



COLLABORATING FOR CURES:

***Leveraging global public-private partnerships to
accelerate biopharmaceuticals development***

**First Joint IMI – C-Path meeting
Brussels 7 March 2013**

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Collaborating for Cures Leveraging Global Public-Private Partnerships to Accelerate Biopharmaceutical Development

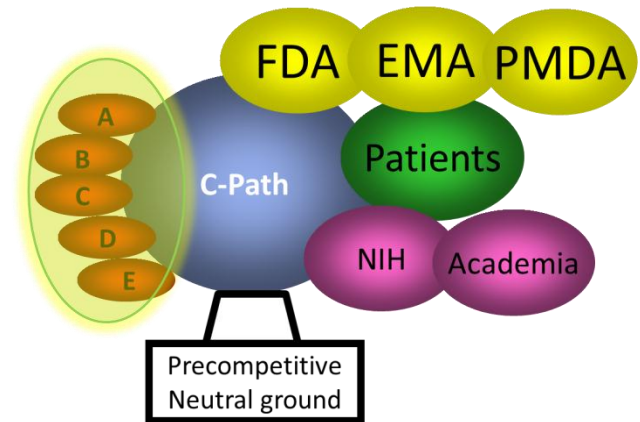
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Martha A. Brumfield, Ph.D.,
CEO and President
Critical Path Institute (C-Path)
7 March 2013 Bruxelles

C-Path: A Public-Private Partnership

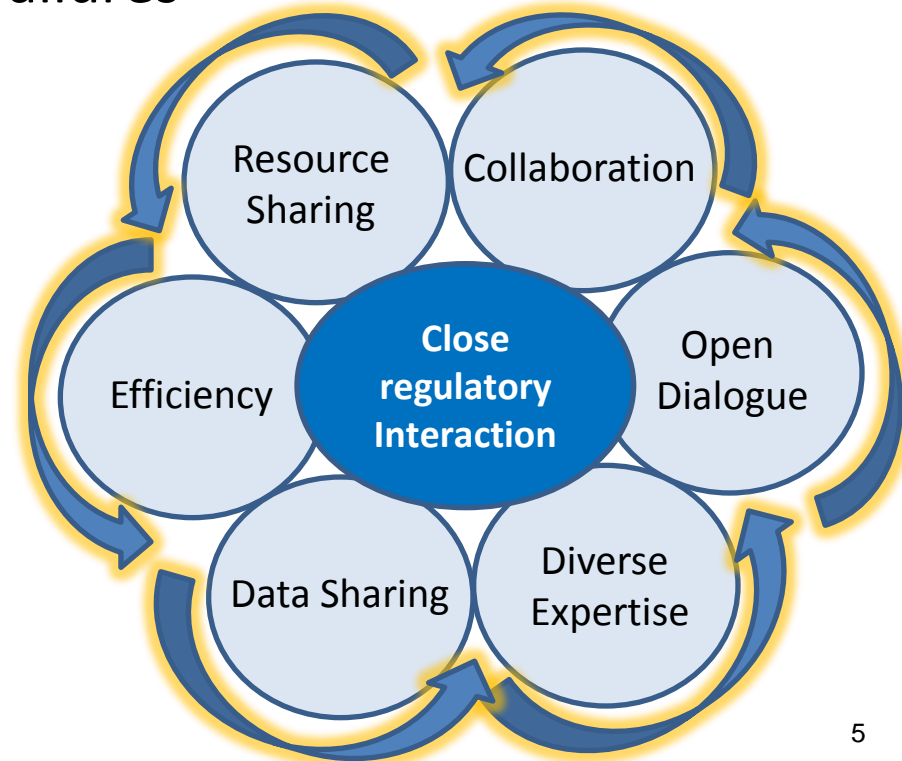
- ❑ Act as a trusted, neutral third party
- ❑ Convene scientific consortia of industry, academia, and government for pre-competitive sharing of data/expertise
 - ❑ The best science
 - ❑ The broadest experience
 - ❑ Active consensus building
 - ❑ Shared risk and costs
- ❑ Enable iterative EMA/FDA/PMDA participation in developing new methods to assess the safety and efficacy of medical products
 - ❑ Official regulatory recognition through “qualification” of Novel Methodologies and Drug Development Tools and acceptance of data standards



