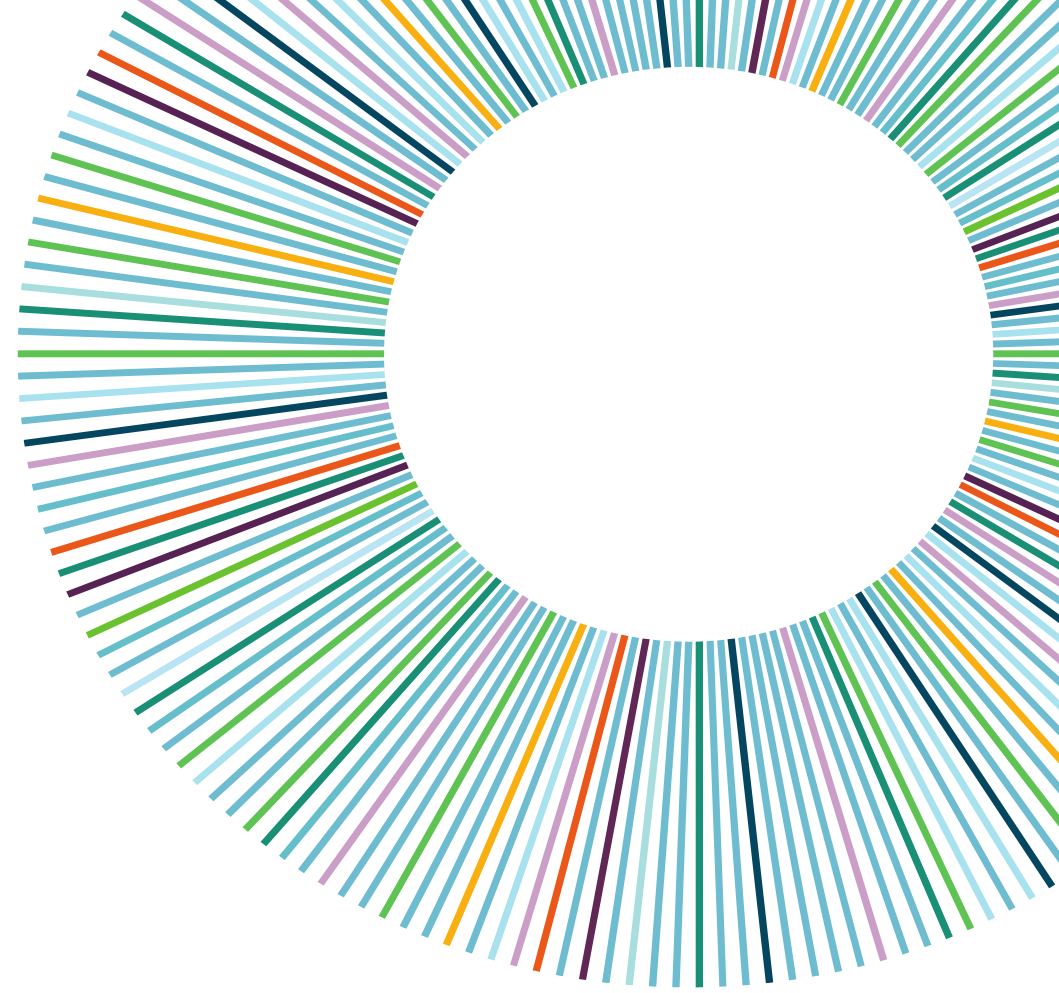




The Innovative Medicines Initiative – Europe's partnership for health

Tek-Ang LIM,
20 June 2018, Brussels

10 YEARS OF LIGHTING THE WAY



**10 YEARS OF
BREAKTHROUGHS**
A HEALTHIER
FUTURE

IMI – Why Europe's partnership for health?

Because despite decades of research we still don't have...

enough
antibiotics in
development

a cure for
diabetes

an HIV
vaccine

a cure for
dementia

So IMI is...

