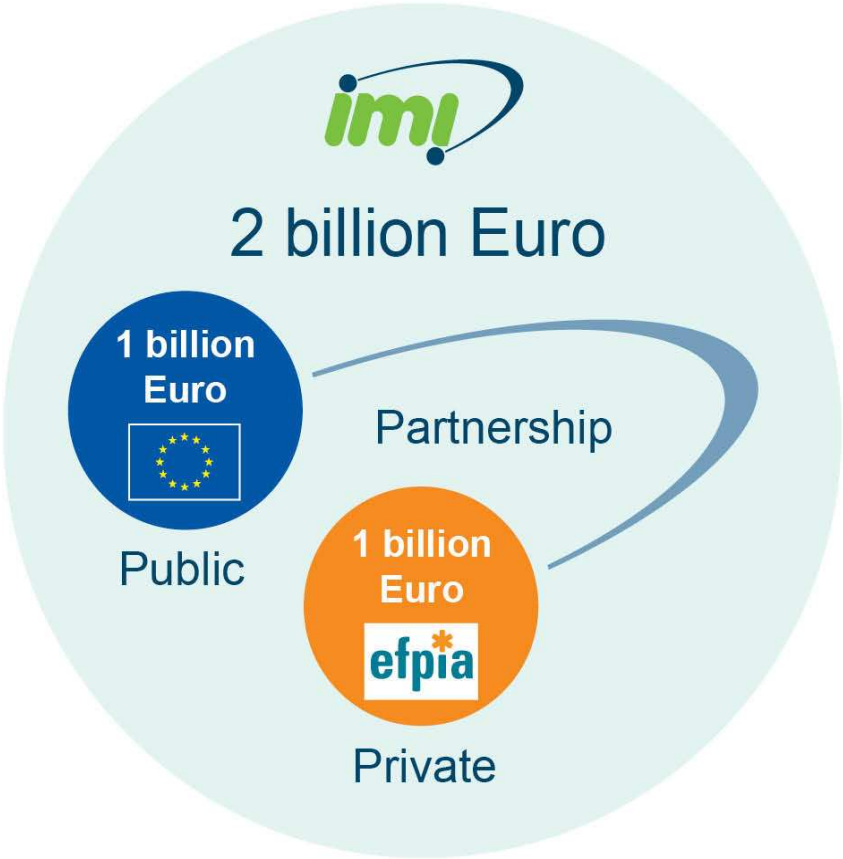
Innovative partnerships for innovative medicines

Innovative Medicines Initiative – IMI
EuroBio 2009

Irene Norstedt, EC, September 2009

vB1

Innovative Medicines Initiative
IMI - What is it ?



- Largest public-private partnership in the area of medical research
- Innovative collaboration established between the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA) as a Joint Technology Initiative under FP7
- The objective is to make the drug discovery and development process more efficient to bring better medicines faster to patients, and to attract investment to Europe
- Support / Funding of research activities following open Calls and independent review

Diapositive 2

vB1 see word document for reformulation
von Bethlenfalvy; 02/07/2009

Innovative Medicines Initiative
Founding Members EC and EFPIA

Almirall
AMGEN
AstraZeneca INTERNATIONAL
Bayer
Boehringer Ingelheim
Chiesi
A lot to discover ESTEVE
genzyme
MERCK SHARP & DOHME
sanofi aventis
NOVARTIS
gsk GlaxoSmithKline
Schering-Plough
IPSEN Innovation for patient care
novo nordisk
SERVIER
sigma-tau
Johnson & Johnson
Lilly
ORION
SOLVAY
Lundbeck
Pfizer
ucb
MERCK SERONO
Roche
Wyeth

The drivers for action for setting up IMI

- The need to enhance Europe's competitiveness
- Increasing timelines and cost of drug development
- Wealth of novel opportunities from genomics
- The potential for increased cooperation between stakeholders

➔Creation of Innovative Medicines Initiative by EFPIA and the European Commission

IMI Aims

- Modernize drug development via new approaches, methods and technologies, better use of research results and data, and more skilled staff
- Support ‘pre-competitive pharmaceutical research and development’, in order to accelerate the development of safer and more effective medicines for patients.
- Foster collaboration between all stakeholders, e.g. industry, academia, patients organisations, public authorities (including regulators), clinical centres, etc.
- Not developing any new medicines!

