

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

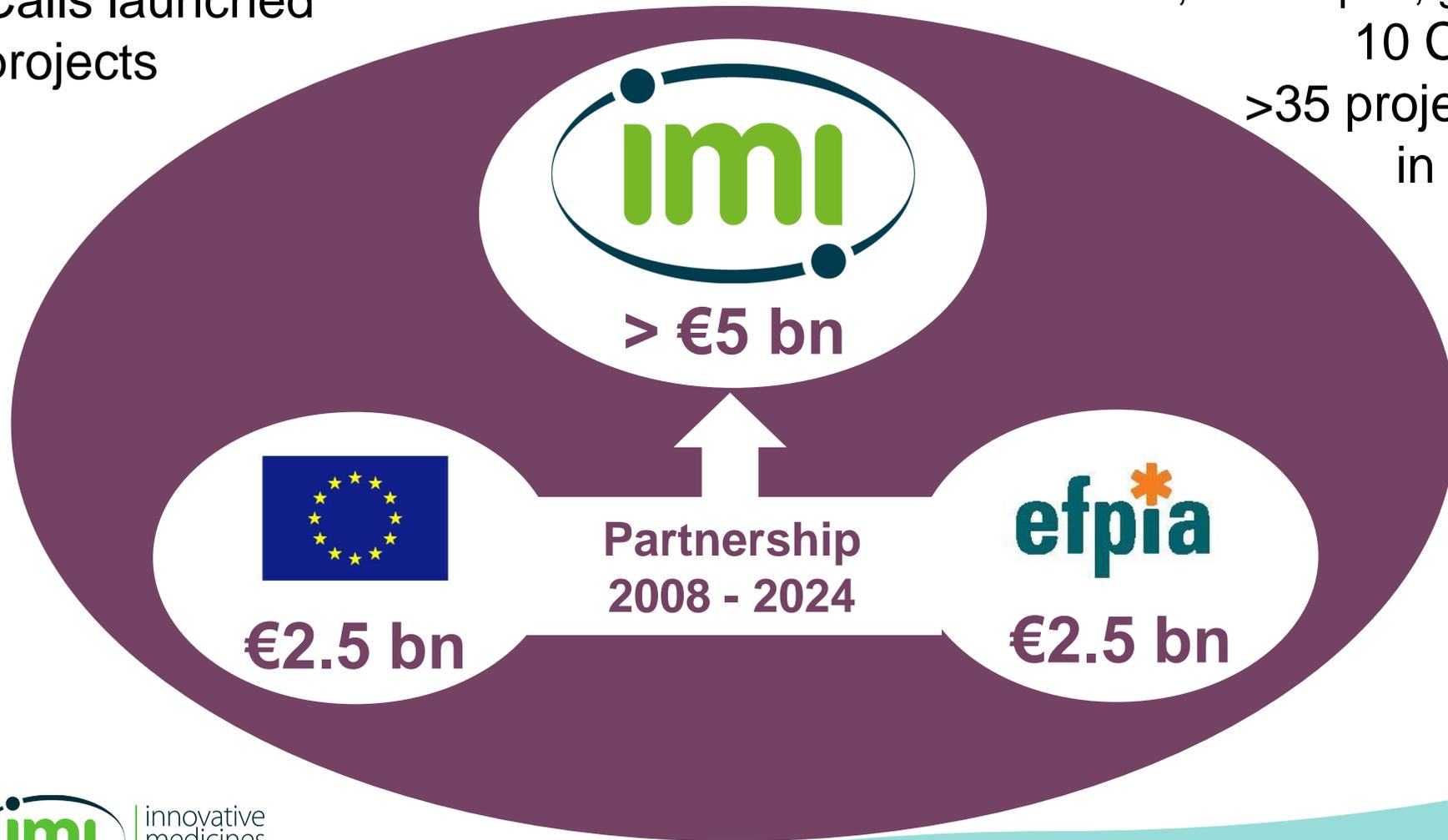
IMI – Europe's partnership for health

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



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**

What does a typical IMI project look like?

