# IMI as a Unique Public Private Partnership

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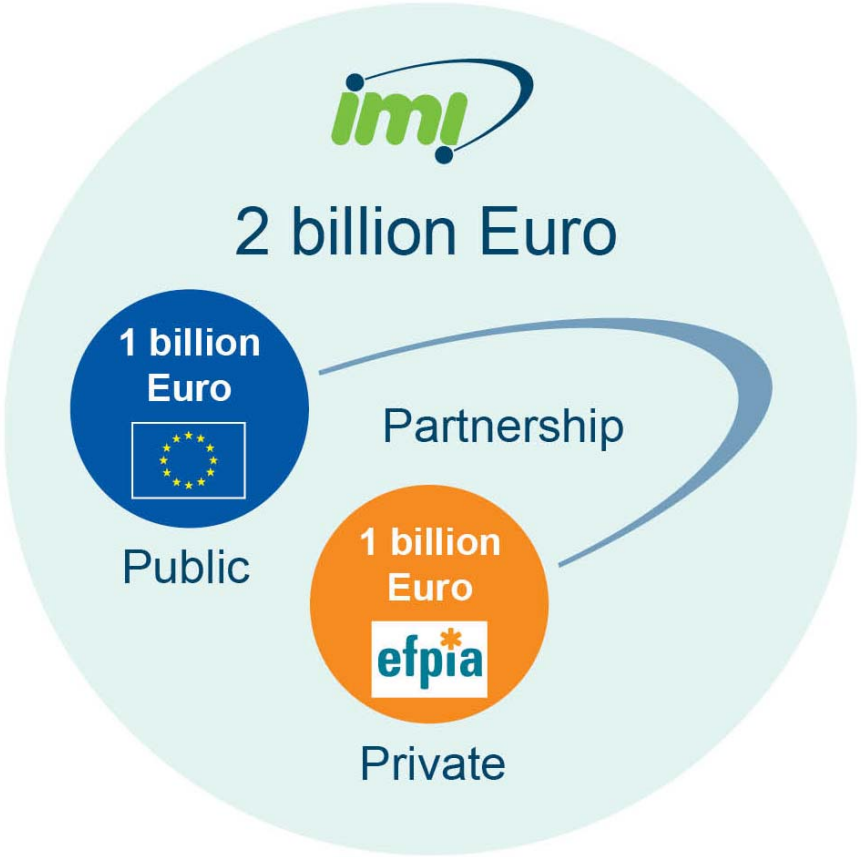
**ETP, Brussels, 12 May 2010**

vB1

# Innovative Medicines Initiative
## What is it?




A European Public-Private Partnership Focused on Needs Common to Pharmaceutical Industry and Patients

## Slide 2

**vB1** see word document for reformulation
von Bethlenfalvy; 2/07/2009

# Public-Private Partnership in the Health Sector: the Time is Now !

- Innovative medicines require in-depth knowledge of disease pathways and molecular targets

- Anticipating potential side effects of new drugs is a must

- The pharmaceutical industry builds new business models based on collaboration and transparency

JCI The Journal of Clinical Investigation
FREE ACCESS TO ALL RESEARCH

# Trio receives 2009 Lasker Foundation Clinical Award for breakthroughs in leukemia treatment

## Partnership is the key

"Breakthroughs don't come about without lots of different areas of investigation converging,"
"We shared a common vision — to get a tyrosine kinase inhibitor into the clinic. The partnerships between academia and industry have gotten much more difficult in the last 10 years and drug development has become a much more lengthy process

Brian J. Druker  Nicholas B. Lydon  Charles L. Sawyers

EDITORIAL

nature medicine

# Mechanism matters

**The path of drug development is fraught with hurdles. Gaining a clear understanding of how a drug works before it enters clinical trials is the intelligent route to drug discovery and could increase the likelihood for drug success.**

Drug development is a risky business. According to the US Food and Drug Administration (FDA), only eight percent of drugs that enter clinical trials are eventually approved. For a drug to gain FDA approval, it must be safe and show some efficacy. Because the FDA does not require any understanding of the mechanism by which a drug acts, it could be tempting to move into clinical trials without this knowledge. However, this may set the stage for failure. An investigational

It is true that we use many highly prescribed drugs without a clear idea of how they work—which targets they hit, what processes they alter and which of these actions are required for therapeutic efficacy. For instance, lithium, used to treat bipolar disorder, modulates many molecular targets, but which—or how many—of these are required for its beneficial effects is uncertain. Nevertheless, understanding a drug's mechanism could guide drug development and help to prevent late-stage failures such as Dimebon's.

