

Innovative Medicines Initiative

IMI: A Public Private Partnership Approach to the Boosting of Pharmaceutical R&D

Elisabetta Vaudano Innovative Medicines Initiative

Hurdles to Better Healthcare

Society

- Healthcare challenges continue to raise around the world
- A lot of these challenges are not addressed
- Pressure on healthcare systems and budgets

continue to rise

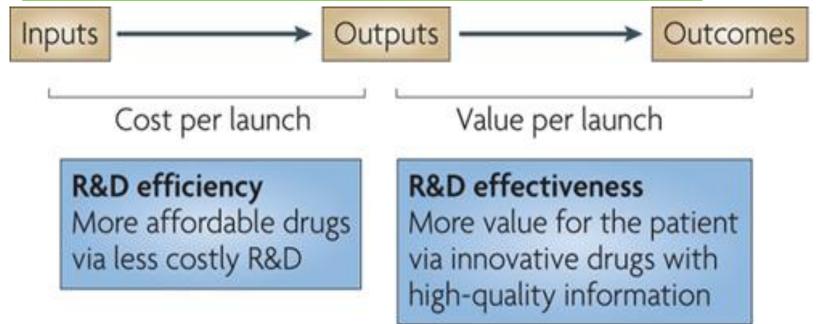
Industry

- Progress in basic science is not translated to medical innovation and benefits to patients
- Costs for developing new drugs continue to increase
- Pharma incentive systems and profitability are under pressure



Key changes are Needed to the Pharma R&D Model





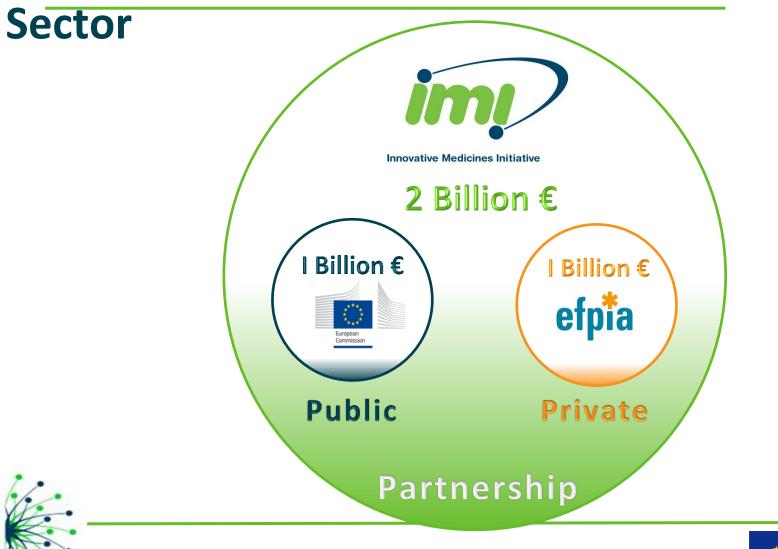
Nature Reviews | Drug Discovery

How to improve R&D productivity: the pharmaceutical industry's grand challenge Steven M. Paul, Daniel S. Mytelka, Christopher T. Dunwiddie, Charles C. Persinger, Bernard H. Munos, Stacy R. Lindborg & Aaron L. Schacht Nature Reviews Drug Discovery 9, 203-214 (March 2010)