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

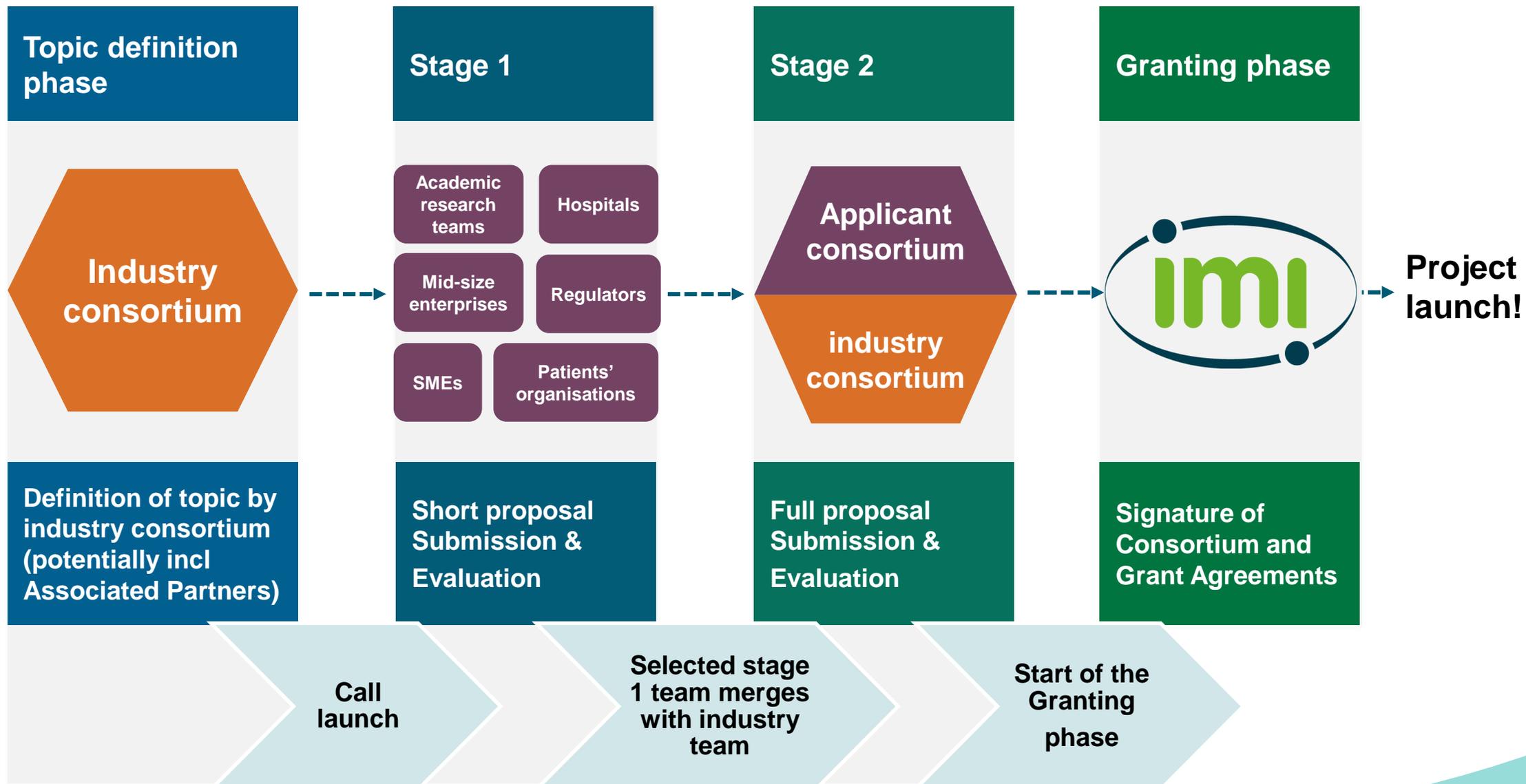
An international, cross-sector community



