

Introducing the Innovative Medicines Initiative

Prof. Dr. med. Isabelle Bekeredjian-Ding
Schloß Löwenstein, 25.1.2020

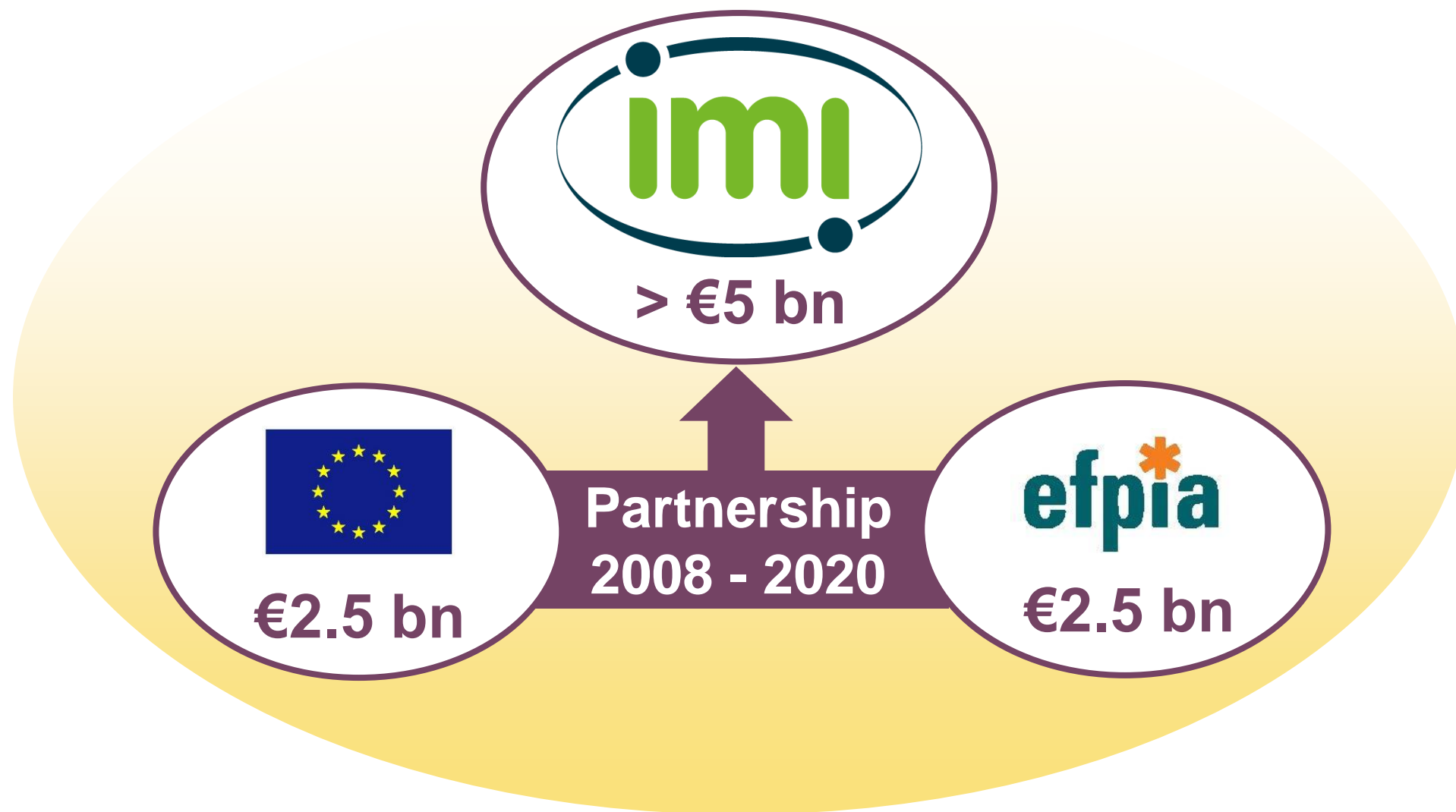
Public-private partnerships in health care

- **Public interest**

- cost minimization and lean management structures
- leverage the risk of setting up infrastructural measures to improve health care that would otherwise not seem beneficial to the private sector

1. **Product development PPP:** access to medicines and diagnostics in middle to low income countries
2. **Precompetitive PPP:** new solutions to outstanding problems requiring pharmaceutical research