Innovative Medicines Initiative: Joining Forces in the Healthcare







Key Concepts underlying IMI





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

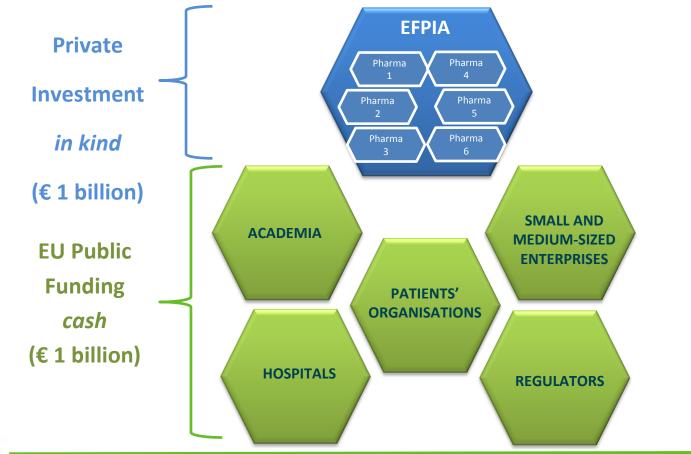




How IMI works – Project Architecture





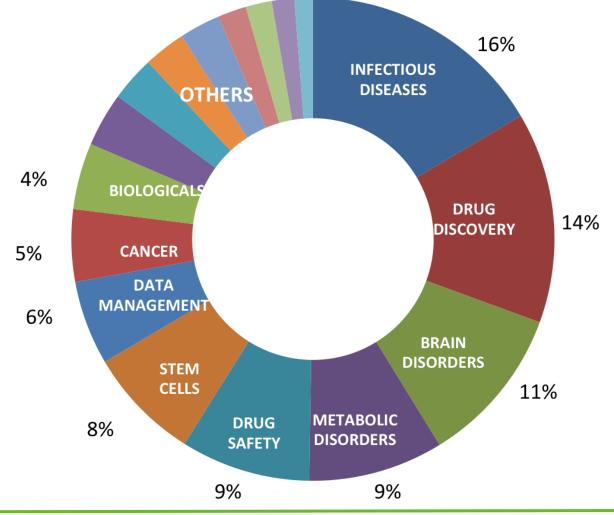






IMI portfolio – Budget Breakdown



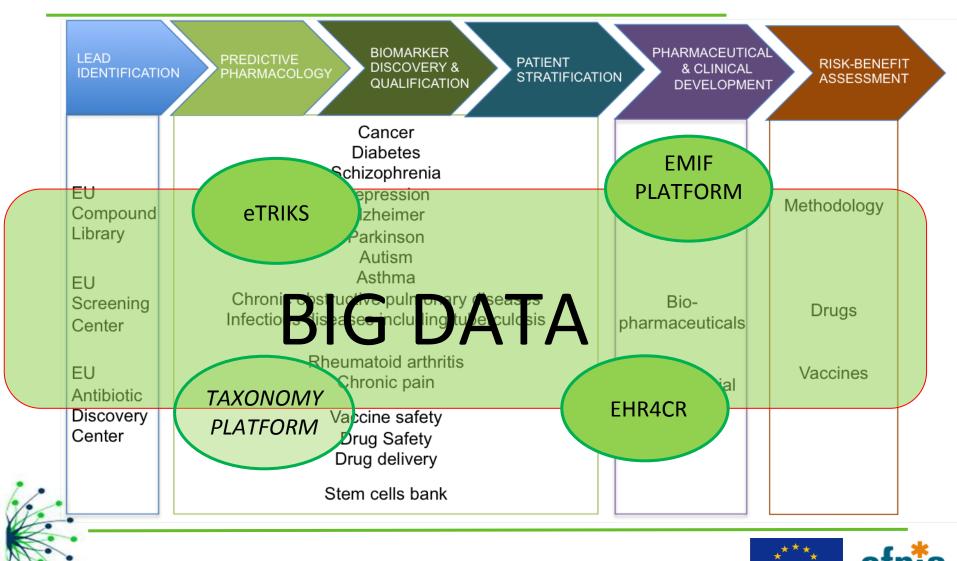






Mapping of Ongoing IMI Projects







Creating new models for R&D in areas of unmet clinical need: Autism Spectrum Disorder *Will Spooren*, Head of Behavioural Pharmacology and Preclinical Imaging, Hoffmann-La Roche

Addressing the challenges of diabetes and its complication: The IMI Diabetes Platform Bernd Jablonka, External Alliances, Diabetes Division, Sanofi–Aventis

A PPP approach to boost antimicrobial resistance R&D: the ND4BB IMI platform *Seamus O'Brien*, Therapeutic Area Clinical Director, Lead Infection Global Medicines Unit, AstraZeneca





AUTISM SPECTRUM DISORDERS: A Paradigm for Non-Competitive Public-Private Partnership



