The Innovative Medicines Initiative New Drugs for Bad Bugs programme

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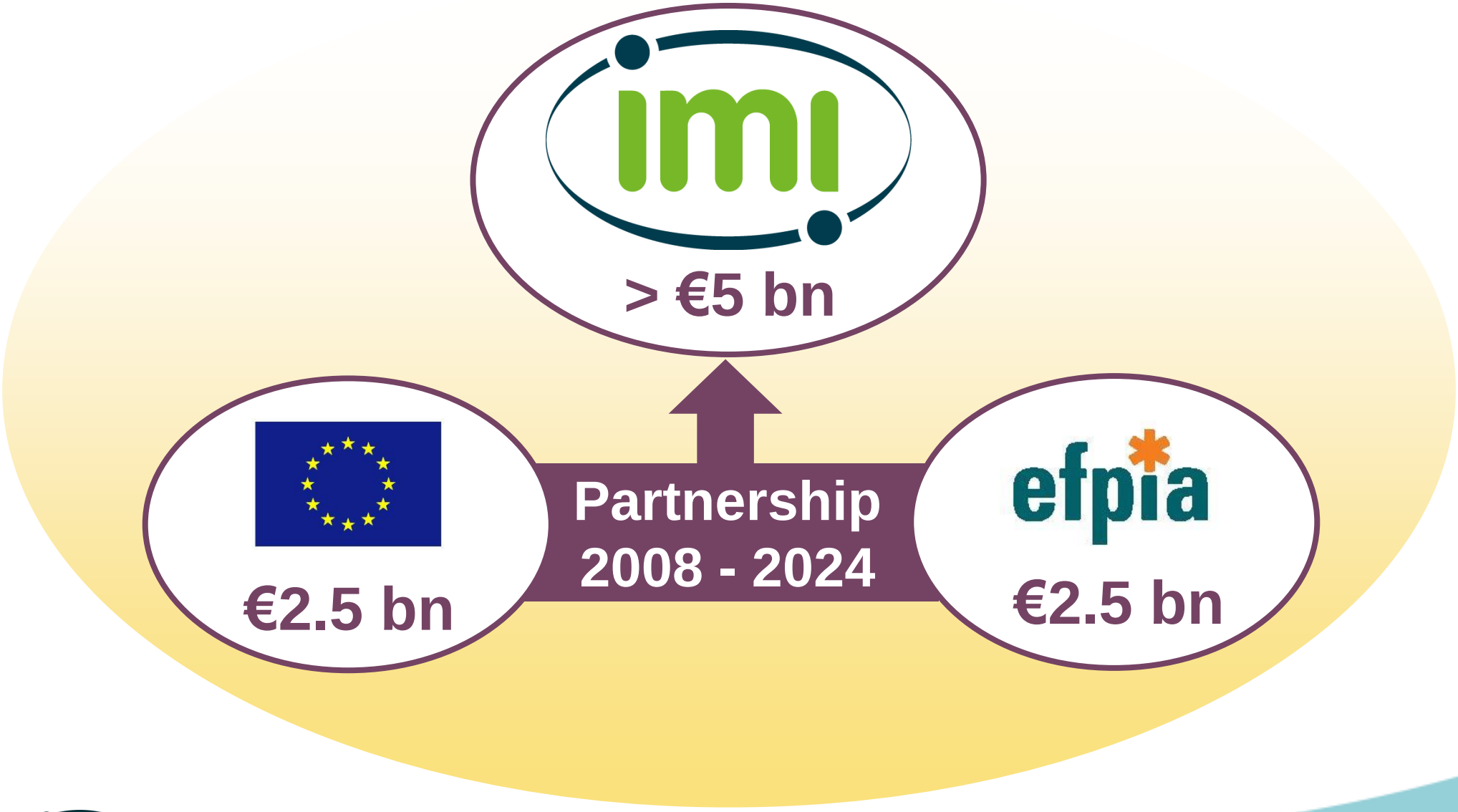
IMI – Europe's partnership for health



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Why do we need IMI?

Because drug development is very…

risky

inefficient

complex

time consuming

expensive

Because…

Clinical trial designs not always optimal

Not enough science throughout development

Regulatory pathways not always optimised

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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**.