IMI – Europe's partnership for health



Goals of IMI2 programme

- ✓ **Improve the drug development process** by creating tools to assess the efficacy, safety and quality of medicines
- ✓ **Develop biological markers to diagnose** diseases and **assess** treatments
- ✓ **Speed up the earlier stages** of drug development
- ✓ **Increase the success rate of clinical trials** of priority medicines
- ✓ **Develop new therapies** for diseases with a high unmet need / limited market incentives
- ✓ Reduce the failure rate of **vaccine candidates** in clinical trials



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|---|
| Official Journal of the European Union |
| COUNCIL REGULATION (EU) No 557/2014 |
| of 6 May 2014 |
| establishing the Innovative Medicines Initiative 2 Joint Undertaking |
| (Text with EEA relevance) |

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**

European Lead Factory



efpia

Joint European Compound Library

>500,000 screening collection

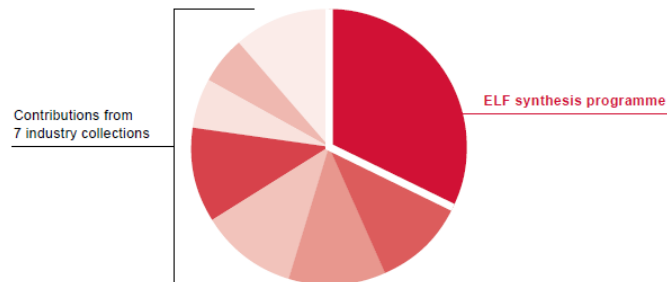


Figure 3. The composition of the Joint European Compound Library (JECL).

