



Innovative Medicines Initiative: Current Status And Future Calls

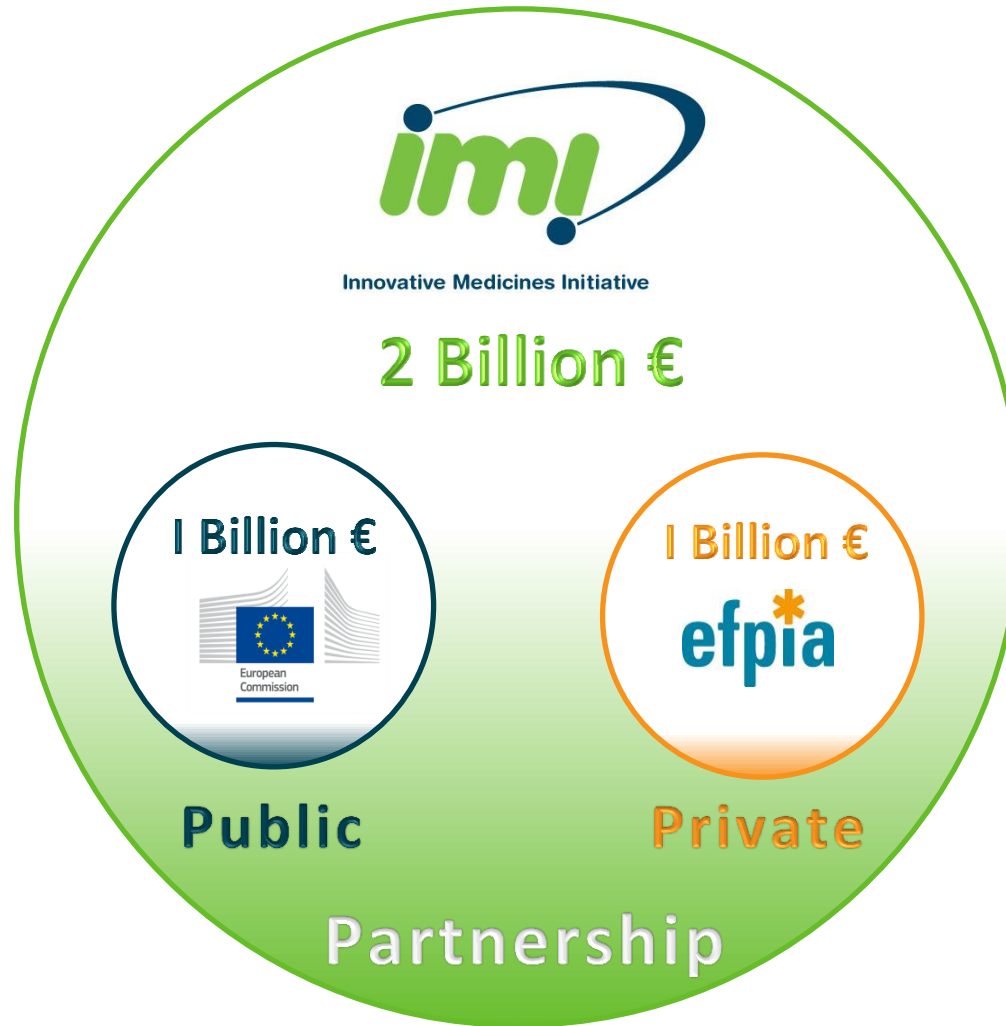
Hugh Lavery

Senior Scientific Project Manager



Innovative Medicines Initiative:

Joining forces in the healthcare sector



- **Disease heterogeneity**
- **Need for new standards for drug development**
- **Lack of predictive biomarkers for drug action**
- **Outdated clinical designs and regulatory processes**
- **Insufficient incentives for industry**
- **Need for mindset shift in stakeholder communities**