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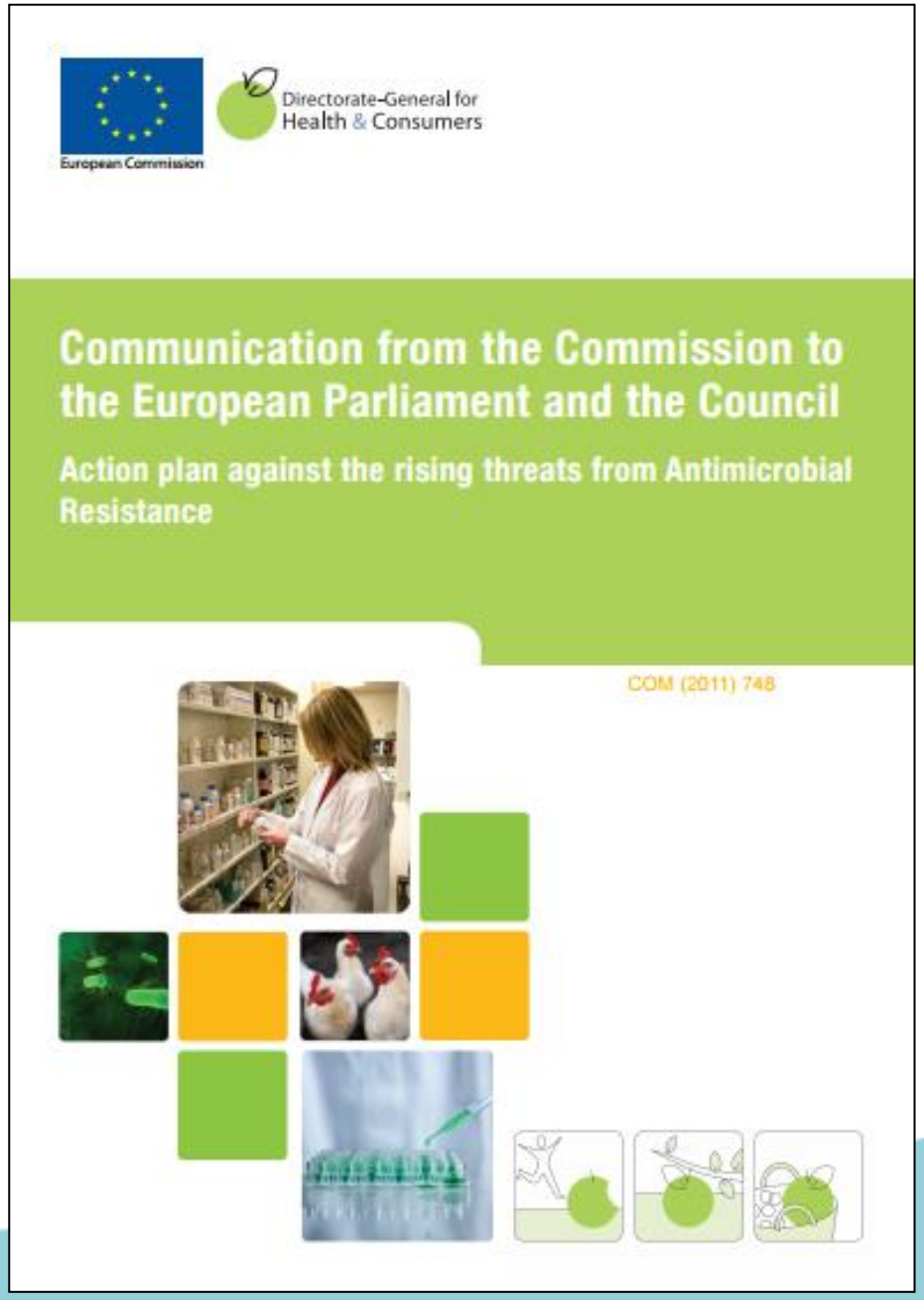
IMI and antimicrobial resistance

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



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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