IMI key features

- A specific legal entity (IMI JU) has been set up to implement IMI

- IMI has a unique call process
  - Research topics defined by industry addressing the highest needs
  - The two-stage call process matches EFPIA companies with other partners
  - Strong industry commitment with EFPIA companies contributing at least the same resources as the IMI JU funds available for research

- Specific Rules for participation and Intellectual Property Rights Policy
  - Developed to ensure that IMI objectives are reached

IMI will be implemented by a new legal entity, the IMI Joint Undertaking

COUNCIL REGULATION (EC) No 73/2008

of 20 December 2007

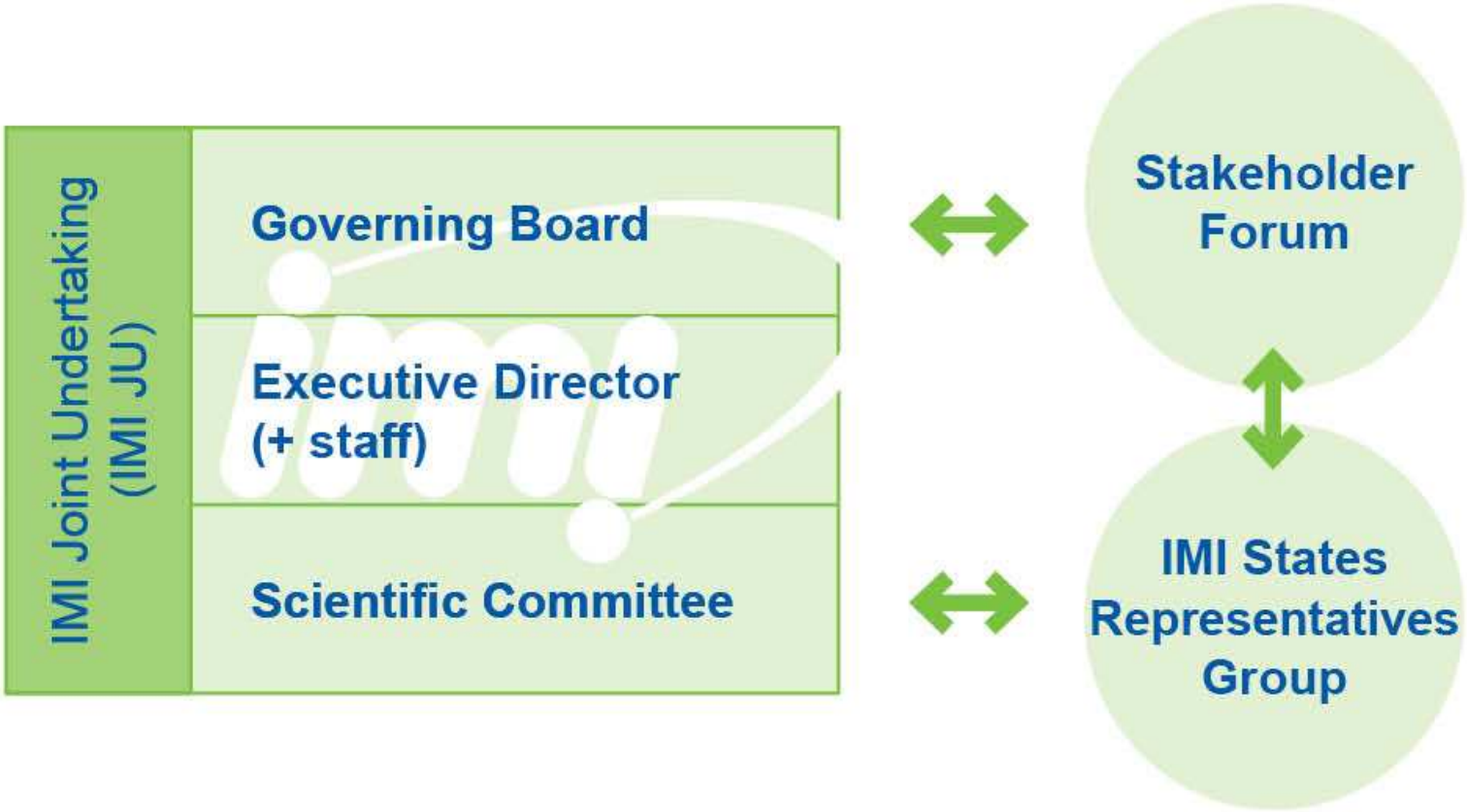
setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on

Innovative Medicines

Official Journal 04.02.2008

IMI Governance

IMI is composed by the IMI Joint Undertaking and it has two External Advisory Bodies



Setting up IMI's Governance

- **IMI Governing Board**

  Chair Ruxandra Draghia-Akli, European Commission, Vice-Chair Jonathan Knowles, EFPIA/Roche