- supporting projects across the whole spectrum of medical R&D and drug development, incl. understanding diseases;
- identifying & developing potential drugs;
- testing safety / efficacy;
- improving clinical trial design

IMI – Europe's partnership for health

IMI mission

IMI facilitates open collaboration in research to advance the development of, and accelerate patient access to, personalised medicines for the health and wellbeing of all, especially in areas of unmet medical need.

IMI 2 Strategic Research Agenda

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegenerative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan Diseases
- Vaccines



The right prevention and treatment
for the right patient at the right time

Strategic Research Agenda for
Innovative Medicines Initiative 2

**Aligned with
WHO priorities**

IMI2 overall objectives

- **improve the current drug development process** through development of tools, standards & approaches to assess **efficacy**, **safety** & **quality** of health products.
- **develop diagnostic & treatment biomarkers** for diseases clearly linked to clinical relevance & approved by regulators
- **reduce time to clinical proof of concept** (e.g. for cancer, immunological, respiratory, neurological/neurodegen. diseases)
- **increase success rate in clinical trials** of priority meds (WHO)
- **develop new therapies** for diseases with **high unmet need**, (e.g. Alzheimer's) & **limited market incentives** (e.g. AMR)
- **reduce failure rate of vaccine candidates** in phase III trials through new biomarkers for efficacy & safety checks

