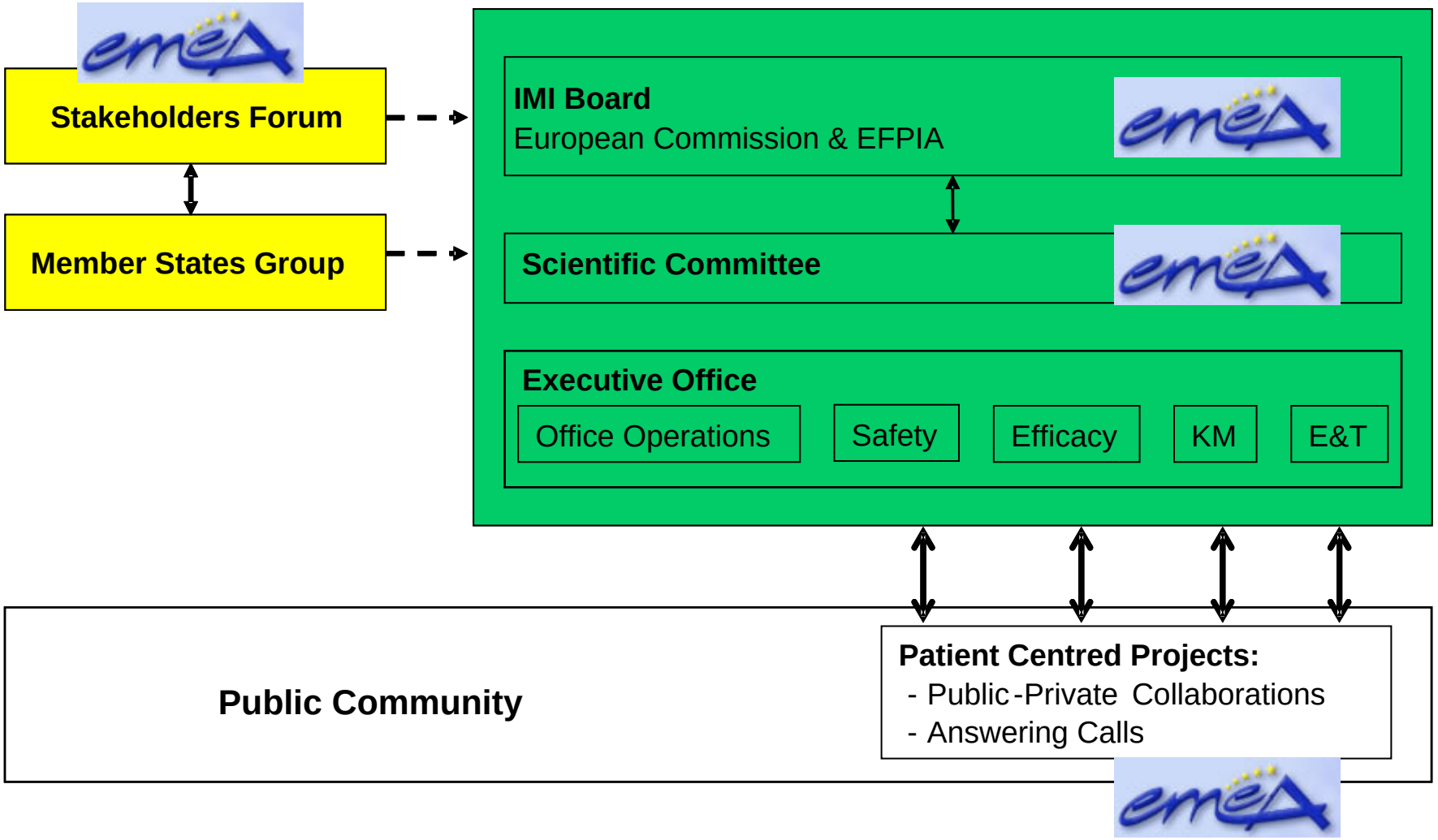
IMI is Aligned with the EMEA Road Map to 2010

- Top-quality scientific assessment
  - network of excellence
- Continuous monitoring of medicinal products
  - pharmacovigilance network
- Access to information
  - information to patients and healthcare professionals, transparency, measures for SMEs
- Allow rapid access to safe and effective medicines
  - partnering with interested parties