# Major Hurdles for the Development of Innovative Therapies

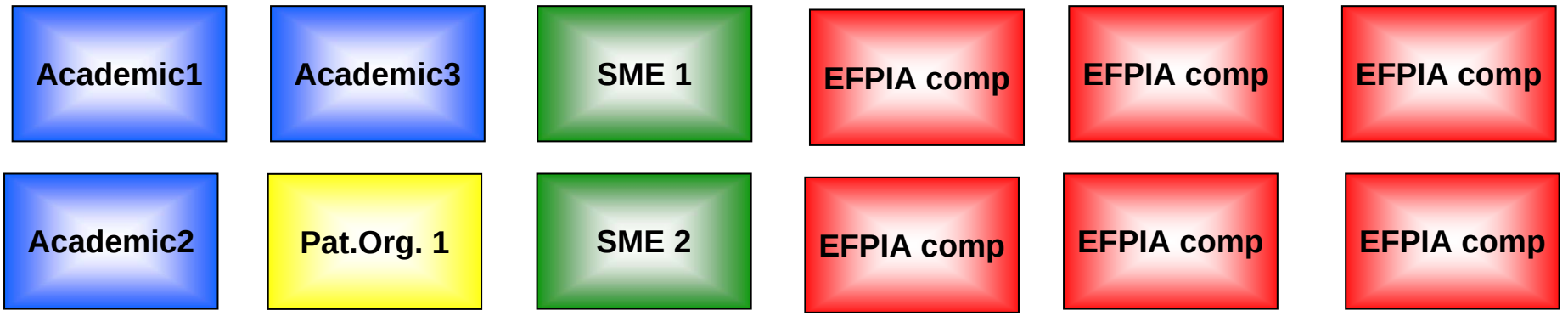
- Unpredicted failures at late stage of drug development

- Fragmented knowledge

# IMI Executive Office as a Neutral Third-Party

- To implement programmes and activities in the common interest of all stakeholders
- To monitor the combined use of public funds and industry investment
- To guarantee fair and reasonable conditions for optimal knowledge exploitation

# Overall Structure of Research Projects




**“Applicants consortium”**

IMI beneficiaries

**“EFPIA consortium”**

EFPIA *in kind* contribution

(no public funding)

# First Two Calls for Proposals

- Number of Applicants: > 2000
- Number of Expression of Interests: 258
- Number of  Projects: 24
- Total Budget:  ≈400 millions €

# 2nd Call Stage 1: First Statistics

## 124 Expression of Interests - 1118 Participants

## 64 Experts - 3 Independent Observers

- Participation of **25 Member States** (All 27 MS except Malta and Latvia) ;
- Participation from **7 FP7 Associated Countries**: Albania, Bosnia, Israel, Norway, Serbia, Switzerland, Turkey;
- Participation from **7 FP7 Third Countries**: Canada, China, Korea, Russian Federation, Senegal, Ukraine, United States

38 patient organizations
204 SMEs

# Scientific Priorities
# - 3rd Call for Proposals -

1. Assessment of drug-induced toxicity in relevant organs - surrogates for early drug failure
2. Immunological safety of biopharmaceuticals
3. Assessment of inflammatory disease
4. Improve the scientific and pre-clinical infrastructure for tuberculosis medicine
5. Enhancing translation in neurological disease
6. Development of personalized medicine in diabetes
7. Fostering a broader understanding of pharmaceutical R&D in the broader public

# Building on Strengths and Tackling Weaknesses in the EU

## STRENGTHS

- Major pharma companies based in Europe
- High-quality research and medical centres
- Critical masses assembled through EU programmes
- Biomedical clusters based on PPP across Europe

## WEAKNESSES

- Insufficient global investment in R&D
- Legal framework for IP management
- Insufficient incentives for « bioentrepreneurs »
- Education programmes not adapted to industry needs

# Open Innovation in the Health Sector: Major Challenges Ahead

- Involvement of patients and laypersons
- Frontiers of pre-competitive research
- Indicators of performance
- Management of intellectual property
- Adaptation of education and training programmes

# THANK YOU