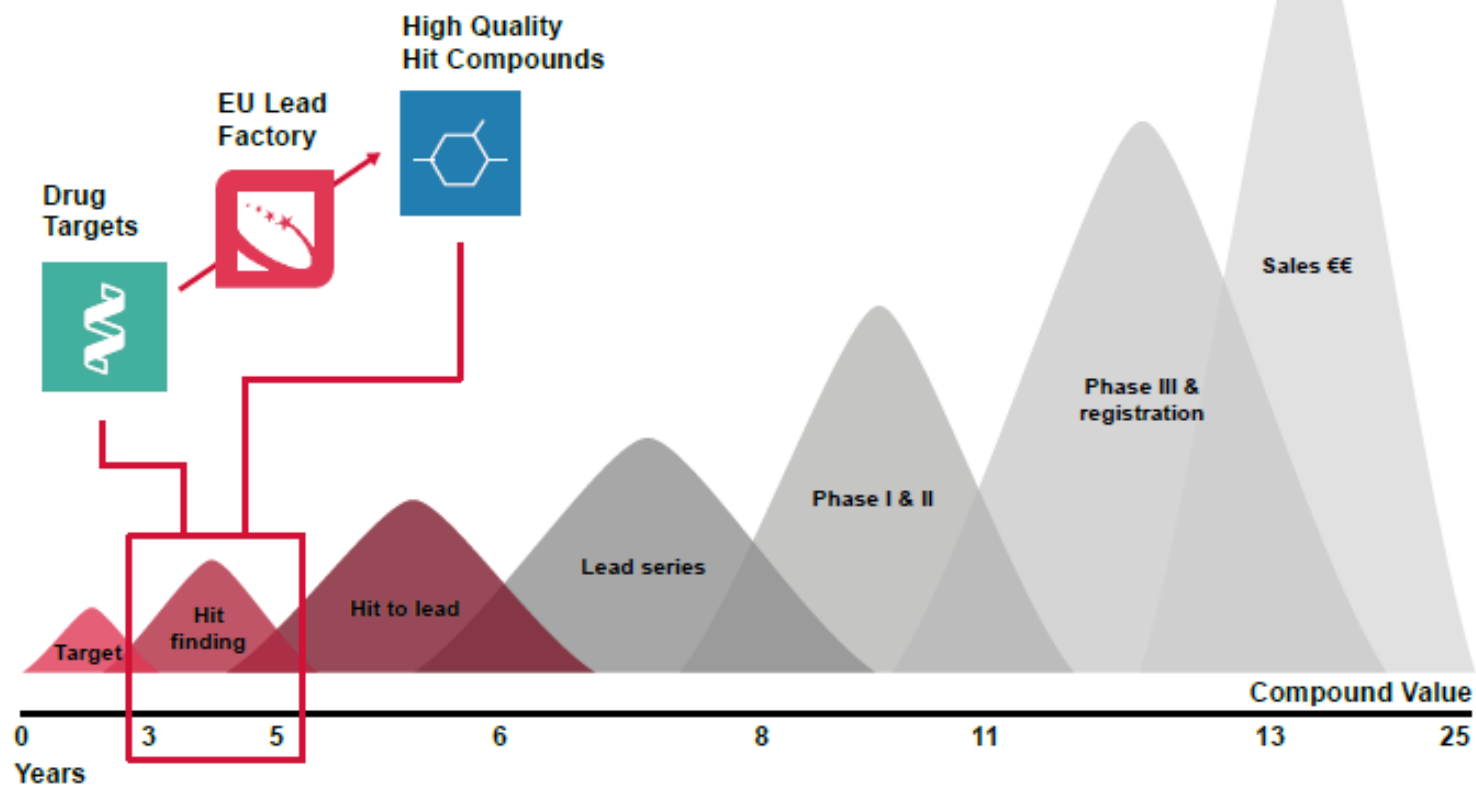
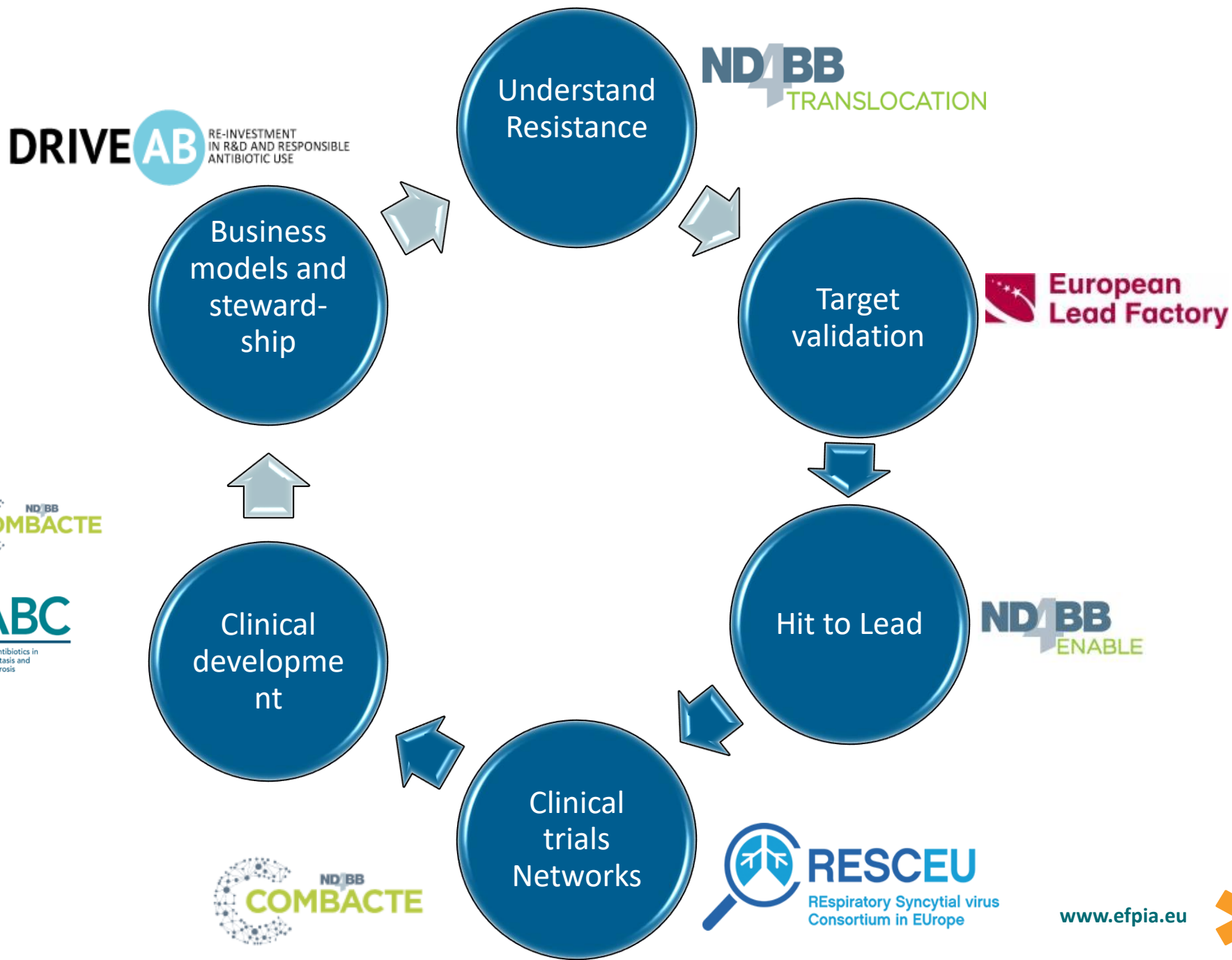
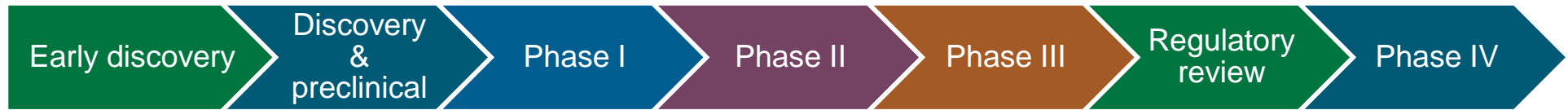