IMI2 legislation

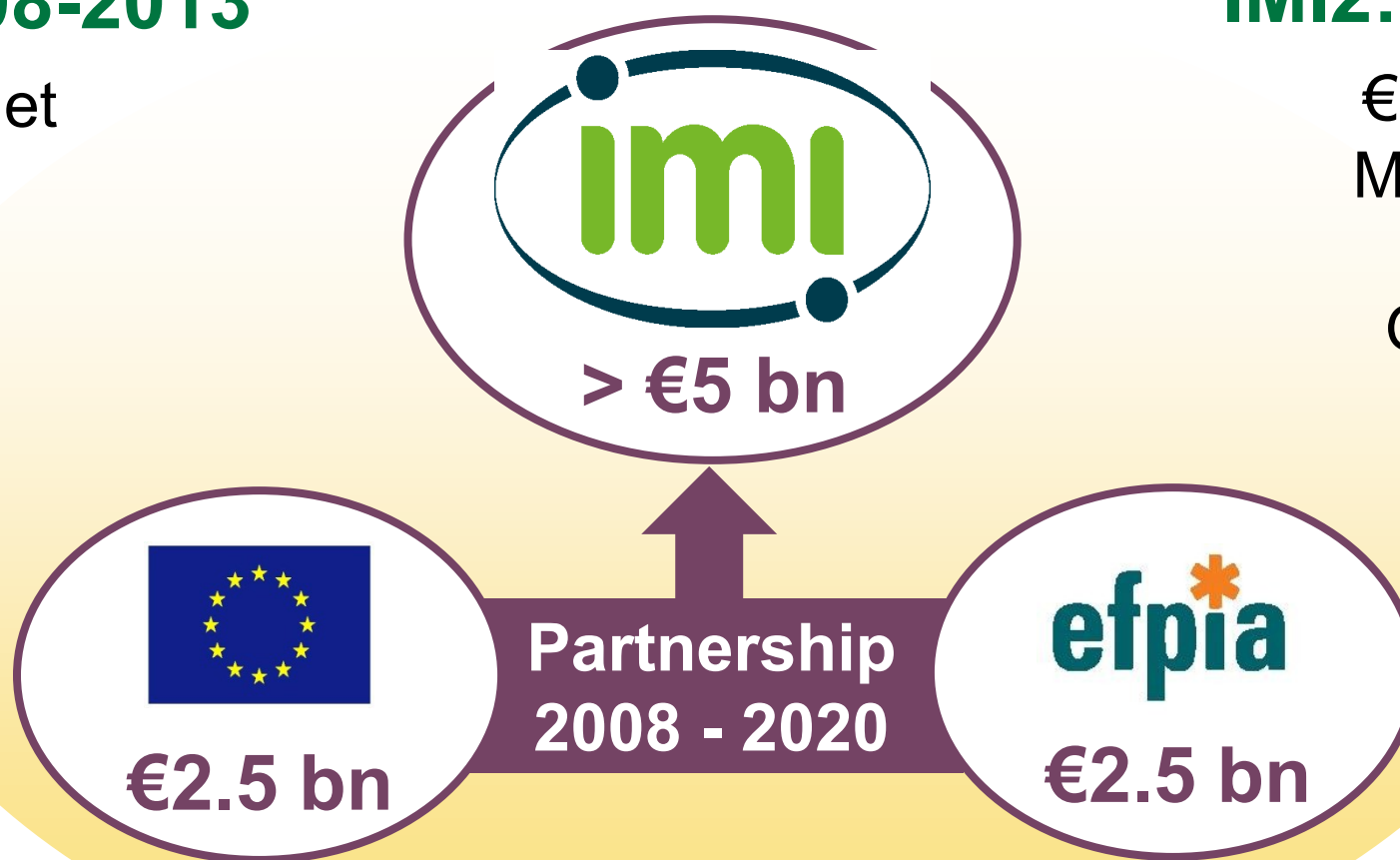
IMI – Europe's partnership for health

IMI1: 2008-2013

€2 bn budget
59 projects

IMI2: 2014-2020

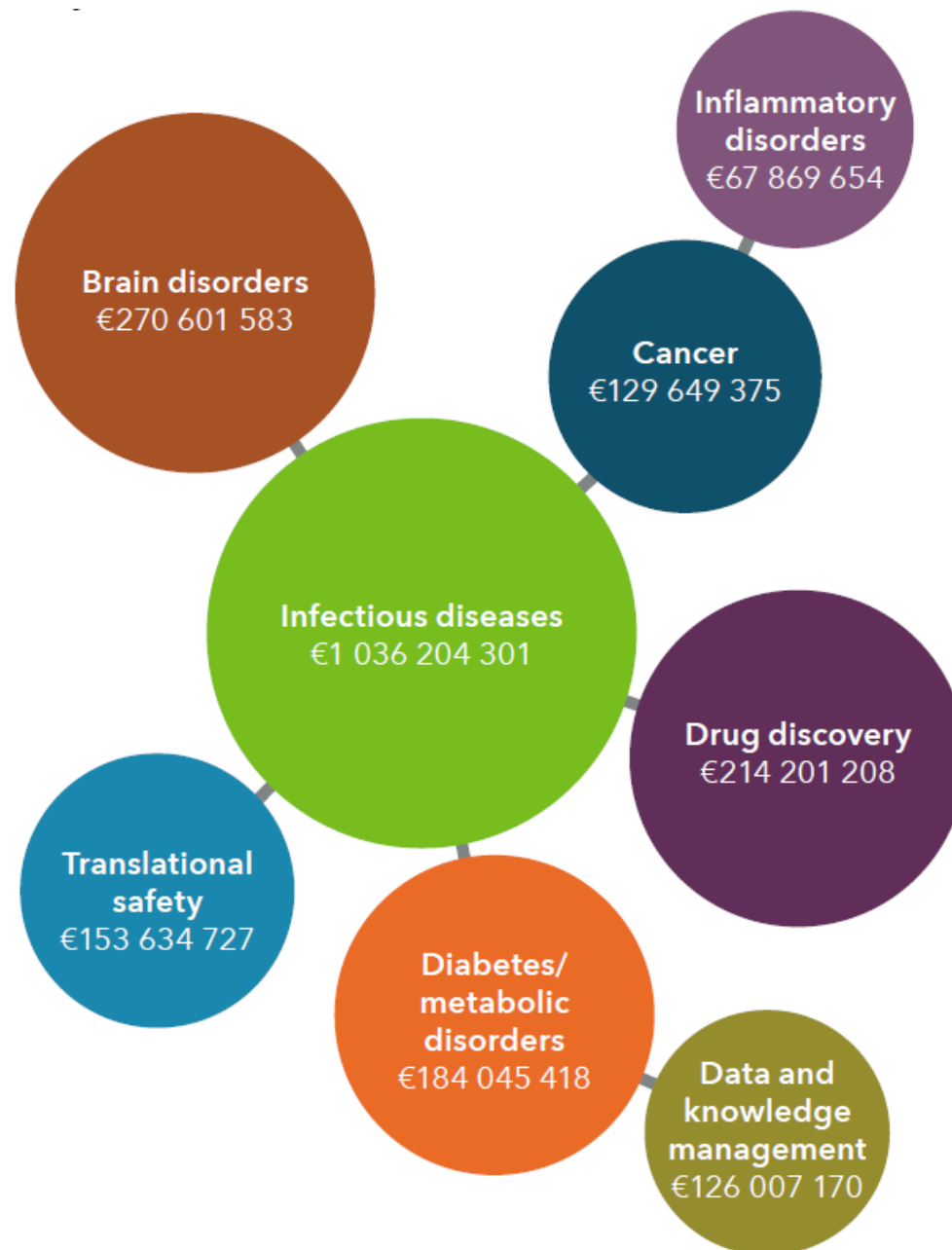
€3.3 bn budget
More ambitious
More open
Greater scope



