Boosting drug development through Public-Private Partnerships: The IMI Model

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Innovative Medicines Initiative



The European Union and the pharmaceutical industry

have joined forces to make

drug R&D processes in Europe more innovative and efficient

and enhance Europe's

competitiveness in the sector

& address key societal challenges

by forming

the biggest PPP in Life Science





Key Concepts



"Non-competitive" collaborative research for EFPIA companies

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

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



IMI Governance



Governing Board

efpia

Executive Director (+ staff)

Stakeholder Forum

IMI States Representatives Group

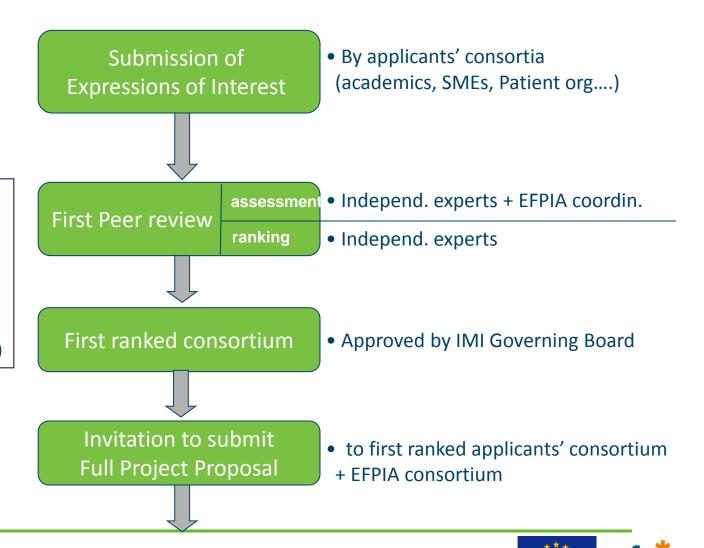




Building an IMI Project (1/2)



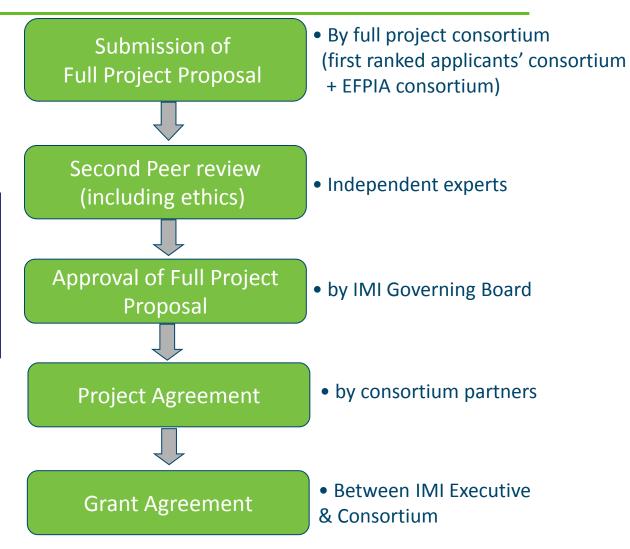
Competition
between
applicants'
consortia
(potential IMI beneficiaries)



Building an IMI Project (2/2)