Figure 1. The position of the European Lead Factory in the drug research value chain.

IMI End-to-End R&D accelerator



New Drugs for Bad Bugs (ND4BB)



Penetration barriers & efflux



Drug discovery engine



Clinical trial networks

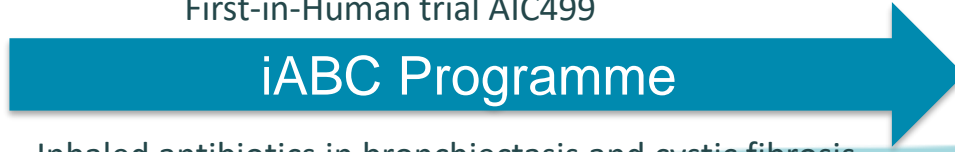
Observational and epidemiology studies
 MEDI4893 in *S. aureus* infections
 Minocycline in *A. baumannii* infections



Clinical management & outcomes of patients with CRE
 Microbiological analysis and biomarkers
 ATM-AVI clinical development



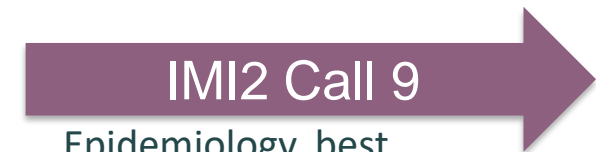
Epidemiology network and support
 MEDI3902 anti-*P. aruginosa*
 First-in-Human trial AIC499



Inhaled antibiotics in bronchiectasis and cystic fibrosis
 Bronchiectasis patient registry (EMBARC)



New economic models



Epidemiology, best practices, burden of CDI

Total budget
 >650 million Euro



EBODAC

Communication strategy and tools for optimizing the impact of Ebola vaccination deployment
Ongoing | IMI2 | [Infectious diseases](#), [Ebola and related diseases](#), [Vaccines](#), [Ebola+](#), [Tools for predicting/monitoring efficacy](#)



Ebola+

Ebola and other filoviral haemorrhagic fevers
Ongoing | IMI2 | [Infectious diseases](#), [Ebola and related diseases](#), [Vaccines](#), [Diagnostics](#), [Ebola+](#), [Manufacturing technologies](#)

EbolaMoDRAD

Ebola virus: modern approaches for developing bedside rapid diagnostics
Ongoing | IMI2 | [Infectious diseases](#), [Ebola and related diseases](#), [Diagnostics](#), [Ebola+](#)



EBOMAN

Manufacturing and development for rapid access Ebola vaccine
Ongoing | IMI2 | [Infectious diseases](#), [Ebola and related diseases](#), [Vaccines](#), [Ebola+](#), [Manufacturing technologies](#)

EBOVAC1

Development of a prophylactic Ebola vaccine using an heterologous prime-boost regimen
Ongoing | IMI2 | [Vaccines](#), [Ebola+](#), [Clinical trial design](#), [Conducting clinical trials](#)

EBOVAC2

Development of a prophylactic Ebola vaccine using an heterologous prime-boost regimen:
phase II
Ongoing | IMI2 | [Infectious diseases](#), [Ebola and related diseases](#), [Vaccines](#), [Ebola+](#), [Conducting clinical trials](#)



EBOVAC3

Bringing a prophylactic Ebola vaccine to licensure
Ongoing | IMI2 | [Infectious diseases](#), [Ebola and related diseases](#), [Vaccines](#), [Ebola+](#), [Conducting clinical trials](#)