EU contribution from FP7 / H2020

Pharma contribution 'in kind'

Current IMI investment in major research areas



An international, cross-sector community

198

SMEs

29

Patient Groups

530

Universities /academic organisations

43

EFPIA members

14

EFPIA Partners in Research

26

Regulators

6

Associated Partners

Over 11 500 researchers
working for:

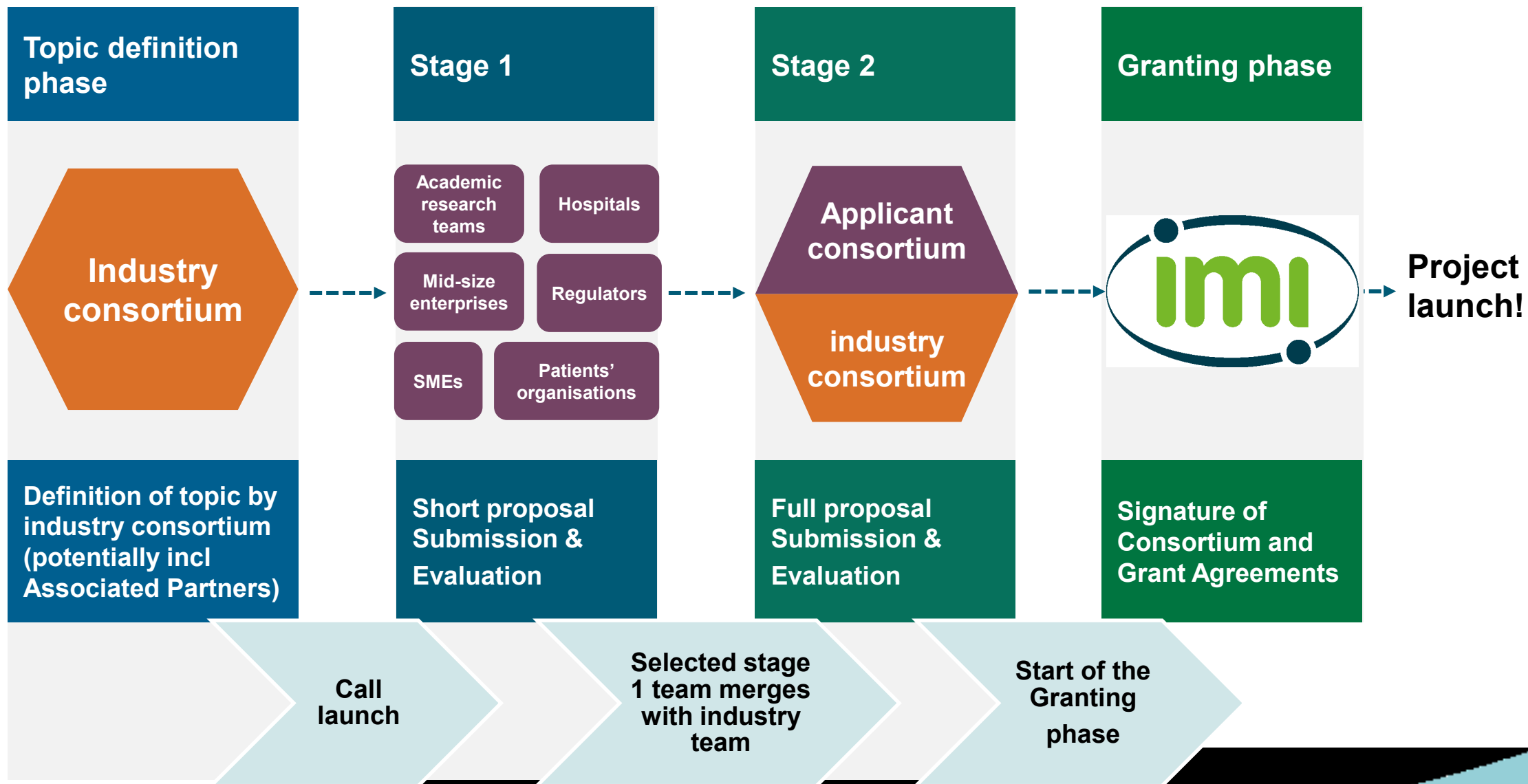
- open collaboration
- improved R&D productivity
- innovative approaches to unmet medical needs