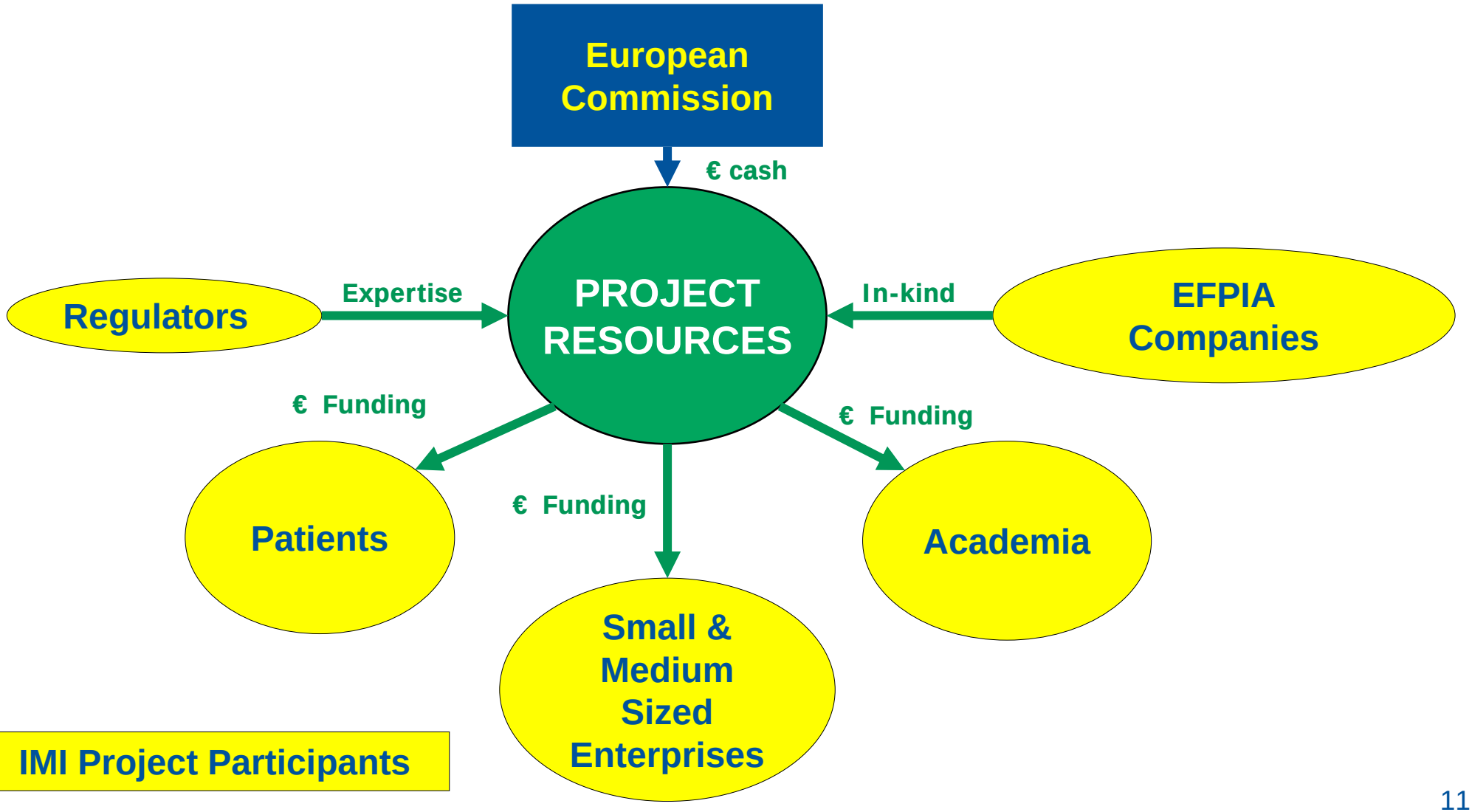
About the European Centre of Drug Safety Research (ECDSR)

- Small and independent centre composed of a core group with a wide network of academics, industry scientists and regulators;
- Non-clinical safety;
- Pharmacovigilance & Risk management;
- Objectives:
  - co-ordinate research needs in safety sciences,
  - enhance training and education of drug safety scientists,
  - materialise the benefits of knowledge management.

Proposed Participation of the EMEA in the IMI Governance Structure



Resources of the IMI Patient Centred Projects



Roles of the EMEA in IMI

- Direct impact on decisions through participation in the IMI Board, the Scientific Committee and Stakeholders Forum;
- Direct participation in IMI Patient Centred Projects;

- Regulatory expertise to help identify needs and solutions;
- Co-ordination with regulatory initiatives.

Impact of IMI on Benefit/Risk Assessment

- Open and scientific forum allowing early involvement and collaboration of all stakeholders;
- Access to pre-competitive knowledge that was previously out of reach;
- Faster application of new technologies for regulatory purposes;
- Improved scientific information to support decision making in regulatory approvals;
- Fewer post-marketing withdrawals.

IMI Implementation Plan

• Adoption by the European Commission	March
• Submission to the European Council	April
• Consultation of the European Parliament	April
• Approval by the European Council	November
• Start of Research Projects	2008

The Ultimate Beneficiaries ...

... All EU citizens