- **Executive Director**

  Michel Goldman

- **Scientific Committee**

  Chair Christian Noe and Vice Chair Daan Crommelin

- **IMI States Representatives Group**
  - including EU Member States and countries associated to the 7th EC Research Framework Programme

  Chair: Stavros Malas, CY and Vice-Chair Kathleen D'Hondt, BE

IMI will fund research recommended in its Research Agenda

The Innovative Medicines Initiative (IMI)
Strategic Research Agenda

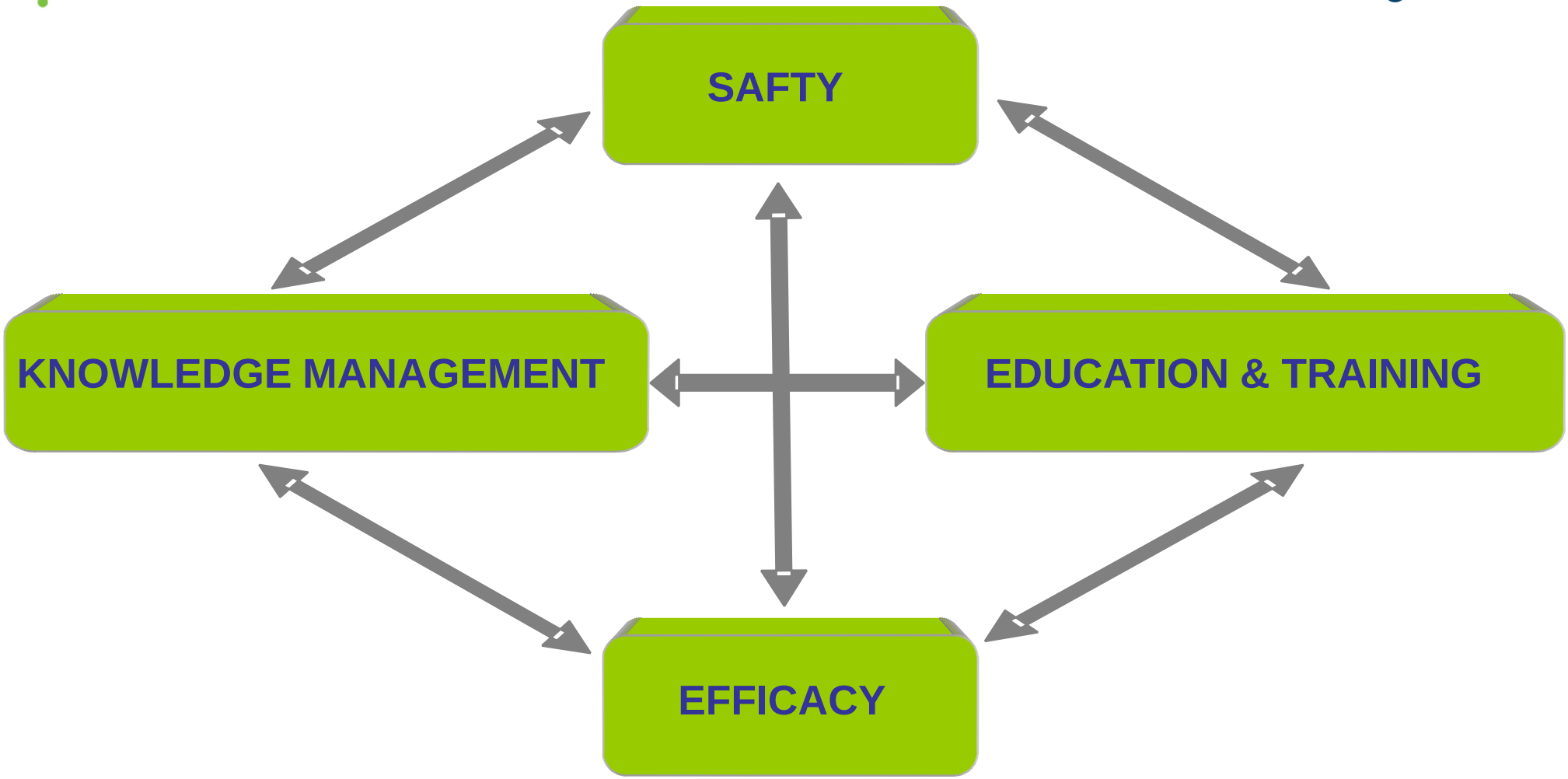
Creating Biomedical R&D Leadership for Europe to Benefit Patients and Society

DATE OF PREPARATION: 15 September 2006 (Version 2.0)