Key concepts underlying IMI



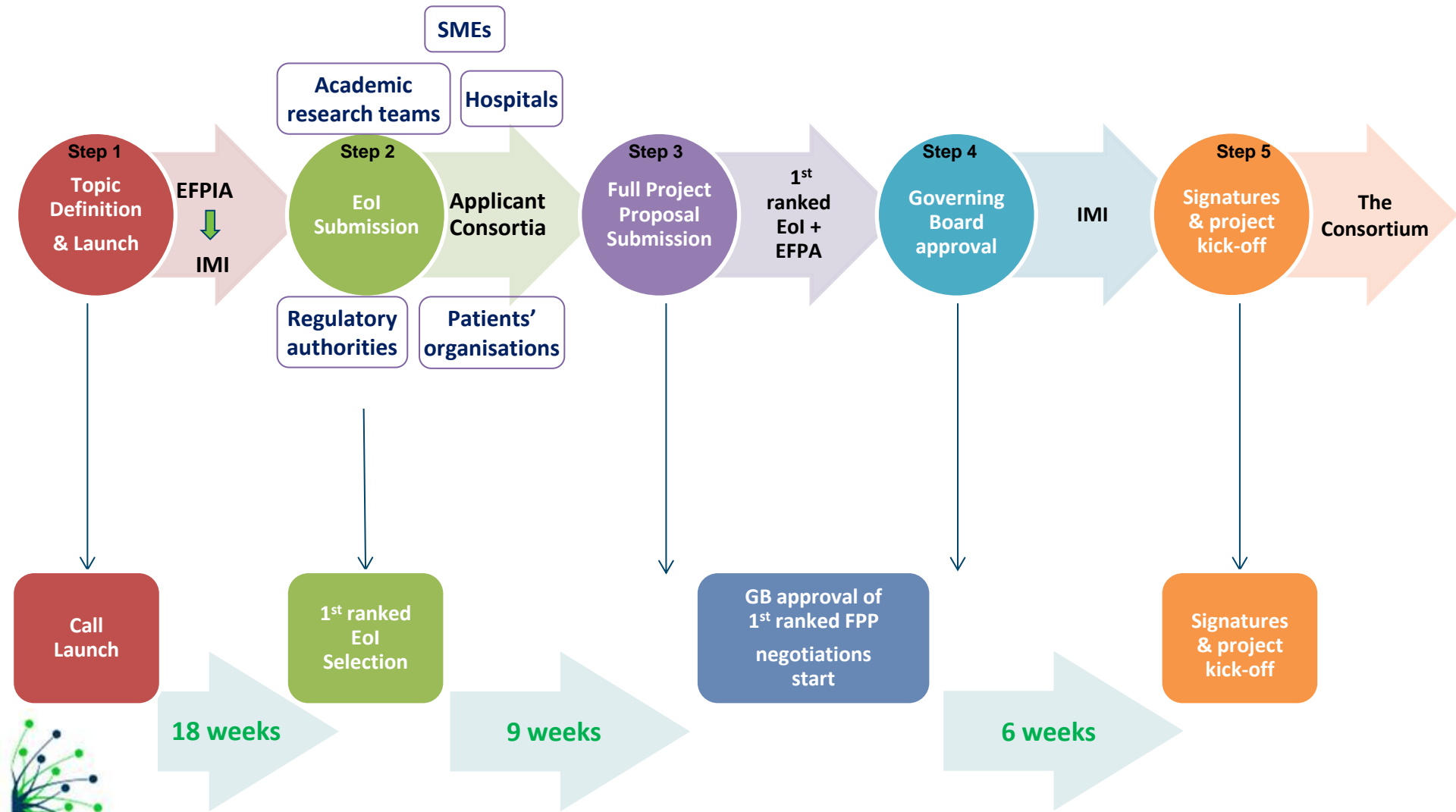
**Open innovation in
public-private consortia**