- **Individual Companies or Research Institutions Will Not Solve Challenges to Medicine's Future Alone**
 - No single entity has the answer
 - De-risking development and regulatory pathways is critical
- **Different Model for Partnering is Needed**
 - Expertise from all sectors must be involved
 - International participation is necessary
 - Willingness to share critical information/data is required

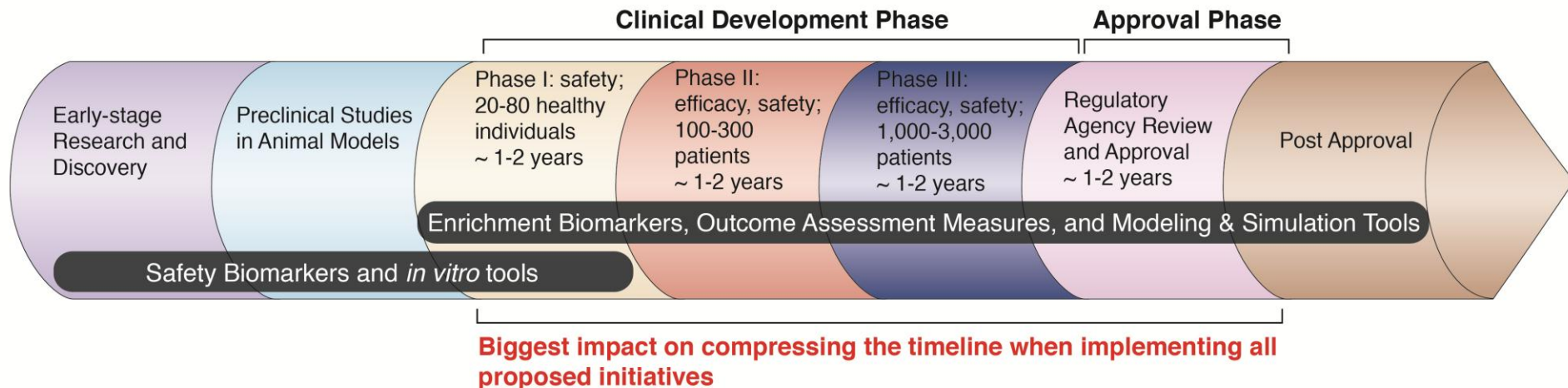
Factors Impacting Future Success

- Resource constraints at all levels
- Consortia fatigue
- Organizational Structure and Governance
- Data Sharing and Learning from failures
- Communication among partners
- Culture
- Financing
- Incentives
- Risk Mitigation
- Respect for confidentiality



Shared learning can shorten the timeline








- **Data Standardization and Sharing**
- **Biomarker Development and Qualification**
- **Outcome Assessment Measures**
- **Modeling and Simulation**



C-Path Consortia

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Seven global consortia collaborating with 1,000+ scientists and 41 companies

 <p>CAMD CRITICAL PATH INSTITUTE</p>	Coalition Against Major Diseases UNDERSTANDING DISEASES OF THE BRAIN
 <p>CPTR</p>	Critical Path to TB Drug Regimens TESTING DRUG COMBINATIONS
 <p>CRITICAL PATH INSTITUTE MS National Multiple Sclerosis Society</p>	Multiple Sclerosis Outcome Assessments Consortium DRUG EFFECTIVENESS IN MS
 <p>PKD CONSORTIUM CRITICAL PATH INSTITUTE</p>	Polycystic Kidney Disease Consortium NEW IMAGING BIOMARKERS
 <p>PRO CONSORTIUM CRITICAL PATH INSTITUTE</p>	Patient-Reported Outcome Consortium DRUG EFFECTIVENESS
 <p>ePRO CONSORTIUM CRITICAL PATH INSTITUTE</p>	Electronic Patient-Reported Outcome Consortium DRUG EFFECTIVENESS
 <p>PSTC CRITICAL PATH INSTITUTE</p>	Predictive Safety Testing Consortium DRUG SAFETY

- Biomarkers
- Clinical Outcome Assessment Instruments
- Clinical Trial Simulation Tools
- Data Standards



C-Path Collaborators



Consortia Members



Partners



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C-Path gratefully acknowledges the support of