Joint Preparation of Full Project Proposal



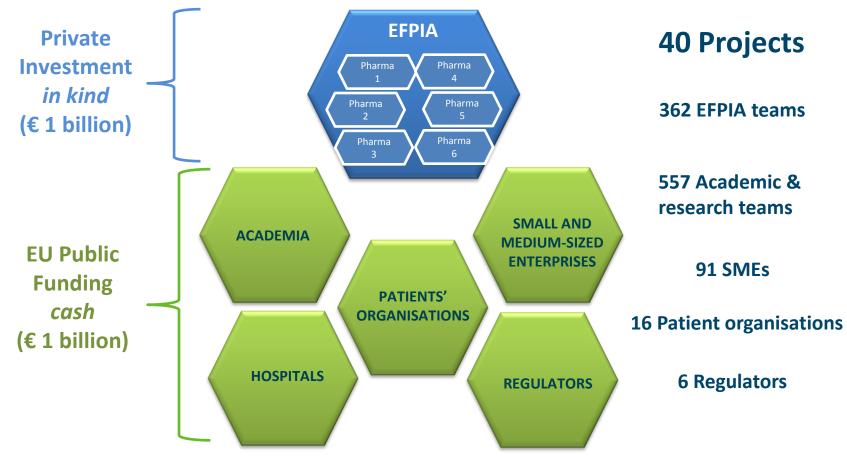




IMI Project Architecture



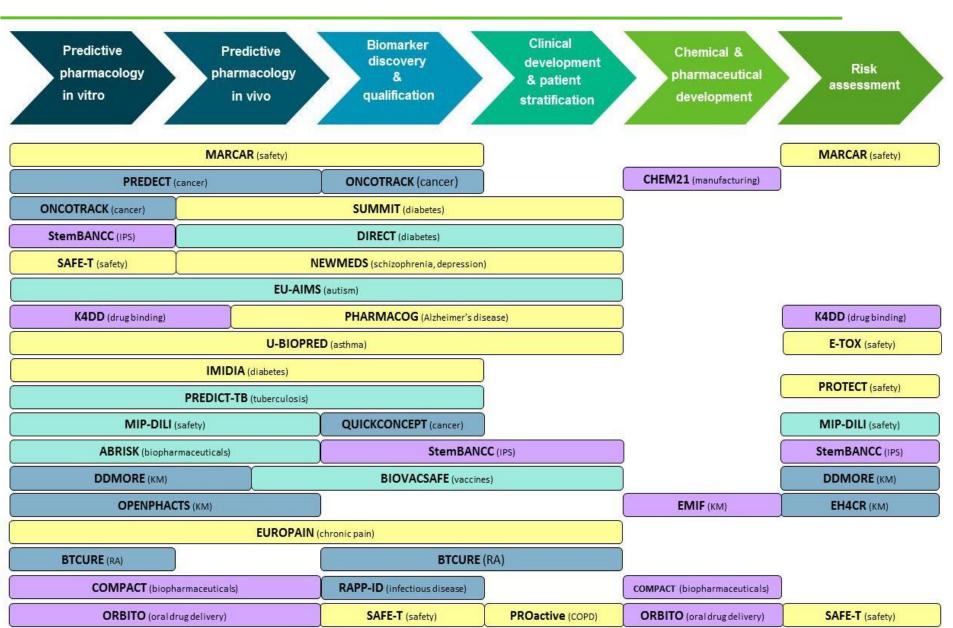
A Typical IMI Consortium





Value Chain Coverage - Calls 1 2



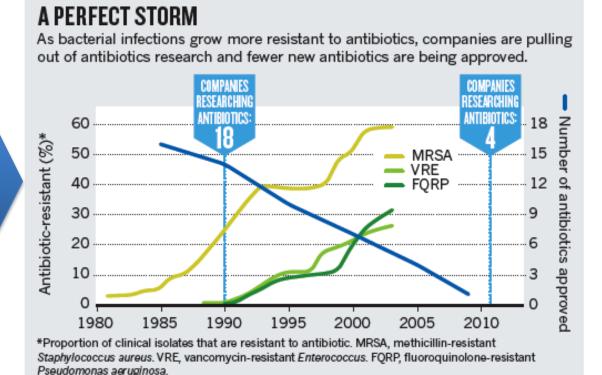


Antibiotic drug development: 'New Drugs 4 Bad Bugs'



Challenges of AB R&D:

- Unique scientific bottlenecks
- Challenging regulatory environment
- Low return on investment



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Challenges too great for any single entity to solve, collaboration is essential

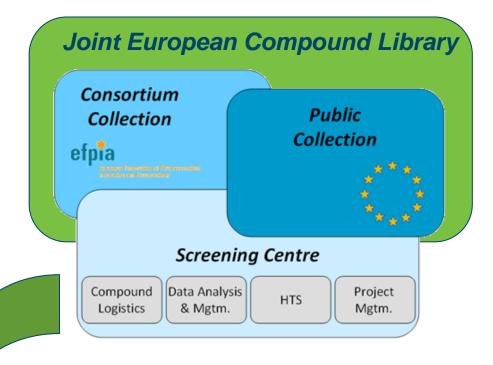




European Lead Factory



- Joint European Compound Library accessible for private and public lead discovery projects
- JECL is comprised of a Pharma Consortium Collection (≥ 300.000 compounds) and a Public Collection (up to 200.000 cpds.)
- □ The Screening Centre as an independent novel business entity takes responsibility for cpd. logistics, HTS (internal and out-sourced), data analysis & handling, and project mgtm.
- Screening Centre functions as a market place to broker public-private
 discovery projects with the Pharma Consortium



- Lead Structures for drug discovery programs
- "Tool Compounds" for target/mechanism validation



How IMI makes a difference



Fosters large scale industry collaboration and engagement with scientific community

Promotes active involvement of patients, regulators and payers

Enables innovation via join effort where singular approach has failed so far

Facilitates Intellectual Property agreements





One IMI IP policy, multiple interests



Direct exploitation rights
(academia /SME)
Terms known at outset
(Pharma)

Fair and reasonable terms for Research Use purposes for third parties

Innovative Medicines

Dissemination within a year

Terms accommodate the needs of a spectrum of interests - large and small

Only necessary background included Compensation within fair and reasonable terms



The Evolution of IMI

From bottlenecks in industry to bottlenecks in society



FUTURE PPP

INNOVATIVE MEDICINES INITIATIVE

+ Drive Regulatory Change

What: translate science into regulatory pathways: real life data

How: Collaborate with regulators and payers

Since 2012

+ Facilitate 'pull' incentives

What: Reconcile research and health care agendas

How: Engage with regulators and payers

Since 2011

Reduce Attrition and Time to Market

What: Decrease risk by developing improved tools and methodologies, secure sustainability of outputs

How: <u>Large scale</u> industry collaboration and engagement with scientific community Since 2008







The Challenges



Difficulties reaching international agreement on common priorities

Insufficient modalities of funding

Obstacles to the transfer of science, technology and innovation into practice

Insufficient participation of relevant actors in society

The lack of integration of countries with weak scientific infrastructure

Problems of intellectual property management for applications of new technologies





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Ensuring success from future global initiatives



Mechanisms to allow individuals and institutions to engage internationally

Inclusive and flexible approach

Focus on addressing societal needs

Clearly defined IPR Policy

Neutral broker





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THANK YOU!