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

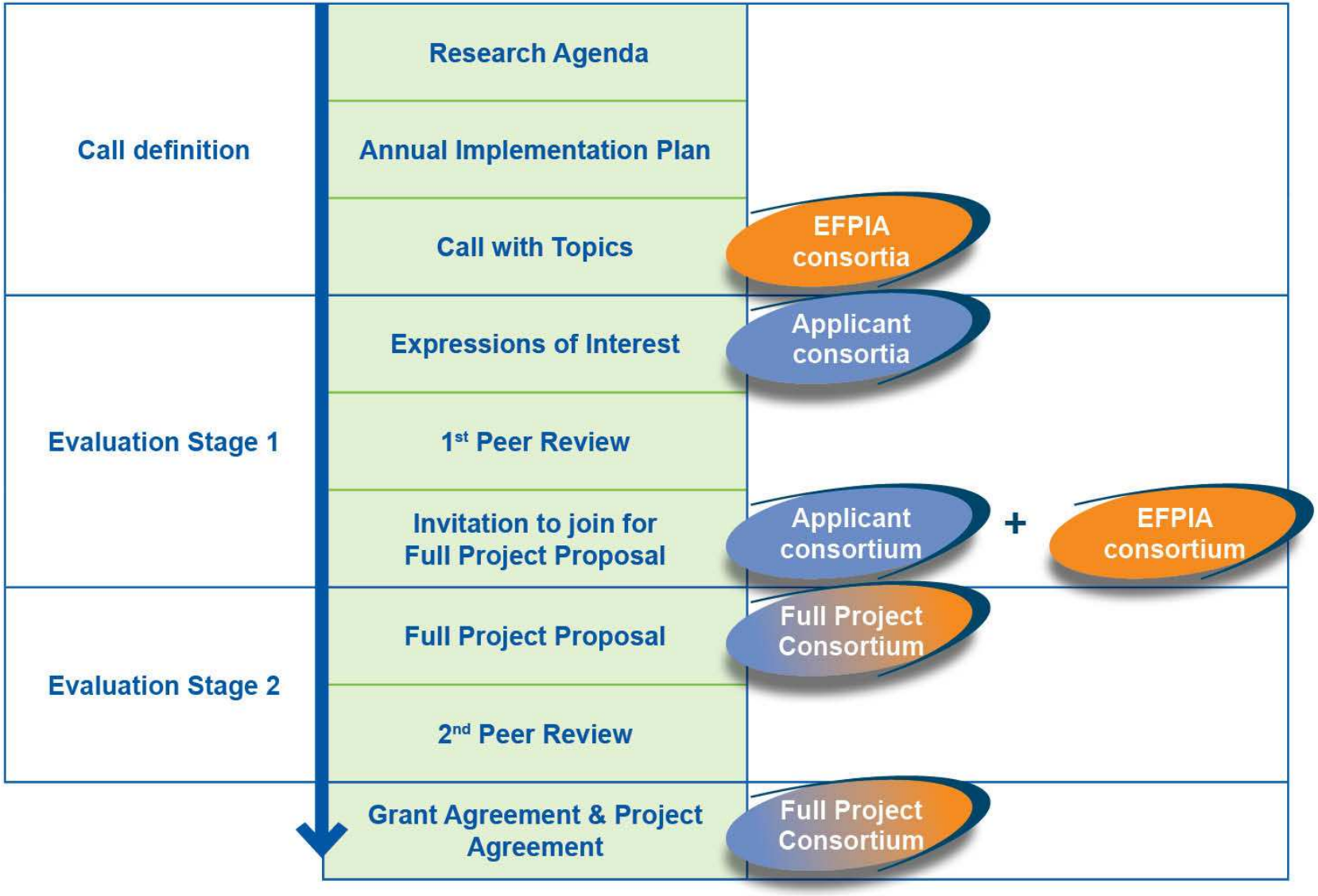
- The IMI Research Agenda describes the research bottlenecks in drug development and recommendations how to solve those.
- These recommendations represent the outcome of an extensive consultation between Europe's key stakeholders under the lead of EFPIA, organised within the European Technology Platform on Innovative Medicines Initiative
- The review of the IMI Research Agenda will start in 2010 with the IMI Scientific Committee.

