The Innovative Medicines Initiative

New Drugs for Bad Bugs programme
IMI – Europe’s partnership for health

Partnership 2008 - 2024

€2.5 bn (European Union)

> €5 bn

€2.5 bn (EFPIA)

Innovative Medicines Initiative
Why do we need IMI?

Because drug development is very...

- risky
- inefficient
- complex
- time consuming
- expensive

Because...

- Not enough science throughout development
- Clinical trial designs not always optimal
- Regulatory pathways not always optimised
How is IMI addressing the challenges in drug development?

Through IMI’s projects we are trying to...

- put patients at the centre
- share risk (among public & private players)
- increase efficiency (by developing common tools)
- reduce duplication of effort (esp. at early stages)
- reduce timelines (by using a personalised medicine approach)
- integrate the latest science into drug development
- use data and knowledge management to work more effectively

We do this by creating a neutral platform where all involved in drug development – academics, industry, SMEs, patients, regulators, others – can engage in open collaboration on shared challenges.
IMI and antimicrobial resistance

Nov. 2011 – EU action plan on AMR calls for rapid launch of IMI programme on AMR

May 2012 – IMI launches first Call for proposals on AMR

Jan. 2013 – first projects (COMBACTE & TRANSLOCATION) start
# New Drugs for Bad Bugs

## Challenge 1: Getting the drug into the bug

**TRANSLOCATION**: Addressing scientific challenge of penetration barriers & efflux

## Challenge 2: Translation from early discovery to clinic

**ENABLE**: Combine academia / industry expertise to work on early-stage novel molecules

## Challenge 3: Clinical dvpt long, costly & often inefficient

**COMBACTE family, iABC**: Creating sustainable clinical investigator / laboratory / epidemiology networks; clinical studies

## Challenge 4: Low return on investment

**DRIVE-AB**: Options for a new economic model of antibiotic development & stewardship. Buy in from all stakeholders
TRANSLOCATION – getting drugs into bugs (& keeping them there)

- Focus on Gram-negatives
- Developed new techniques to analyse the uptake of antibiotics by bacteria
- Worked out structure of 20 proteins found in membranes of bacteria.
- Greater understanding of workings of efflux pumps
- Creation of database to gather data from both new antibiotic research projects and abandoned ones.
ENABLE – a platform for antibiotic development

Drug Discovery Platform

Novel molecules (SMEs, universities)

Novel ‘hit’ molecule

Optimised ‘Lead’ molecule

Clinical candidate

Phase 1 clinical trial

Open Calls to attract best programmes

Supported by Drug Discovery Platform

Supporting multiple programmes

Portfolio Management Committee

Controls progression decisions

Supported by innovative medicines initiative
COMBACTE – a pan-European network for clinical studies

CLIN-Net hospital network
- 697 hospitals
- 437 cities
- 39 countries in Europe

LAB-Net network
- 426 laboratories

Programmes
- 6 clinical development programmes active
- Observational studies, epidemiology
- Links with BARDA studies on ATM-AVI
**iABC – focus on inhaled antibiotics**

- Respiratory infections = main cause of disease and death in people with cystic fibrosis & bronchiectasis
- No. inhaled antibiotics available for these patients is limited
- Infections in both CF and BE patients are increasingly resistant to treatments

**Goal of iABC**

- Advance development of two inhaled antibiotics for patients with CF & BE → First trial due to start soon!
- Identify ways of improving clinical trials of treatments for CF & BE
**DRIVE-AB – a new economic model for antibiotic R&D**

<table>
<thead>
<tr>
<th>Innovation</th>
<th>Conservation</th>
<th>Access</th>
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<tbody>
<tr>
<td>New antibiotics that address extensively or pan-resistant bacteria</td>
<td>Sustainable use, prevention of excessive use, includes diagnostics, biomarkers, alternative treatment strategies</td>
<td>Access to new antibiotics when needed, excludes extremely high prices</td>
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**Return on investment de-linked from sales volume**

**Challenge:** Buy-in from all stakeholders: public health, government / payers, clinical societies, academia, industry
Summary

- IMI can address challenges related to discovery & development of new medicines against AMR
- Collaboration is key!
- Support for early stage programmes from academia & SMEs is vital
- We will see more international collaboration in clinical trials in AMR
- We see increasing activity on new economic models of antibiotic R&D
Thank you

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