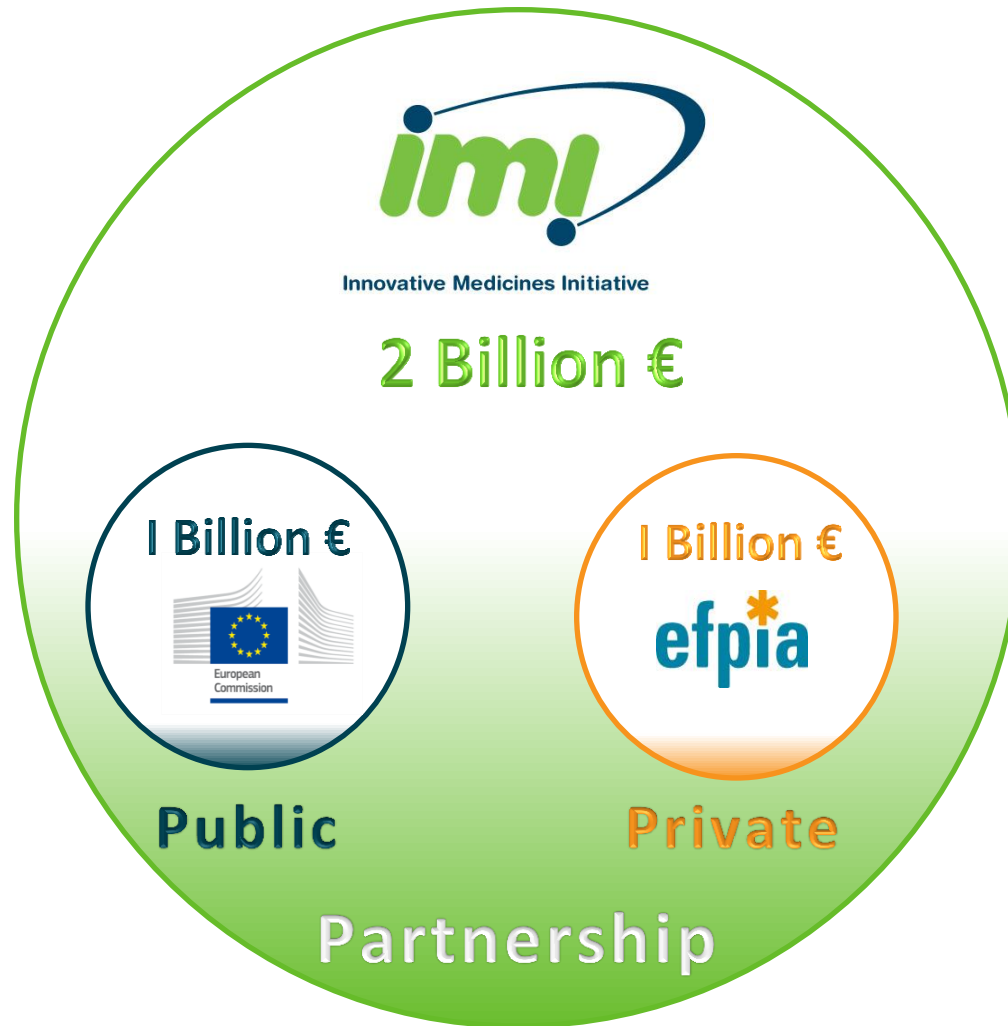
The Innovative Medicines Initiative: A driving force in the quest for new therapies

Michel Goldman, MD, PhD
Executive Director, Innovative Medicines Initiative



Innovative Medicines Initiative:

Joining forces in the healthcare sector



Key concepts underlying IMI



“Non-competitive” collaborative research for EFPIA companies

Competitive calls to select partners of EFPIA companies (IMI beneficiaries)