**Non-competitive collaboration
between large pharma companies**

**A new ecosystem for sustainable healthcare
across Europe, involving all stakeholders**



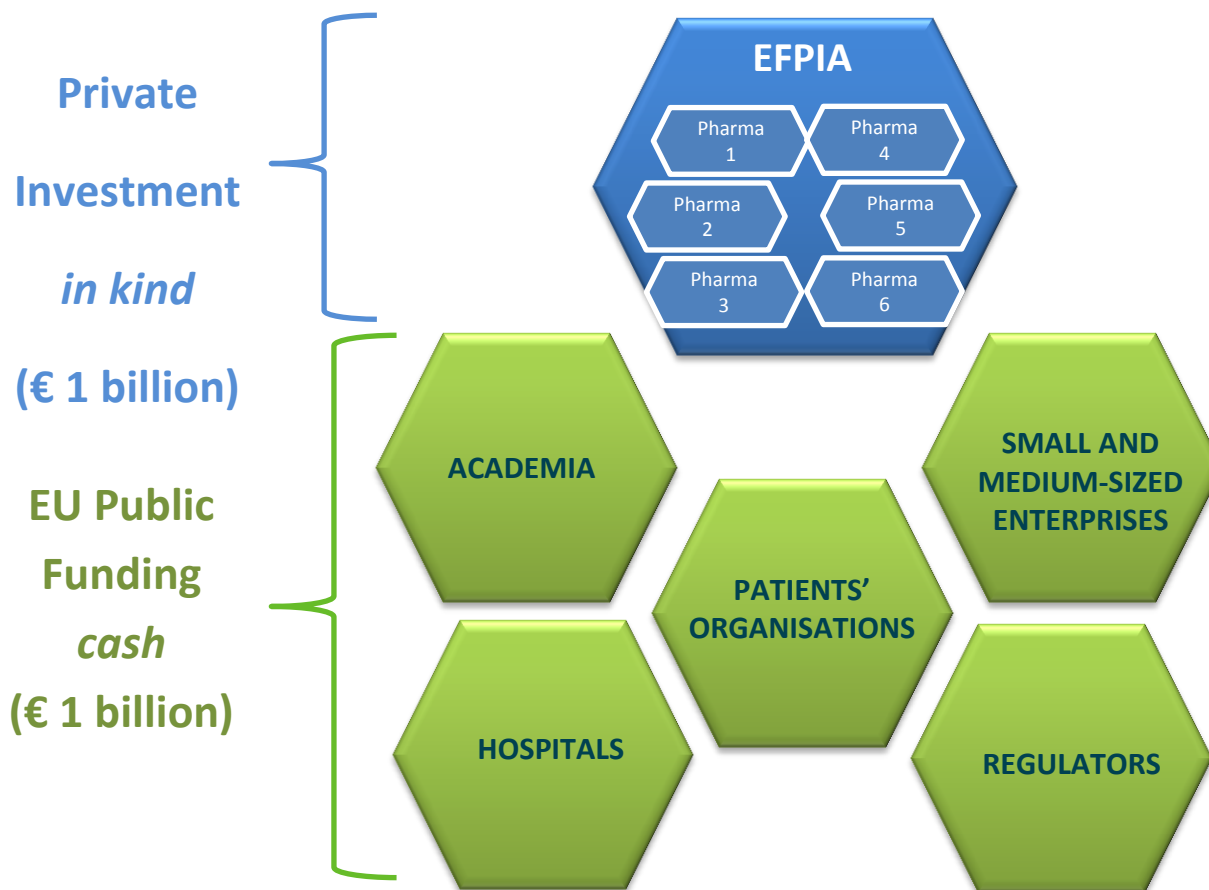
How it works - Optimized timelines



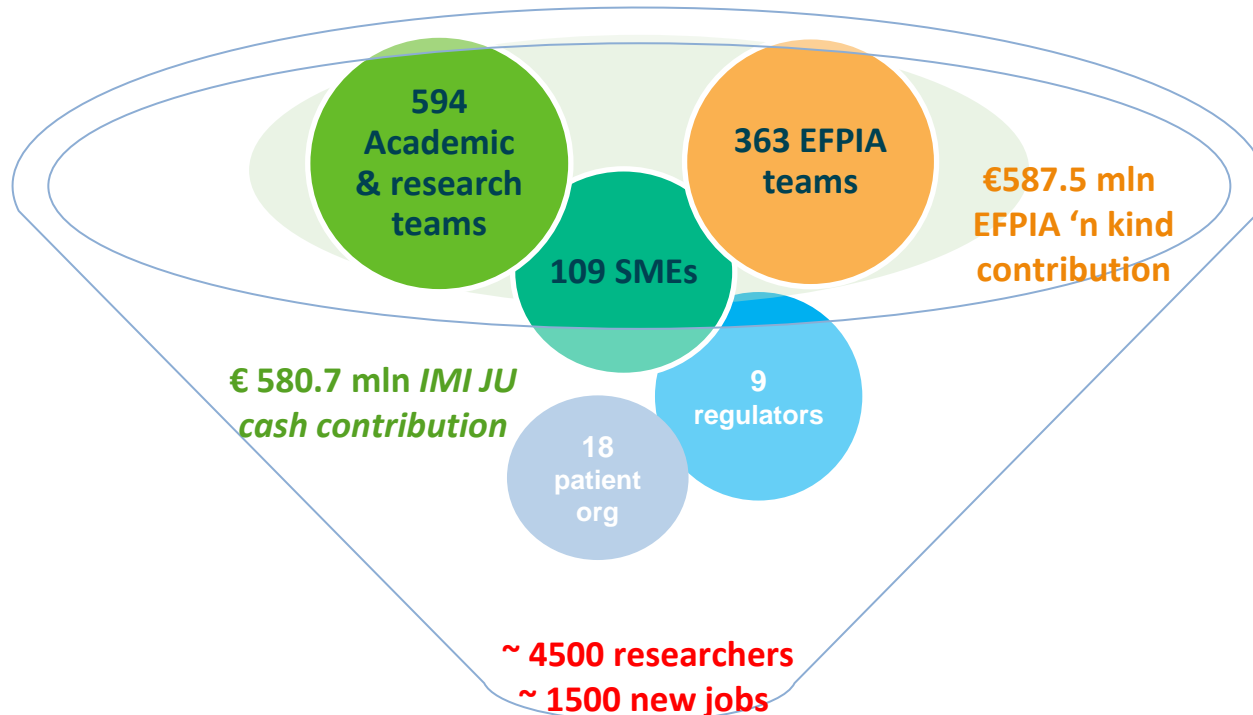
How IMI works – Project architecture



A Typical IMI Consortium



Key Figures of 40 on-going Projects



Collective intelligence networks

Improved R&D productivity of pharma industries

Innovative approaches for unmet public health needs



IMI's ongoing projects



 EUROPEAN LEAD FACTORY

COMBACTE

TRANSLOCATION

www.imi.europa.eu/content/ongoing-projects





- ✓ **EU-AIMS** collaboration with EMA triggered drafting a concept paper on the development of medicines in autism
- ✓ **PROactive** submitted qualification advice documents to the EMA on their patient reported outcome tool
- ✓ Identification of IMI projects with potential regulatory impact :

Safety projects: **MARCAR, eTOX, SAFE-T, MIP-DILI**

Efficacy in neurology: **NEWMEDS, PHARMA-COG**

Efficacy in diabetes: **IMIDIA, SUMMIT, DIRECT**



Proposed Topics For Launch 2013



Call 11 Topic

- 1 Identification and validation of innovative clinical endpoints for osteoarthritis
- 2 European platform for proof of concept for prevention in Alzheimer's disease
- 3 Blood-based biomarker assays for personalised tumor therapy: the value of circulating tumor cells, tumor DNA, and miRNA
- 4 Zoonoses anticipation and preparedness Initiative (ZAPI)
- 5 Generation of research tools to translate genomic discoveries into drug discovery projects
- 6 ND4BB Topic 6 – Clinical development of novel systemic antibacterial molecules against healthcare-associated infections (HAIs) caused by *Pseudomonas aeruginosa* and other Gram-negative bacterial pathogens
- 7 ND4BB Topic 7 – Development of novel inhaled antibiotics treatment regimen in patients with cystic fibrosis (CF) and patients with chronic obstructive pulmonary disease (COPD)
- 8 EcoRiskPrediction (ERP)



The measures of success



SUCCESS

New models
developed &
published

Setting new
standards

In house
implementation
by industry

Impact on
regulatory
guidelines

Better Science = Better Decisions



efpia

Science is leading to a revolution in healthcare:



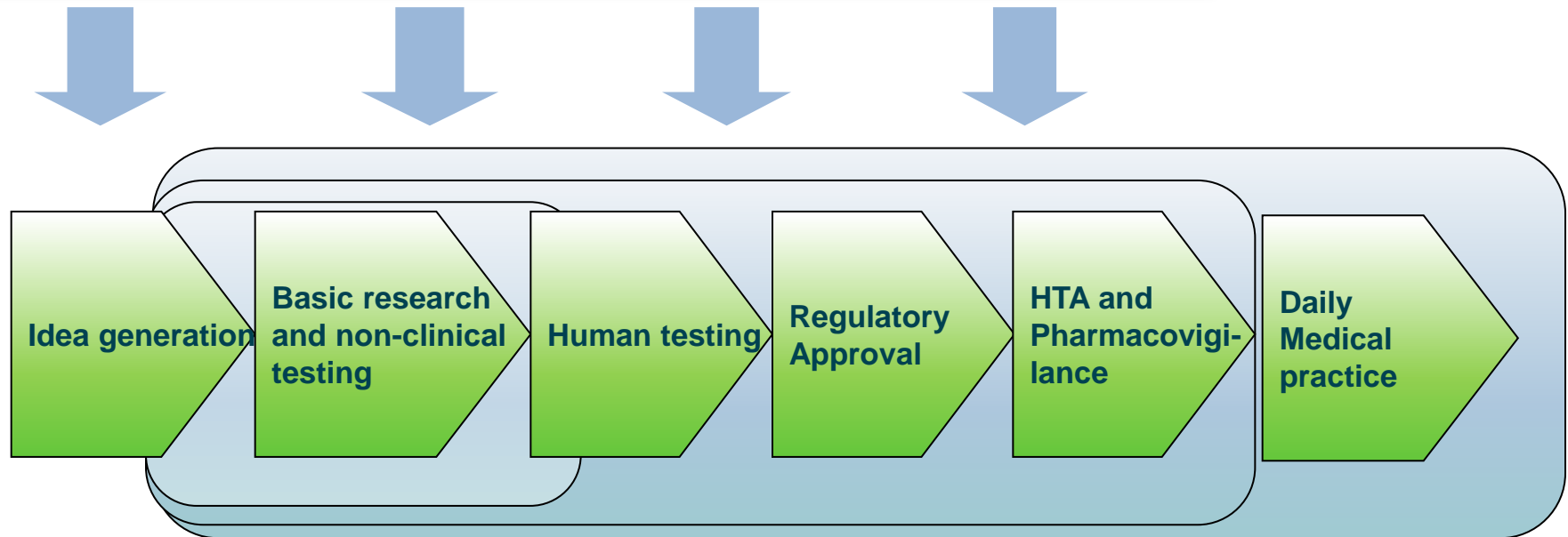
- **The conventional “notion” of diseases will break-down**
 - Every disease will be a molecular “fault” defined ‘orphan disease’
- **The molecular “fault” directs treatment**
 - Diseases with similar molecular ‘faults’ will have common therapies
- **Therapies will target a smaller group of individuals**
 - Diagnostic tests will determine who is ‘right’ and thus will benefit from the new treatment
- **Testing/evaluation of new treatments requires better use of data**
 - Capturing data from the ‘real world’



The Evolution of IMI: From bottlenecks in industry – to bottlenecks in Industry and Society



Make Drug R&D processes in Europe more efficient and effective and enhance Europe's competitiveness in the Pharma sector



Primary focus of early IMI calls
2007 SRA

Shift to also addressing challenges in society and healthcare
2011 SRA

IMI 2 includes real life medical practice
2013 SRA





European
Commission



Innovative Medicines Initiative 2: Europe's fast track to better medicines

- Next generation vaccines, medicines and treatments, e.g. new antibiotics;
- Faster roll-out of effective and sustainable healthcare;
- Leveraging public and private research funding to lower investment barriers;
- Supporting the global competitiveness of Europe's pharmaceutical industry.



© Minerva Studio, #53141299, 2013. Source: Fotolia.com



efpia

**Fosters large scale industry collaboration and engagement
with scientific community**

**Promotes active involvement of patients, regulators and
payers**

**Enables innovation via joint effort where singular
approach has failed so far**

Facilitates Intellectual Property agreements



Thank you

www.imi.europa.eu

Hugh.Laverty@imi.europa.eu



@IMI_JU



efpia*