IMI – Ecosystem for innovative collaborations

- Allow engagement in a cross-sector and multi-disciplinary consortium at the forefront of cutting-edge research;
- Provide the necessary scale by combination of funding, expertise, knowledge, skills and resources;
- Build a trustful collaboration upon a creative spirit, innovative and critical thinking;
- Learn from each other (new knowledge, skills, ways of working)
- Be transformative to make a difference in drug development and ultimately patients' life.

IMI is a **neutral platform** where **all involved** in drug development can engage in **open collaboration** on **shared challenges**.

How does IMI work? Two stage procedure



IMI key concepts

Industrial partners align themselves around a real challenge for industry and agree to work together and commit resources

New ideas from public sector, universities, SMEs etc. are needed to address the challenge

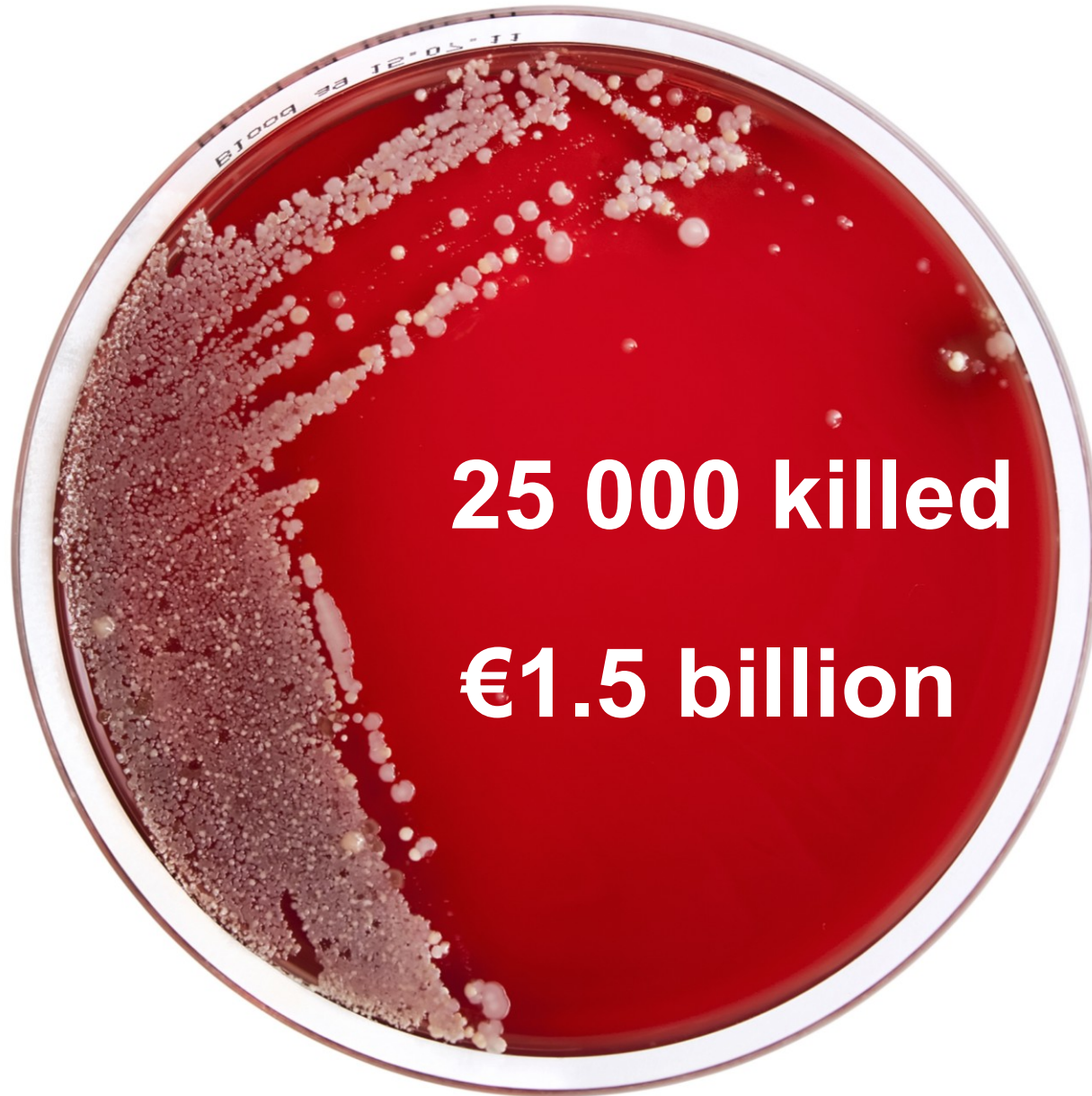
Scale is a key to success and is provided through IMI funding

