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

Inputs → Outputs → Outcomes

Cost per launch

R&D efficiency
More affordable drugs via less costly R&D

Value per launch

R&D effectiveness
More value for the patient via innovative drugs with high-quality information

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)

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Innovative Medicines Initiative: Joining Forces in the Healthcare Sector

Partnership

2 Billion €

1 Billion €

Public

Private

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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

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How IMI works – Project Architecture

A Typical IMI Consortium

Private Investment
in kind (€ 1 billion)
EU Public Funding
cash (€ 1 billion)

EFPIA
Pharma 1
Pharma 2
Pharma 3
Pharma 4
Pharma 5
Pharma 6

ACADEMIA
HOSPITALS
PATIENTS’ ORGANISATIONS
SMALL AND MEDIUM-SIZED ENTERPRISES
REGULATORS

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Mapping of Ongoing IMI Projects

**EMIF PLATFORM**

- Methodology
- Drugs
- Vaccines

**TAXONOMY PLATFORM**

- Vaccine safety
- Drug Safety
- Drug delivery
- Stem cells bank

**BIG DATA**

- Cancer
- Diabetes
- Schizophrenia
- Depression
- Alzheimer
- Parkinson
- Autism
- Asthma
- Chronic obstructive pulmonary diseases
- Infectious diseases, including tuberculosis
- Rheumatoid arthritis
- Chronic pain

**eTRIKS**

**EHR4CR**

- EU Compound Library
- EU Screening Center
- EU Antibiotic Discovery Center

**LEAD IDENTIFICATION**

**PREDICTIVE PHARMACOLOGY**

**BIOMARKER DISCOVERY & QUALIFICATION**

**PATIENT STRATIFICATION**

**PHARMACEUTICAL & CLINICAL DEVELOPMENT**

**RISK-BENEFIT ASSESSMENT**

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Today Agenda & Speakers

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
- Impact on familial lives

## 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
EU-AIMS

Unprecedented public-private consortium

**EU-AIMS**

*Autism Research in Europe*

**Target ID**
- Organ screen
- TGF profiling
- Epidemiology

**Target Validation**
- Animal models
- High content
- Human tissue profiling

**Target Prosecution**
- Assay
- Development
- HTS/Lead ID
- Optimization

**Comp De-Nosking**
- Safety
- Toxicology
- PK/PD modeling
- Biomarkers

**Proof of Mechanism**
- Safety
- Time- and dose
- Exposure to target
- Target Engagement
- Efficacy in animals
- CSDE patients

**Proof of Concept**
- Efficacy
- Safety
- Biomarker
- CSDE

**Regulatory Approval**

**Patients**

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## DIABETES:
Fighting the Epidemic through Public-Private Partnership

<table>
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<tr>
<th>Major Public Health Need</th>
<th>Distrust in past-research</th>
<th>Hurdles to drug development</th>
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<tbody>
<tr>
<td>Diabetes will affect 43 million Europeans in 2030</td>
<td>Cardiovascular complications of rosiglitazone and benfluorex</td>
<td>Patients’ heterogeneity</td>
</tr>
<tr>
<td>€89 million spent on 2011 on treating diabetes and its complications</td>
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<td>Lack of reliable markers for disease activity and complications</td>
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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

## Major Public Health Need
- Anti-microbial resistance kills 25,000 European citizens every year and spread at rate that is both alarming and irreversible – similar to global warming.
- Annual costs are estimated at €1.5 billion.

## Distrust in past research
- Guidelines for antibiotics changed several times, contributing to confusion and mistrust.
- Irresponsible use of antibiotics.
- 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.
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