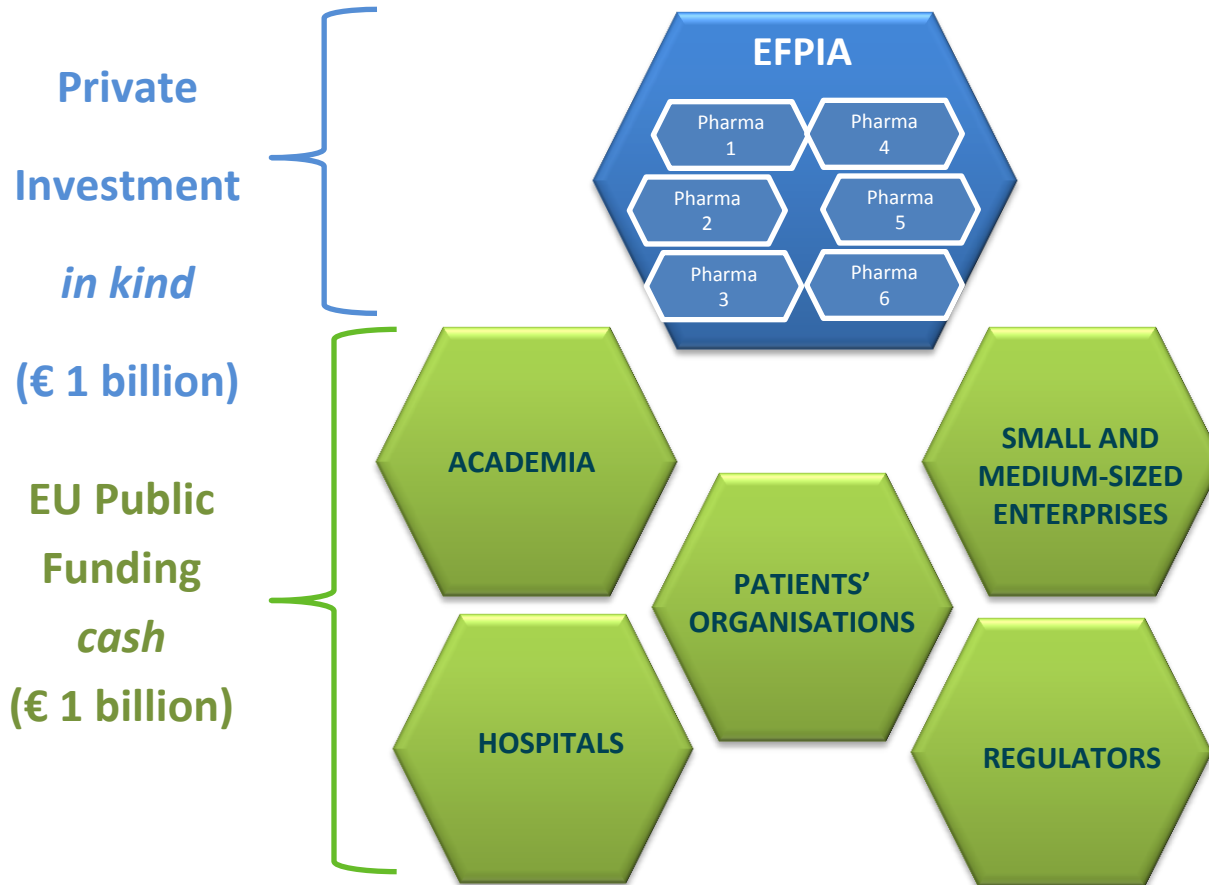
Open collaboration in public-private consortia (data sharing, wide dissemination of results)