IMI – an ecosystem for innovative collaboration

- Allow engagement in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research
- Provide the necessary scale by combining funding, expertise, knowledge, skills and resources
- Build a collaboration based on trust, creativity and innovative and critical thinking
- Learn from each other - new knowledge, skills, ways of working
- Take part in transformative research that will make a difference in drug development and ultimately patients' lives

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

IMI Governance

Governing Board (EC + EFPIA)
Overall strategic orientation & operations

Associated Partners

States Representatives Group
Consultation, opinions

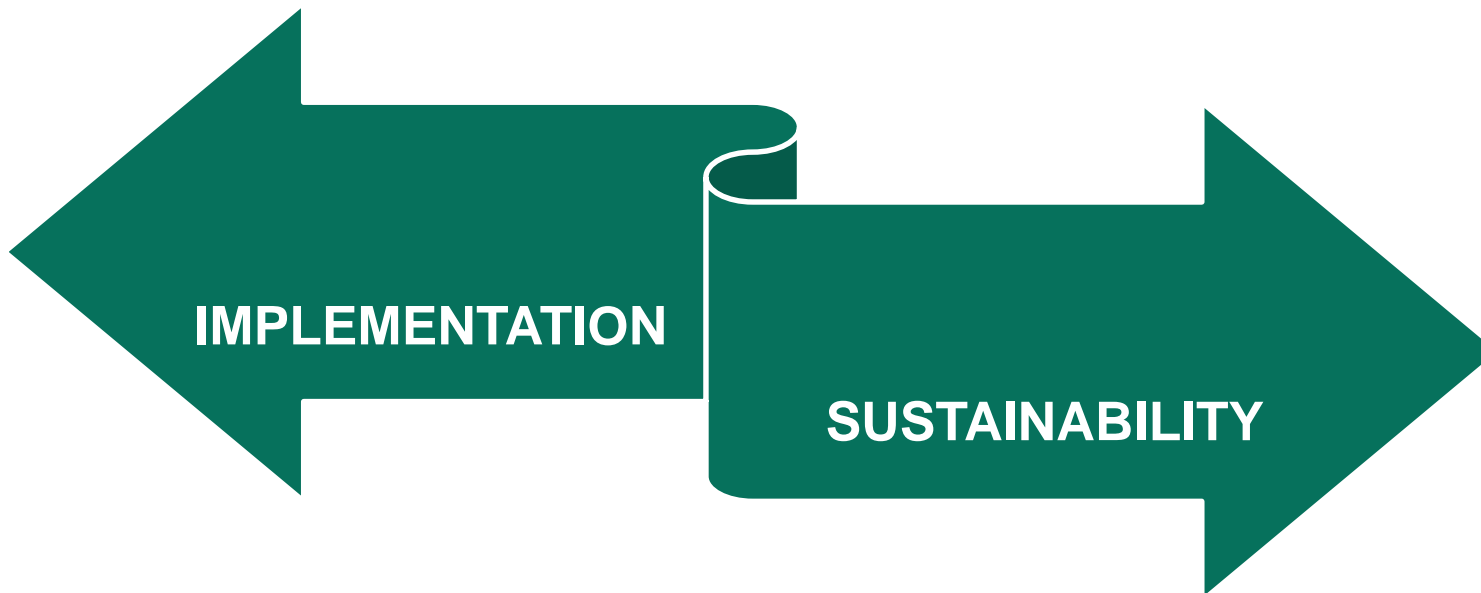


Scientific Committee
Advice on scientific issues

Stakeholder Forum
Input, Information & feedback

Strategic Governing Groups
Identify specific priority areas

IMI Executive Director | Day-to-day management
IMI Programme Office | Day-to-day implementation



IMI Scientific Committee position papers and recommendations

Sustainability

Suitability for PPP

Big data and data integration (2)

Regulatory engagement

Drug repurposing

Equitable access

Rare Diseases

Evolution of the Innovative Medicines Initiative

IMI1

- precompetitive
- drug discovery
- manufacturing



IMI2

- (pre)competitive
- clinical development



(IMI3)

- Digital technologies
- Food technologies
- Other technologies

IHI

Partners is future Health PPP program (IHI?)

- COCIR – European Coordination Committee of the Radiological, Electromedical and Healthcare IT industry
- EBE – Emerging Biopharmaceutical Enterprises
- EFPIA – European Federation of Pharmaceutical Industries and Associations
- EuropaBio – European Associates for Bioindustries
- MedTech Europe – European Association of medical technology industries comprising medical devices, diagnostics and digital health
- Vaccines Europe