

The Innovative Medicines Initiative



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

EMEA-EFPIA INFO DAY, February 5th, 2007

Karima Boubekeur



Agenda



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

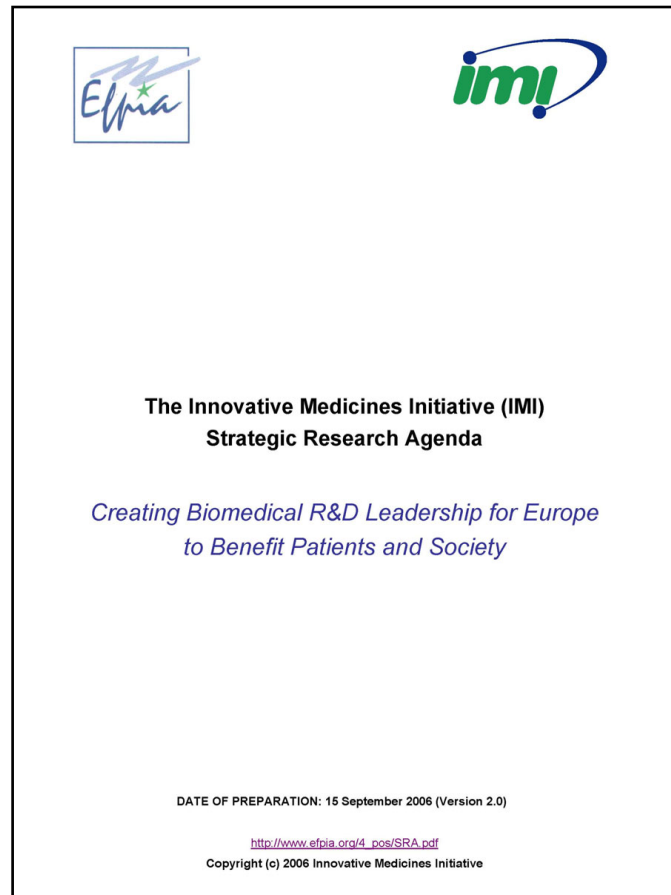
The Drivers for a New R&D Model Based on Public-Private Partnership



- 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>



- 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



Bayer



GlaxoSmithKline



MERCK SHARP & DOHME



Pierre Fabre



Boehringer Ingelheim



NOVARTIS



L'essentiel c'est la santé.

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



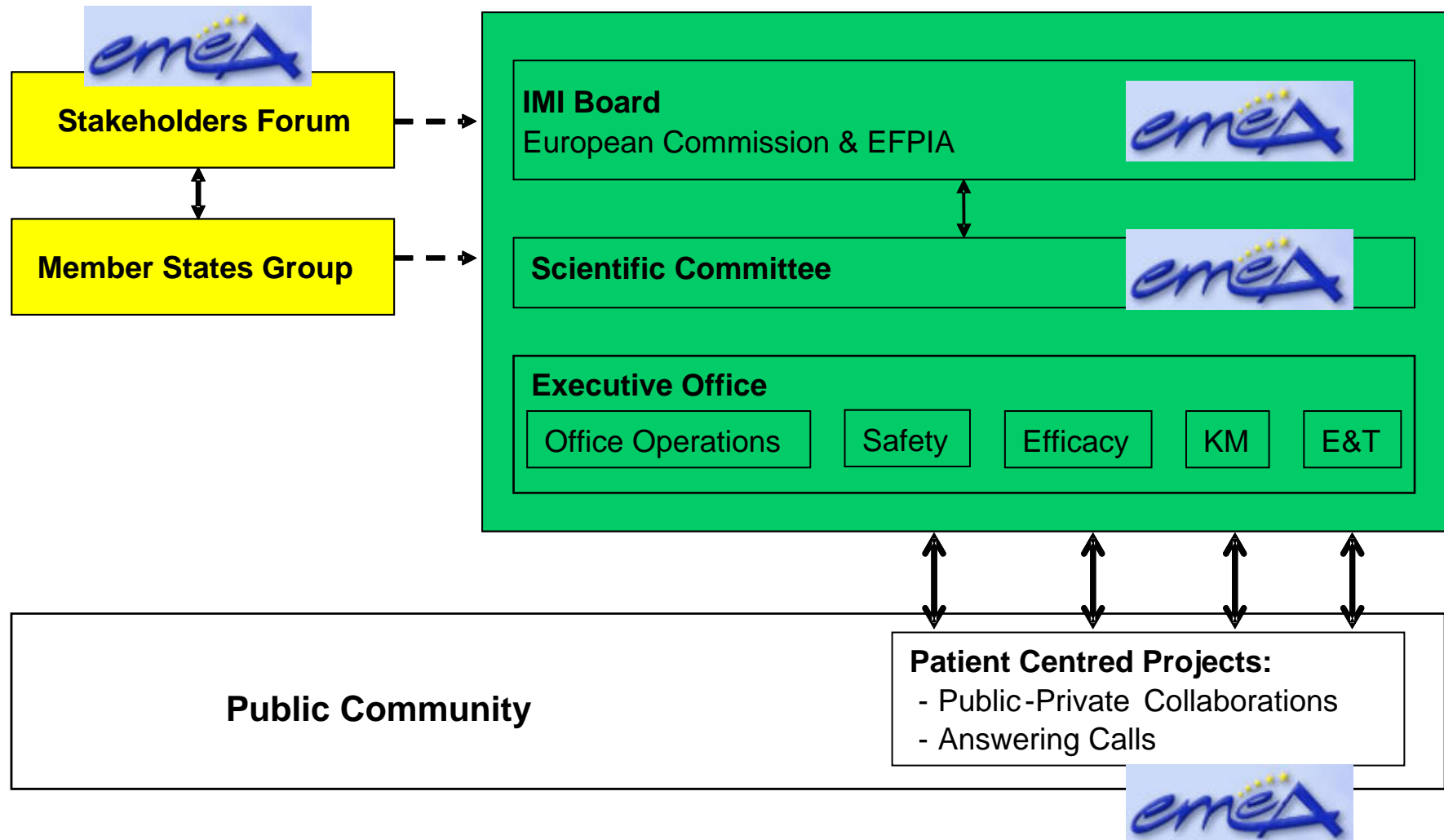
- Top-quality scientific assessment
 - network of excellence
- Continuous monitoring of medicinal products
 - pharmacovigilance network
- Access to information
 - information to patients and healthcare professionals, transparency, measures for SMEs
- Allow rapid access to safe and effective medicines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