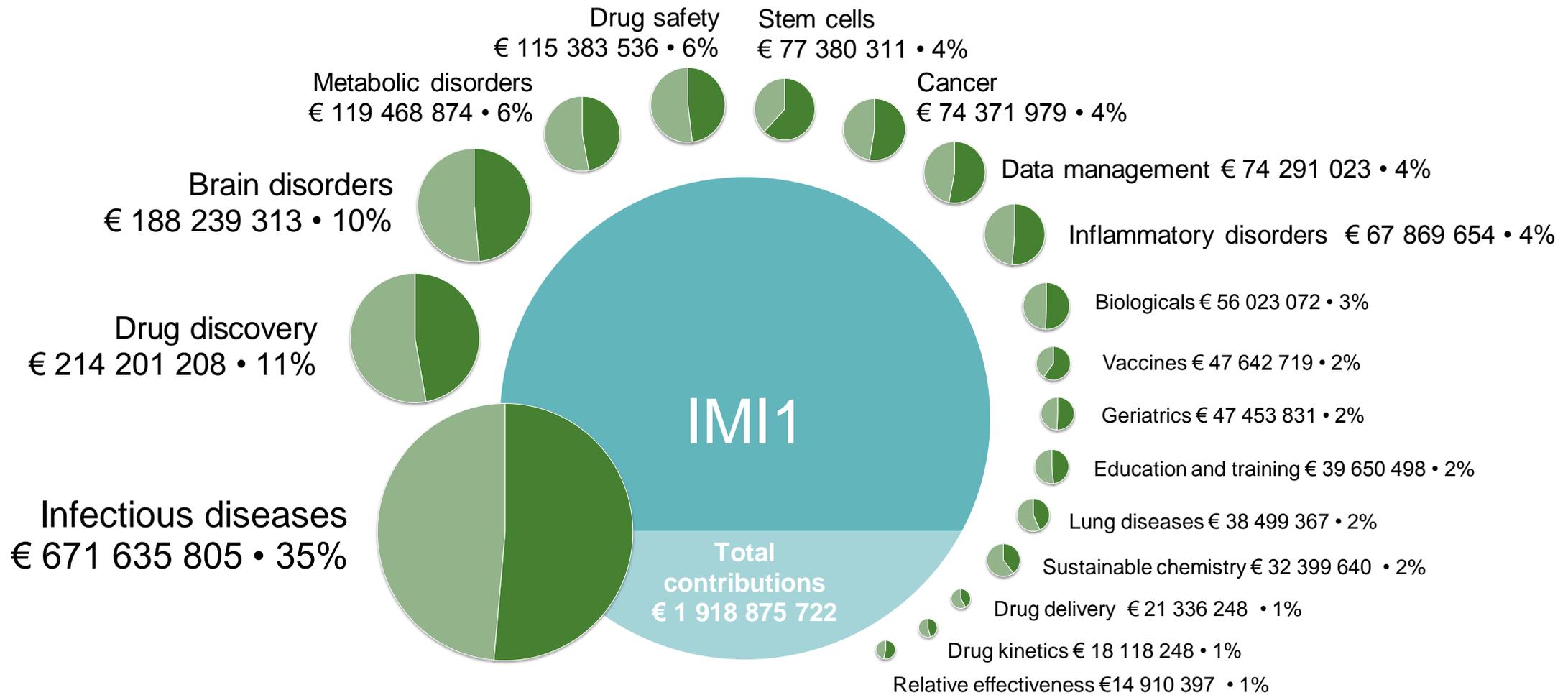
Over 9 000 researchers working for:

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

How does IMI work? Two stage procedure



Distribution of funding per scientific area – IMI1



EFPIA contributions



IMI contributions

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

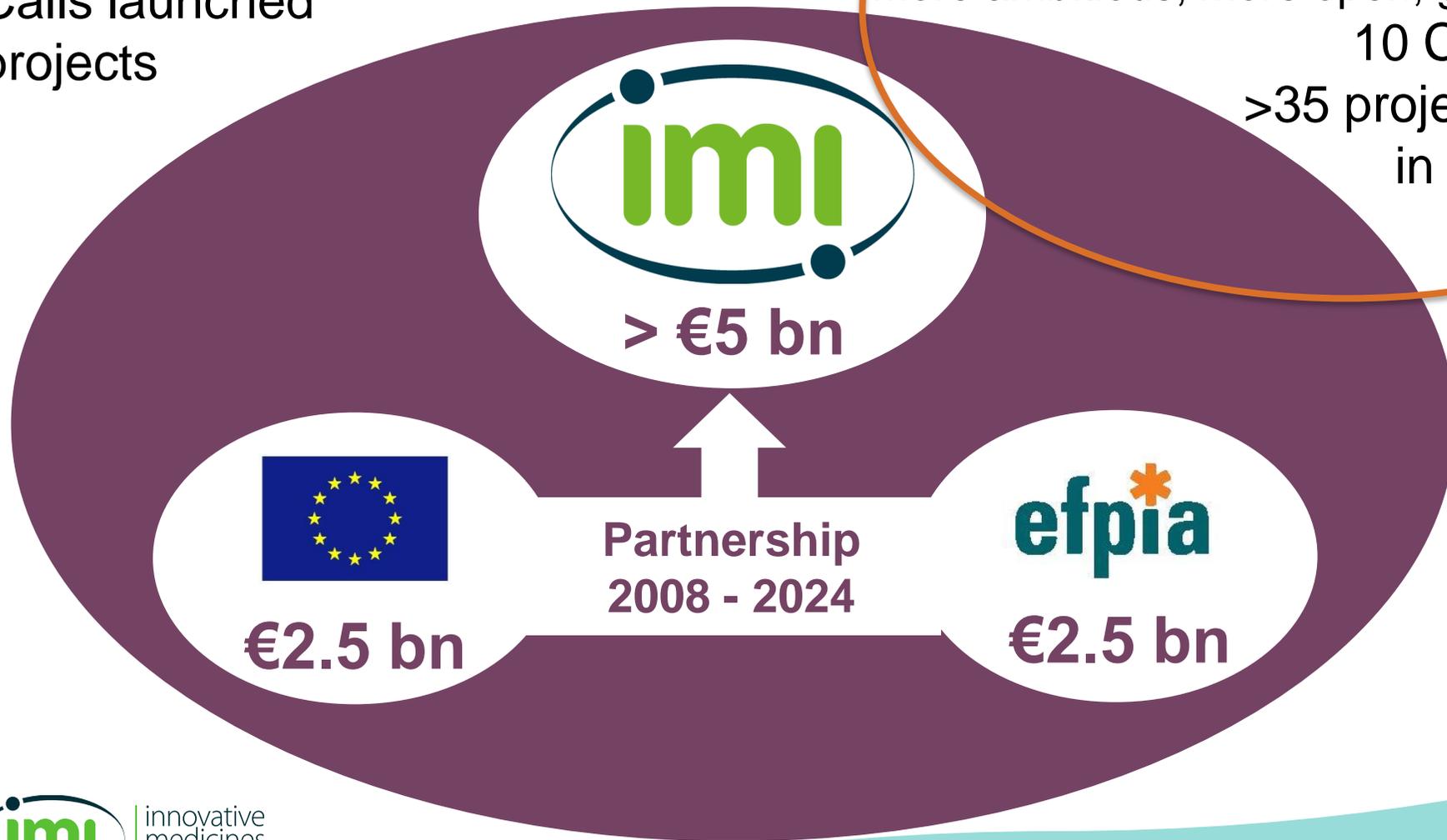
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IMI 2 budget (2014 – 2024)

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc...