Outcomes should be transformative for the industry as well as having a clear “public” value



Fighting AMR : examples of current IMI programmes

Antimicrobial resistance – a growing threat



IMI New Drugs for Bad Bugs programme

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

ND4BB

Challenge 3: Clinical dvpt long, costly & often inefficient

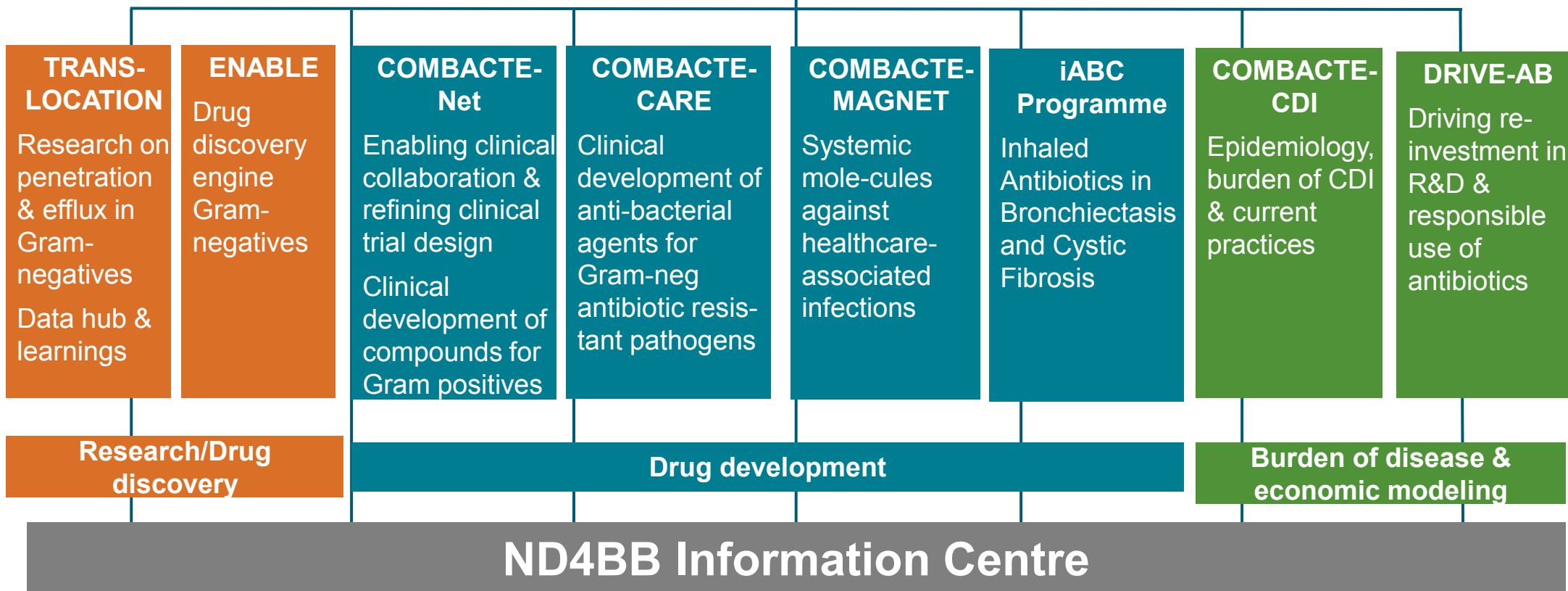
COMBACTE family, iABC:
Creating sustainable clinical investigator / laboratory epidemiology network for clinical studies