Major Public Health Need

1% children affected

High societal burden

- Lifetime cost:
 €3mi/patient
- UK annual cost: €40 billion



Distrust in past-research

MMR vaccine allegation

Psychoanalytic theories (France) Hurdles to drug development

Complexity of brain circuitry

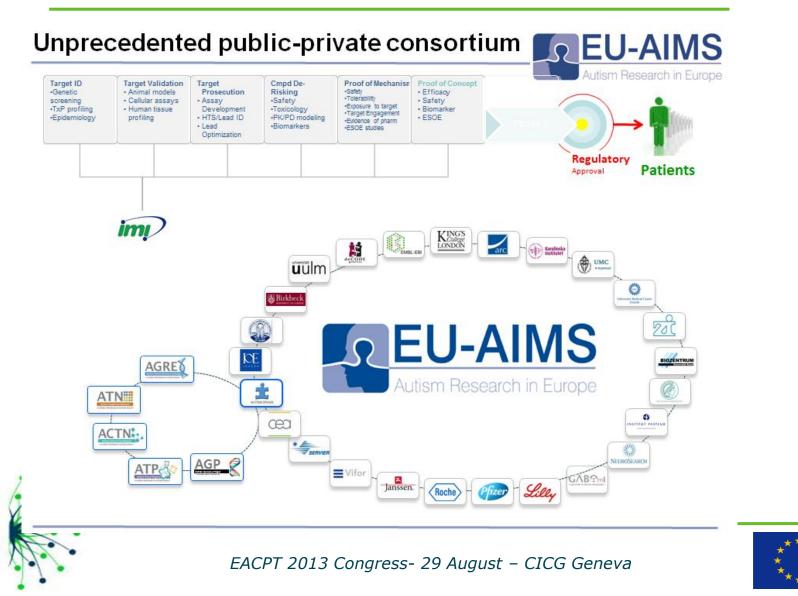
Patients heterogeneity

Lack of validated markers for disease activity









DIABETES: Fighting the Epidemic through Public-

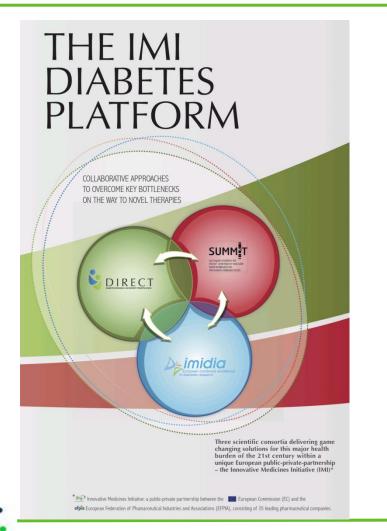
| Major Public Health Need | Distrust in past-research | Hurdles to drug development |
|--|--|--|
| Diabetes will affect 43 million Europeans in 2030 | Cardiovascular complications of rosiglitazone and benfluorex | Patients' heterogeneity Lack of reliable markers for disease activity and complications |
| €89 million spent on 2011 on treating diabetes and its complications | | |





The IMI DIABETES Platform





IMIDIA – DIRECT – SUMMIT: Bringing together experts from academia, industry and biotech to generate novel approaches for diabetes research and treatment in a unique collaborative European Public-Private-Partnership (PPP)



ANTIMICROBIAL RESISTANCE: Reinvigorating Antibiotics R&D



through Public-Private Partnership

Distrust in Major Public Health Need past-research Anti-microbial resistance **Guidelines for antibiotics** kills 25 000 European changed several times, citizens every year and contributing to confusion spread at rate that is both and mistrust alarming and irreversible Irresponsible use of - similar to global antibiotics warming

Annual costs are estimated at €1.5 billion Lack of high quality clinical trial infrastructure

Hurdles to drug development

Low return on investment

Regulatory environment

Lack of sharing R&D experience

Lack of rapid diagnostic tests/ biomarkers

Accessing drug targets is challenging



ND4BB



ND BB

The overall vision of ND4BB is to create an innovative collaborative Public-Private Partnership (PPP)-based approach that will encompass all aspects from the discovery of new antibiotics to Phase 2 and 3 clinical trials with the aim of reinvigorating antibiotic R&D





IMI - The Neutral Trusted Party



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