€1.638 bn



€1.425 bn

Other
€213 m

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

Who can become an Associated Partner ?

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

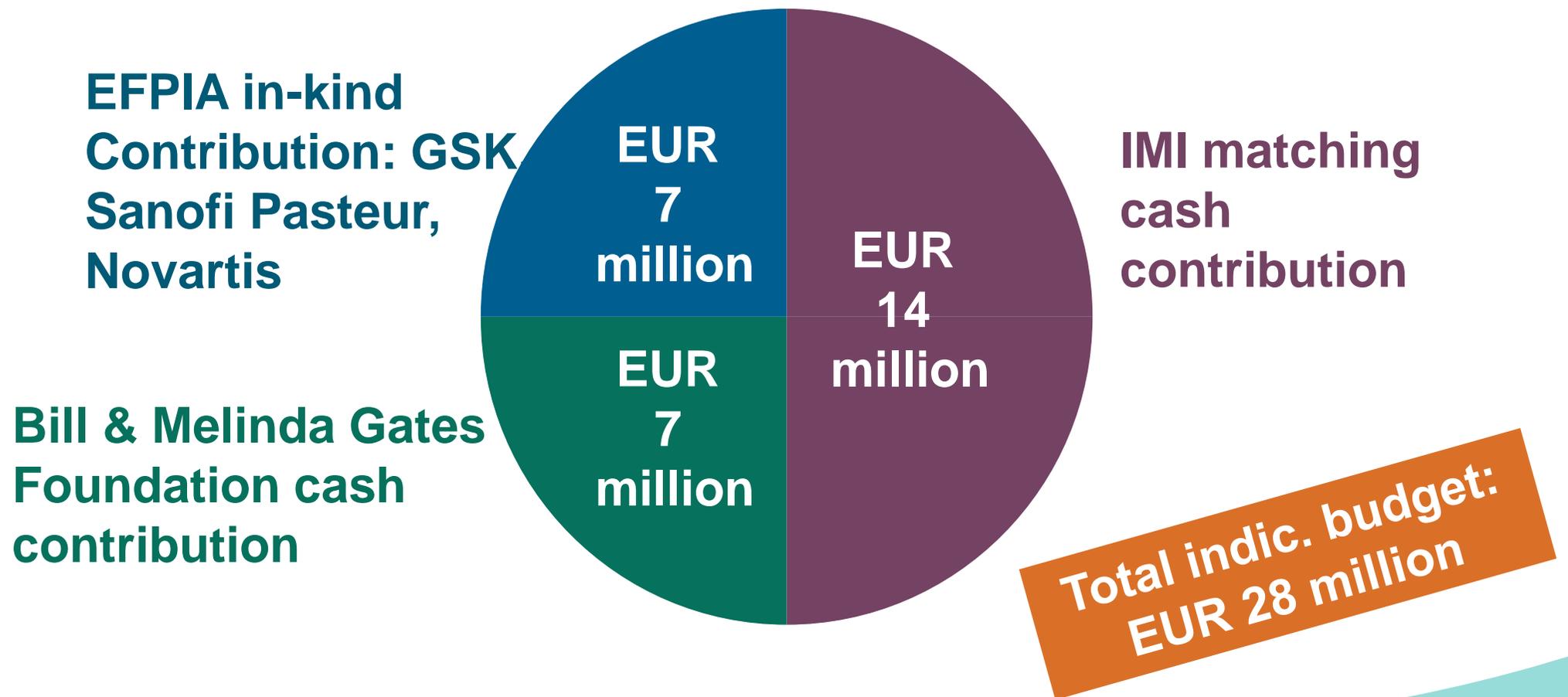
- support the objectives of IMI2 in its specific area of research
- accept the IMI2 Statutes by a letter of endorsement, detailing the scope of the association (in-kind or cash contribution, activities and duration)

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



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 (\leq €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



Explore involvement of other 'contributors'

- Other private companies contributing 'in-kind'
- Associated Partners

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



THANK YOU