Challenge 4: Low return on investment

DRIVE-AB: Options for a new economic model of antibiotic R&D buy-in from all stakeholders

New Drugs for Bad Bugs (ND4BB)

Cross-project communication & collaboration



Broader in scope, players, and geographical outreach

❖ Mobilization of diagnostics industry

- The medical, economical, and public health value of diagnostics to address AMR is insufficiently recognized and studied.
- In past 9 months, leading diagnostics companies have initiated discussions to define a public-private partnership effort under IMI, linking into ND4BB.

❖ Broadening the network

- Transatlantic collaboration clinical trial network: following January 2016 workshop in Stockholm, collaboration between CLIN-Net and LAB-Net and one of NIH/NIAID targeted clinical trials on multidrug resistance
- Plans to increase collaboration between different

Impact and Results

- The New Drugs for Bad Bugs (ND4BB) programme has delivered screening data on the antimicrobial activity and toxicity of several compounds;
- The COMBACTE family of projects is building self-sustaining, pan European antibacterial development networks and using them to run high-quality clinical studies addressing antimicrobial resistance. To date, there are 7 clinical trials and studies running;
- COMBACTE-NET trained 598 people on the creation of a high quality clinical network of investigators supported by laboratory network to conduct high quality studies;
- 46 (of 70 total) applications to enter ENABLE with a new development programme came from SMEs;



The Future

2018-2020 Priorities

Immunology

- Treatment of non-response and remission
- Non-invasive molecular imaging of immune cells

Antimicrobial resistance

- Clinical trials networks
- Accelerator of AMR R&D

Digital Health/Big Data

- Remote clinical trials
- Biosensors/digital endpoints in clinical development

Modernisation of clinical trials and regulatory pathways

- Addressing the challenge of platform trials (Integrated Research Platforms)

Near future:

<https://www.imi.europa.eu/apply-funding/future-topics>



10 years of Europe's partnership for health



[Home](#) | [Apply for funding](#) | [Future topics](#)

Future topics



To give potential applicants as much time as possible to form consortia and prepare their proposals, IMI regularly publishes draft topic texts on this page several weeks before the official Call launch. To ensure you get the latest information on forthcoming Calls, sign up to our [newsletter](#), follow us on [Twitter](#), or join our [LinkedIn group](#).

Draft topic texts are subject to consultations involving IMI's States Representatives Group, Scientific Committee, and the European Commission. They must also be approved by the IMI Governing Board. Depending on the results of the consultations and approval process, the final topic text may differ significantly from the draft versions initially published here, and some topics may not be included in a Call in the end.

The following topics are currently under consideration for inclusion in future IMI Calls for proposals.