IMI Research Areas



Source: EFPIA

IMI Call process



IMI's first call for proposals

18 call topics – two stage procedure

- 6 in safety, 7 in efficacy (CNS, Diabetes, Respiratory Diseases), 5 in education and training

134 Expressions of Interest (EoI) were evaluated

- Almost 1300 applicants in the 134 applicant consortia
- The toped ranked EoI for each topic were invited to proceed with Full project proposals together with EFPIA companies

18 Full project proposals received and evaluated

- 15 projects selected and in negotiations estimated to start Q3-Q4
- Overall budget € 246 million (IMI contribution to participants € 110 mio ' + EFPIA in kind contribution € 136 mio) + € 5 mio for research outside Europe

IMI 1st round selected projects #1

1. Non-genotoxic carcinogenesis: MARCAR

Expected outcome: proven reliable role of early biomarkers in prediction of cancer development.

2. Expert systems for *in silico* toxicity prediction: eTOX

Expected outcome: pharmaceutical toxicity database and *in silico* expert systems for the computational prediction of drug secondary pharmacology and direct drug-induced toxicity.

3. Qualification of translational safety biomarkers: SAFE-T

Expected outcome: new specific and sensitive safety biomarkers and their respective assays for human sample for improved predictivity between non-clinical and early clinical studies.

4. Strengthening the monitoring of the benefit/risk of medicines: PROTECT

Expected outcome: new methodologies in pharmacovigilance and pharmacoepidemiology

5. Islet cell research: IMIDIA

Expected outcome: better understanding of β-cell function and survival so as to :

preserve ß cell functional mass aiding the development of preventive and curative treatments for type 1 and type 2 diabetes. Identify diagnostic biomarkers for treatment monitoring in diabetes, develop non-Invasive imaging of the human endocrine pancreas**.**

IMI 1st round selected projects #2

6. Surrogate markers for vascular endpoints: SUMMIT

Expected outcome: agency acceptable surrogate markers for micro- and macro-vascular diabetic complications to enhance efficiency of drug development studies and shorten clinical trials, novel imaging techniques and models allowing simulated *in silico* trials.

7. Pain research: EUROPAIN

Expected outcome: improved understanding of the pathways and mechanisms mediating different kinds of pain, and markers for patient stratification and quantitative pain assessment for efficient testing of new analgesics.

8. New tools for the development of novel therapies in psychiatric disorders: NEWMEDS

Expected outcome: blood/CSF markers, imaging and/or electrophysiological measures suitable for clinical assessments to be used for preclinical models with sensitive pharmacodynamic markers that are closely linked with psychiatric disorders

9. Neurodegenerative disorders: PHARMACOG

Expected outcome: translatable animal and human volunteer models for better prediction of clinical efficacy of new therapies in patients with Alzheimer's disease

10. Understanding severe asthma: U-BIOPRED

Expected outcome: a large longitudinal patient cohort enabling validation of novel biomarkers and development of diagnostic criteria for mechanistic and therapeutic trials.

IMI 1st round selected projects #3

11. COPD patient recorded outcomes: PROACTIVE

Expected outcome: a comprehensive framework for better understanding of patients' physical activity in chronic obstructive pulmonary disease (COPD) in dimensions considered relevant by the patients and leading to developing strategies for measuring clinical trials outcomes

12. European Medicines Research Training Network: EMTRAIN

Expected outcome: a European biopharmaceutical research training platform providing a sustainable academia-industry cross-disciplinary approach to efficient organisation of training courses on emerging science and technologies across Europe.

13. Safety sciences for medicines training programme:SAFESCIMET

Expected outcome: training programme integrating all safety-relevant disciplines linking animal and human/patient safety data thereby facilitating a more holistic evaluation of new medicines

14. Pharmaceutical medicine training programme: PHARMTRAIN

Expected outcome: establish a network of academic centres that delivers postgraduate training programmes in pharmaceutical medicine including quality management of the processes and outcomes.

15. Pharmacovigilance training programme:EU2P

Expected outcome: pan-European training and education network platform in pharmacovigilance and pharmacoepidemiology to train professionals for the pharmaceutical industry and regulatory authorities, healthcare organisations members and experts for the further development of the academic centres to improve the understanding and effectiveness of risk communication

Key challenges - Stakeholder Partnerships

- Change of behaviors competitors vs partners
- Courage working out of traditional roles and comfort zones
- Honesty long term team consensus vs. short term individual advantage
- Reliability deliverables are highly interdependent
- Fairness Intellectual property policy ensuring wide access to results while providing incentives for all actors to participate while providing a fair return on investment
- The Gain - to be part of an exciting new way of bringing the best ideas to reality

Next steps

- 2nd call topics available www.imi.europa.eu
- 2nd call will open 30 October 2009 deadline January 2010
- IMI JU has its own Executive Director and staff
- IMI JU will organize information meetings and the first stakeholder forum
- All questions should be sent to imi.infodesk@ec.europa.eu