The Innovative Medicines Initiative: building new models of collaborative research

Angela Wittelsberger, Ph.D.
Scientific Officer
Innovative Medicines Initiative
Workshop ‘Diagnostics for reducing antimicrobial resistance’, Brussels, 19 June 2017
IMI – Europe’s partnership for health

**IMI: 2008-2013**
Total budget: €2 bn
11 Calls launched
59 projects

**IMI 2: 2014-2024**
Total budget: €3.3 bn
More ambitious, more open, greater scope
10 Calls to date
>35 projects started/in preparation

- €2.5 bn
- > €5 bn
- €2.5 bn
Public-private partnership: Why IMI?

- Pooling expertise, knowledge and resources
- Developing incentives to address major unmet medical needs
- Providing a neutral trusted platform to align public and private interests
- Facilitating a streamlined innovation process through end-to-end integration
IMI2 overall objectives

- Pre-competitive research and innovation activities of strategic importance to the EU’s competitiveness and industrial leadership, or to address specific societal challenges

- 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

- 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

- IMI2 legislation, Article 2
Industrial partners align themselves around a real challenge for industry and agree to work together and commit resources. Associated Partners might join.

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.
An international, cross-sector community

- 970 academic teams
- 202 SME teams
- 552 EFPIA teams
- 108 other teams
- 31 patient orgs

Over 9,000 researchers working for:
- open collaboration
- improved R&D productivity
- innovative approaches to unmet medical needs

Figures from June 2016
How does IMI work? Two stage procedure

**Topic definition phase**

- **Industry consortium**
  - Definition of topic by industry consortium (potentially incl Associated Partners)

**Stage 1**

- **Short proposal Submission & Evaluation**
  - Academic research teams
  - Hospitals
  - Mid-size enterprises
  - Regulators
  - SMEs
  - Patients’ organisations

**Stage 2**

- **Full proposal Submission & Evaluation**
  - Applicant consortium
  - Industry consortium

**Granting phase**

- **Signature of Consortium and Grant Agreements**

**Key events**

- Call launch
- Selected stage 1 team merges with industry team
- Start of the Granting phase

Project launch!
Distribution of funding per scientific area – IMI1

- Infectious diseases: €671,635,805 • 35%
- Drug discovery: €214,201,208 • 11%
- Brain disorders: €188,239,313 • 10%
- Metabolic disorders: €119,468,874 • 6%
- Drug safety: €115,383,536 • 6%
- Stem cells: €77,380,311 • 4%
- Cancer: €74,371,979 • 4%
- Data management: €74,291,023 • 4%
- Inflammatory disorders: €67,869,654 • 4%
- Biologicals: €56,023,072 • 3%
- Vaccines: €47,642,719 • 2%
- Geriatrics: €47,453,831 • 2%
- Education and training: €39,650,498 • 2%
- Lung diseases: €38,499,367 • 2%
- Sustainable chemistry: €32,399,640 • 2%
- Drug delivery: €21,336,248 • 1%
- Drug kinetics: €18,118,248 • 1%
- Relative effectiveness: €14,910,397 • 1%

Total contributions: €1,918,875,722
New Drugs for Bad Bugs (ND4BB) - Facts

7 projects up and running
EUR 700 million, + 1 project in the pipeline

CLIN-Net hospital network
697 hospitals – 437 cities – 39 countries in Europe
LAB-Net network: >400 laboratories
6 clinical development programmes active
Observational studies, epidemiology

Worked out structure of 20 proteins found in membranes of bacteria & greater understanding of efflux pumps

ENABLE drug discovery engine
60+ hit-to-lead or lead-to-candidate programmes submitted, progression of 15+ early stage programmes, 4+ currently ongoing

Driving discussions on new economic model of antibiotic R&D and stewardship
Contributors and beneficiaries receiving funding
IMI – Europe’s partnership for health

IMI: 2008-2013
Total budget: €2 bn
11 Calls launched
59 projects

IMI 2: 2014-2024
Total budget: €3.3 bn
More ambitious, more open, greater scope
10 Calls to date
>35 projects started/in preparation

Partnership
2008 - 2024

€2.5 bn

€2.5 bn

> €5 bn

efpiA
IMI 2 budget (2014 – 2024)

EU funding goes to:
Universities
SMEs
Mid-sized companies
Patient groups etc…

IMI 2 total budget
€3.276 billion

EFPIA companies receive no funding, contribute to projects ‘in kind’

Associated Partners e.g. charities, non-EFPIA companies

IMI 2 budget
€1.638 bn

Other
€213 m

€1.425 bn
Who can become an Associated Partner?

Any legal entity may apply to join IMI2 as an Associated Partner (AP) provided that they:

- support the objectives of IMI2 in its specific area of research
- accept the IMI2 Statutes by a letter of endorsement, detailing the scope of the association (in-kind or cash contribution, activities and duration)

Any resources they put into a project may be equally matched by IMI2 fund → leveraging resources.

Have become AP: diabetes charity JDRF, the Helmsley Charitable Trust, the Bill and Melinda Gates Foundation (BMGF), Autism Speaks, Simons Foundation Autism Research Initiative (SFARI), T1D Exchange
Associated Partners and other industries: a new dimension of opportunities

Example IMI2 Call 3: Pertussis vaccination research

EFPIA in-kind Contribution: GSK, Sanofi Pasteur, Novartis

Bill & Melinda Gates Foundation cash contribution

IMI matching cash contribution

Total indic. budget: EUR 28 million
Attracting stakeholders

Any legal entity regardless its place of establishment carrying out work relevant to the Call objectives may be part of applicant consortia

But… not all participating entities are eligible to receive funding
Who is eligible to receive funding?

- Academic institutions
- Small & medium-sized enterprises (SMEs)
- Mid-sized enterprises (≤ €500m)
- Non-profit organisations e.g. research organisations, patient organisations, NGOs, public bodies, intergovernmental organisations etc.

Established in:
- EU Member State
- Associated Country

Other countries: No funding unless participation deemed essential by IMI for carrying out the action
IMI expectations for this workshop and next steps
This workshop – objectives

- To consult with the relevant stakeholders on a potential Call for proposals under IMI2 addressing the topic ‘Diagnostics for reducing AMR’ that would aim at establishing a framework for value-based translation of innovative diagnostics into routine use to reduce AMR.

- To better understand the challenges and hurdles faced by diagnostic innovators for translation of early-stage products into validation, and value demonstration in primary and clinical healthcare practice.

- To obtain a better understanding of what evidence is needed from regulators, health technology assessment bodies and payers for implementation and adoption by healthcare systems.
Next steps

**Willingness by a group of diagnostics companies and The Wellcome Trust to develop an IMI call topic**

- Challenges to be addressed
- Scope for collaboration
- Scope for public-private partnership
- First draft of activities to be addressed by potential IMI project

**Consultation workshop**

- Input from stakeholders (needs of SME’s, ideas from academia, input from regulators, HTA, etc)
- Finalise scope and objectives

**IMI Call topic text**

- Write the call text
- Finalise budget & scope

**Explore involvement of other ‘contributors’**

- Other private companies contributing ‘in-kind’
- Associated Partners
THANK YOU