How IMI works – Project architecture



A Typical IMI Consortium



Ongoing IMI Projects

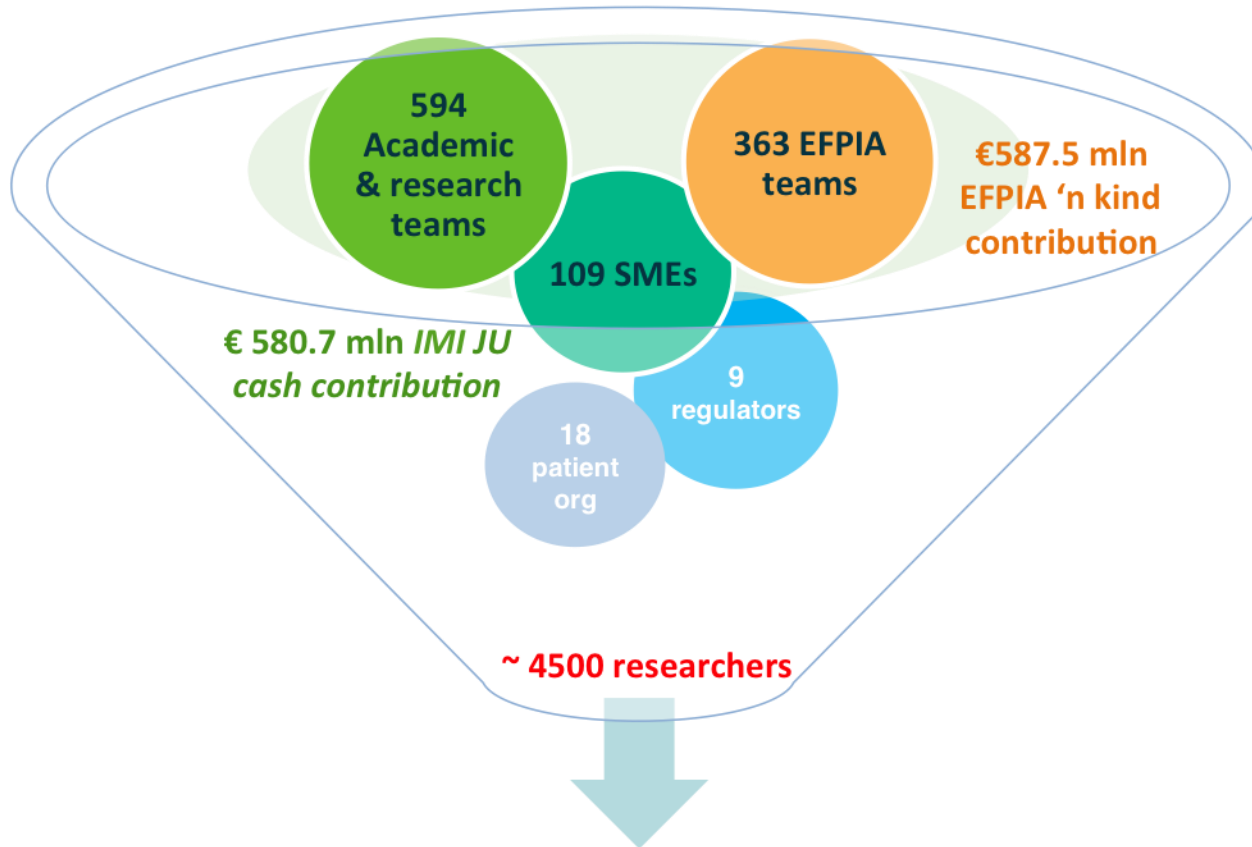


COMBACTE

TRANSLOCATION



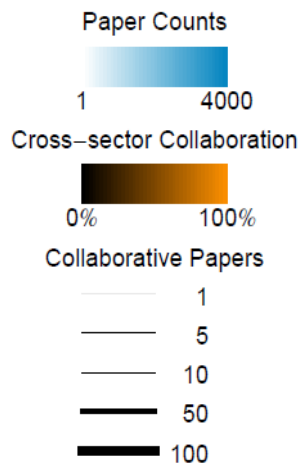
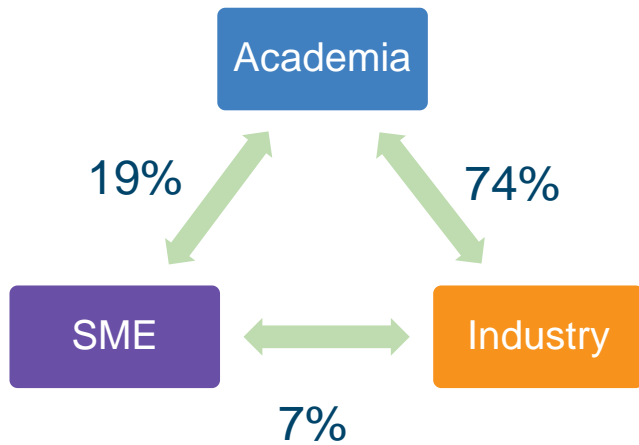
Key figures of ongoing IMI Projects



Increased probability of success
Earlier patient access



Mapping IMI Collaborative Networks



Key challenges addressed



- Disease heterogeneity
- Lack of predictive biomarkers and tools
- Outdated clinical designs and regulatory processes
- Insufficient incentives for pharma industry and biotech companies
- Need for mindset shift in stakeholder communities





THANK YOU



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