About the European Centre of Drug Safety Research (ECDSR)

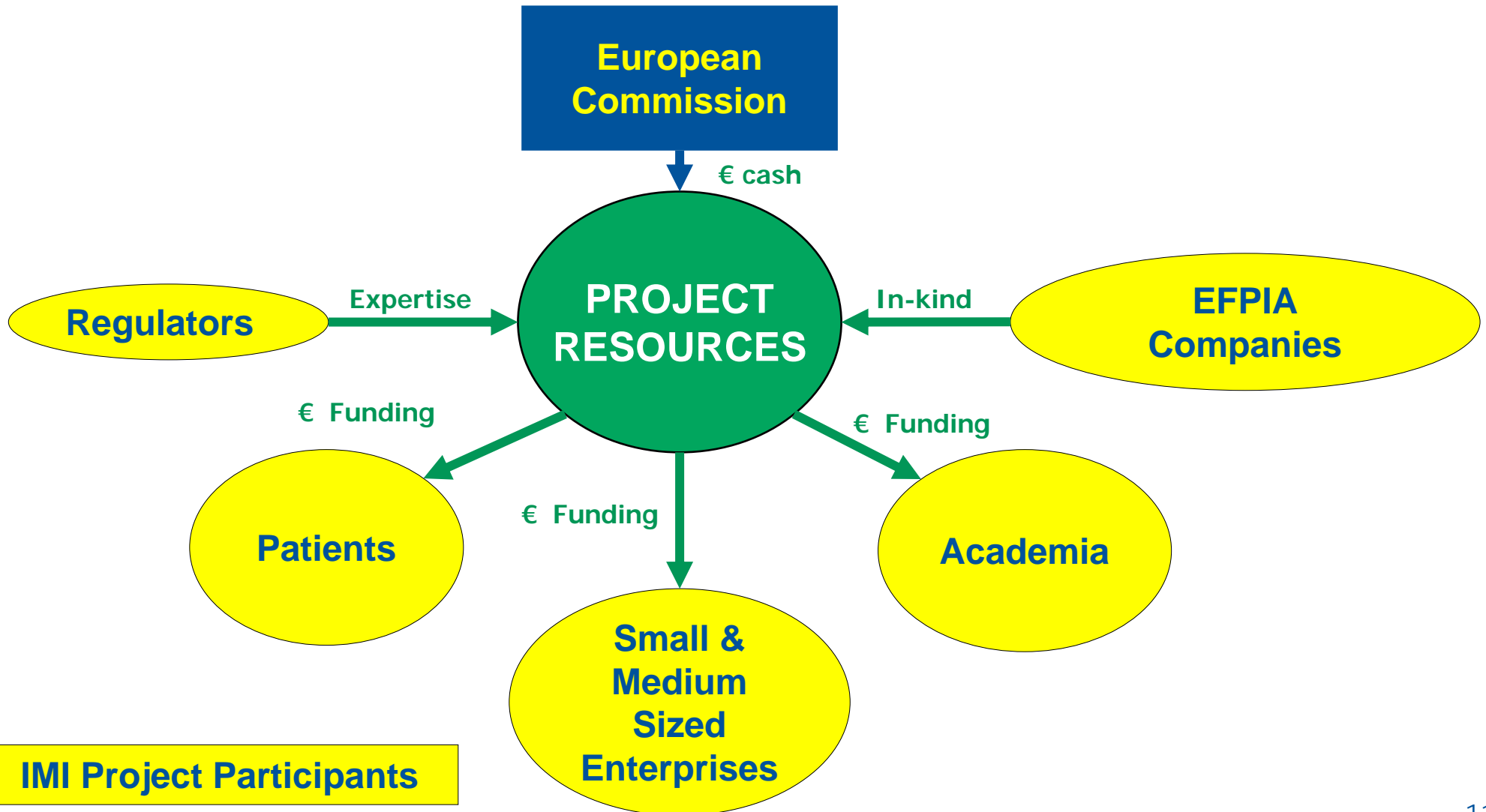


- Small and independent centre composed of a core group with a wide network of academics, industry scientists and regulators;
- Non-clinical safety;
- Pharmacovigilance & Risk management;
- Objectives:
 - co-ordinate research needs in safety sciences,
 - enhance training and education of drug safety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

Proposed Participation of the EMEA in the IMI Governance Structure



Resources of the IMI Patient Centred Projects





- 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.



- 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