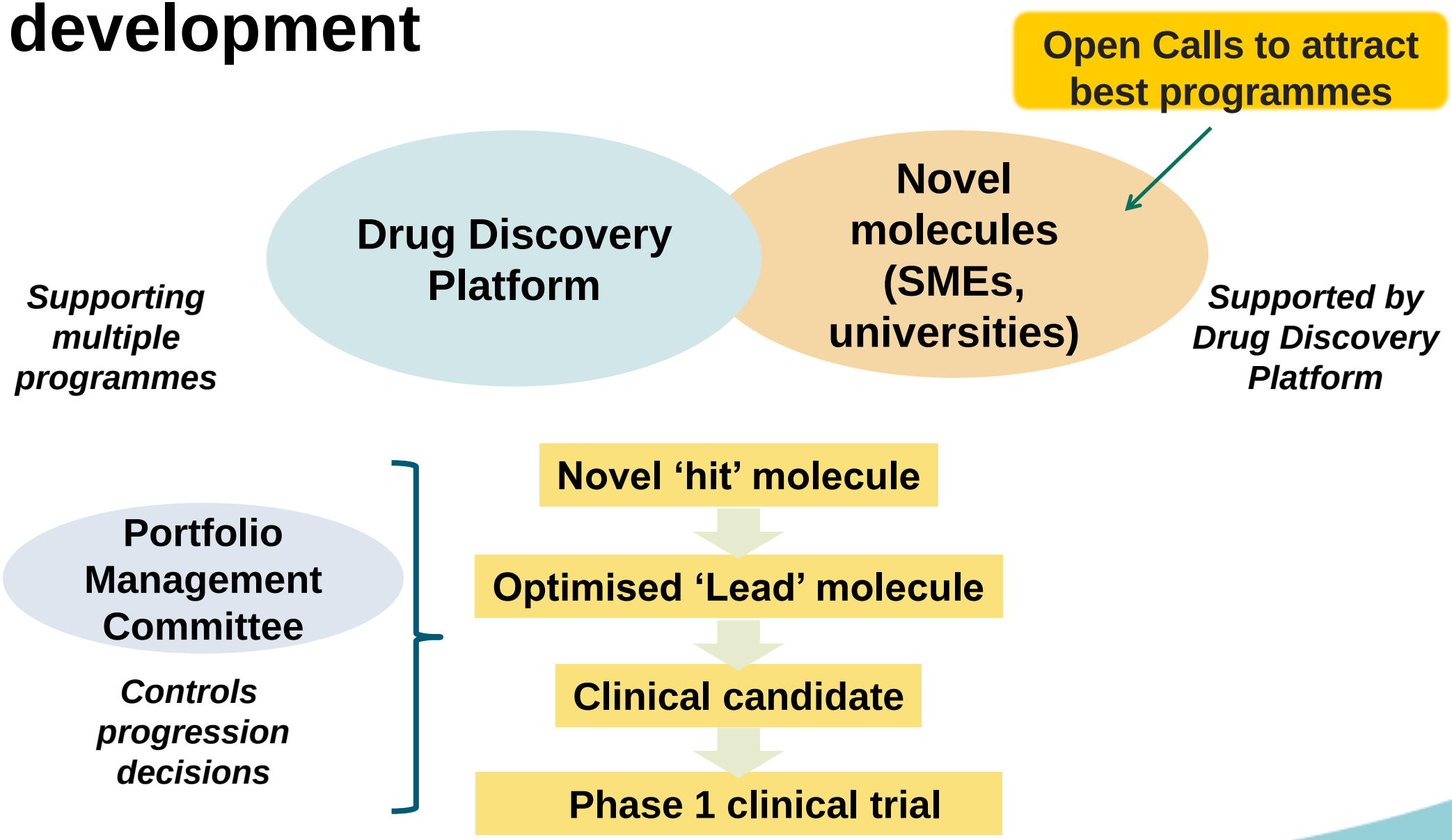
Challenge 4: Low return on investment

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



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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

ND4BB COMBACTE

ND4BB COMBACTE CARE

ND4BB COMBACTE MAGNET

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

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DRIVE-AB – a new economic model for antibiotic R&D

Innovation	Conservation	Access
New antibiotics that address extensively or pan-resistant bacteria	Sustainable use, prevention of excessive use, includes diagnostics, biomarkers, alternative treatment strategies	Access to new antibiotics when needed, excludes extremely high prices

Return on investment de-linked from sales volume

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

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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

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Thank you

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