- [Topic: Integrated research platforms enabling patient-centric drug development](#)
- [Topic: Blockchain enabled healthcare](#)
- [Topic: Microenvironment imposed signatures in tissue and liquid biopsies in immune mediated disease](#)
- [Topic: Emerging translational safety technologies and tools for interrogating human immuno-biology](#)
- [Topic: Development and validation of translational platforms in support of synaptopathy drug discovery](#)
- [Topic: Digital transformation of clinical trials endpoints](#)
(part of an IMI programme on digital transformation of clinical trial endpoints)

Antimicrobial resistance (AMR) accelerator programme

The AMR Accelerator programme consists of three pillars under which multiple projects are expected:



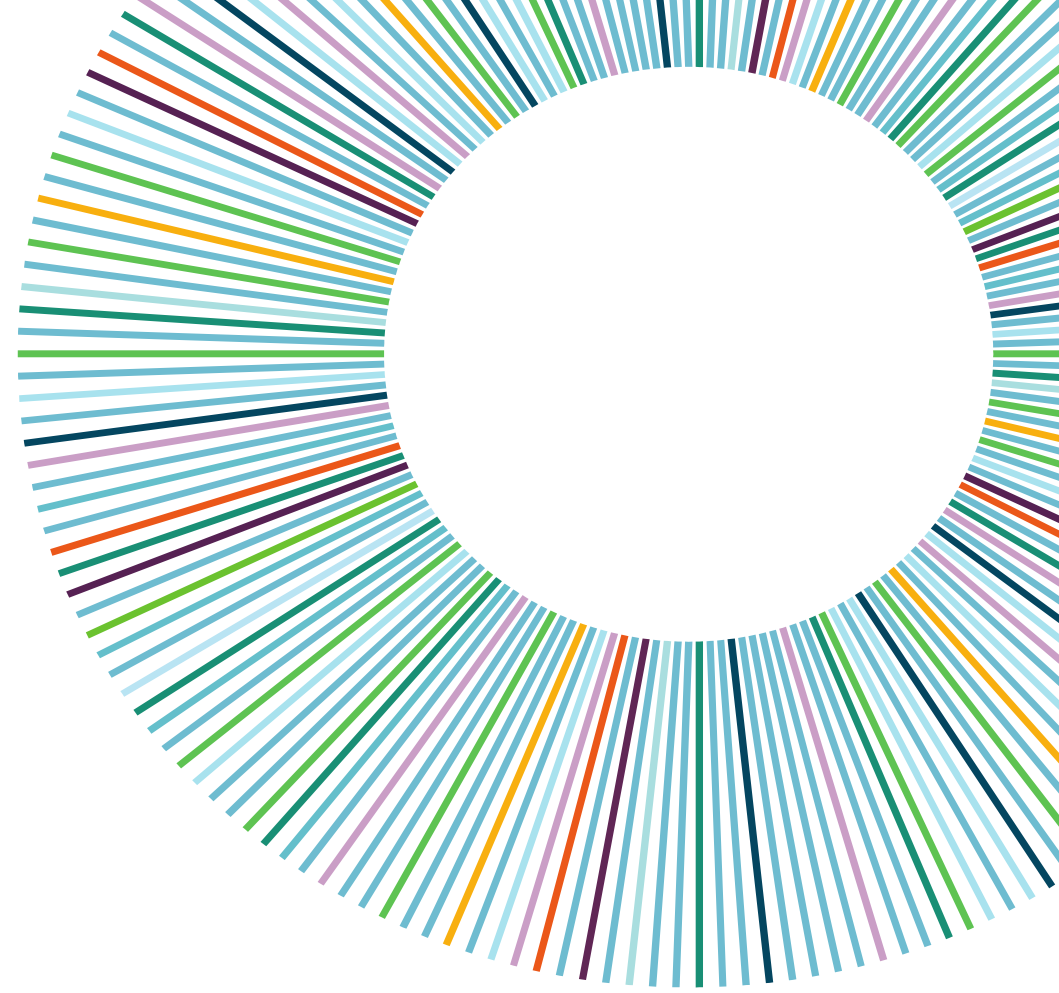
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Thank you