The Innovative Medicines Initiative: Building new models of collaborative research across Europe

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Horizon 2020 'Health, demographic change and wellbeing'

Outline

- IMI in a nutshell
- How IMI works
- IMI and infectious diseases
- How to get involved

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IMI in a nutshell

Innovative Medicines Initiative

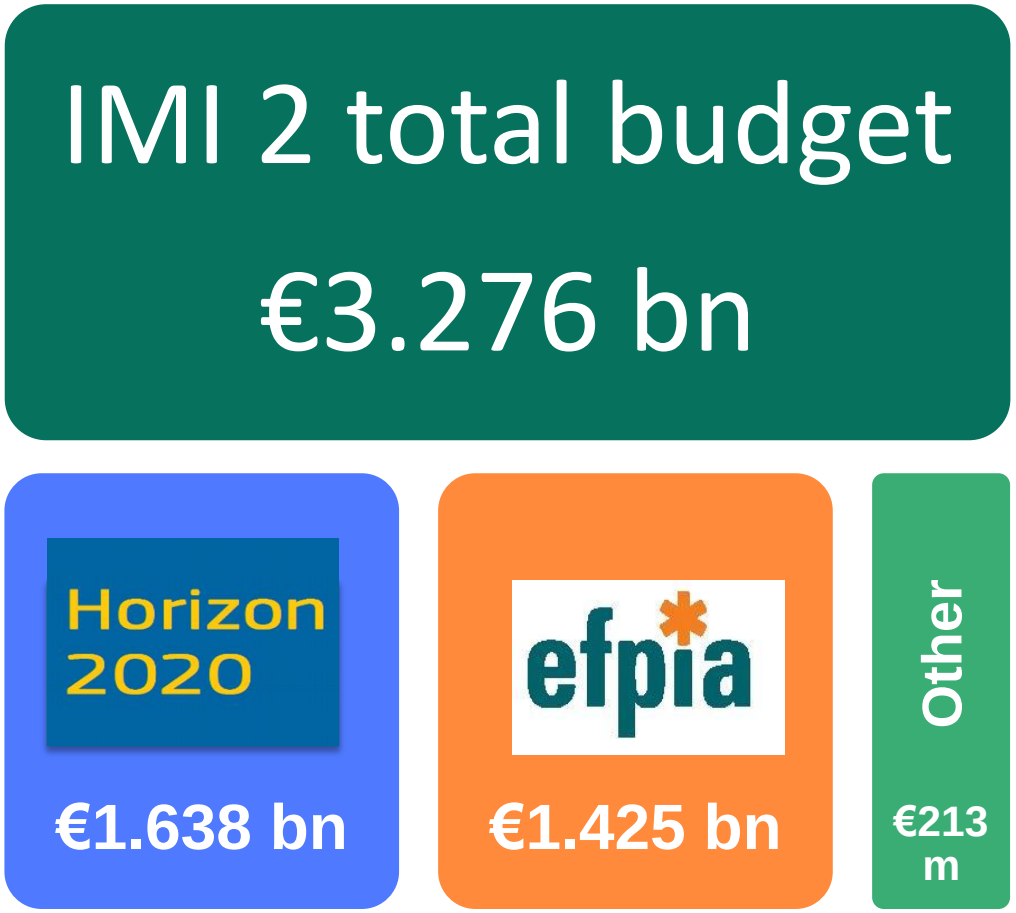
Europe's partnership for health

IMI 1 programme

- 2008-2013
- €2 bn budget
- 11 Calls for proposals
- 59 projects

IMI 2 programme

- 2014-2024
- Bigger budget
- More ambitious
- More open



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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 challenges/ pathways not always adapted

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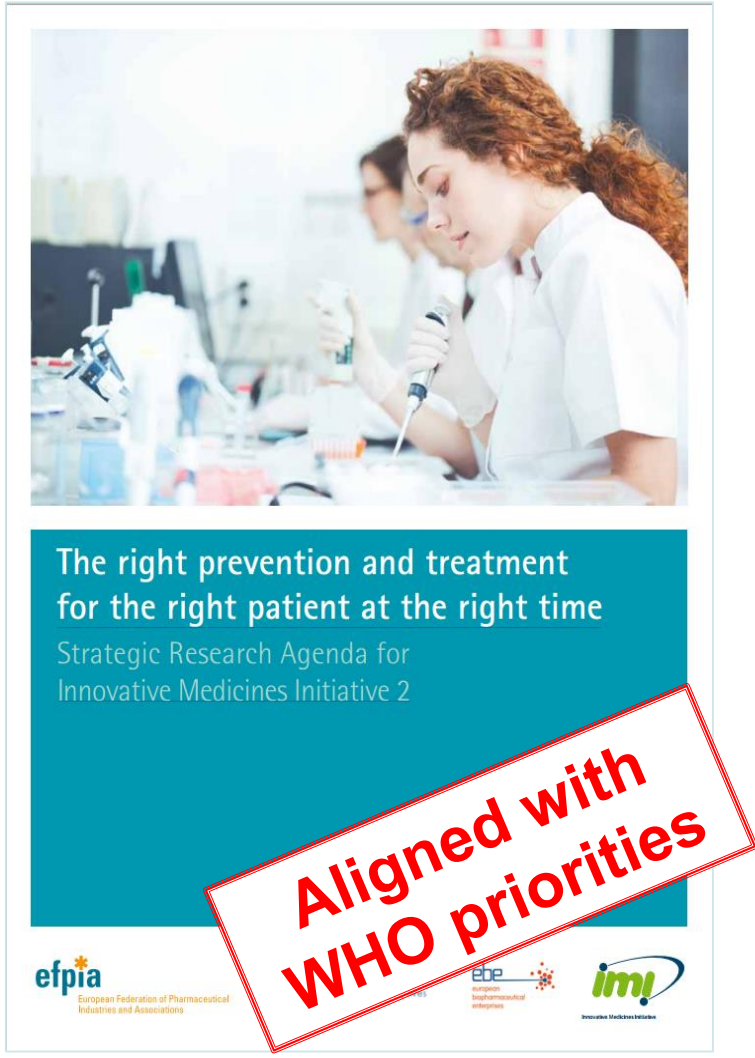
Goals of the IMI2 programme

- **increase success rate in clinical trials**
- **reduce time to clinical proof of concept** (e.g. cancer, immunological, respiratory, neurological/neurodegen. diseases)
- **develop new therapies** for diseases with **high unmet need**, & **limited market incentives**
- **develop diagnostic & treatment biomarkers**
- **reduce failure rate of vaccine candidates**
- **improve the current drug development process** through development of tools, standards & approaches to assess **efficacy**, **safety** & **quality** of health products

IMI2 Legislation, Article 2b



IMI2 Strategic Research Agenda

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Addressing drug development challenges

Through IMI's projects we are trying to…

- **put patients at the centre**
- **share risk** to address both industrial needs and public health challenges
- **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 (end-to-end)
- **use data and knowledge management** to work more effectively

➡ **neutral platform** where **all involved** stakeholders – academics, industry, SMEs, patients, regulators, others – can engage in **open collaboration** on **shared challenges**.

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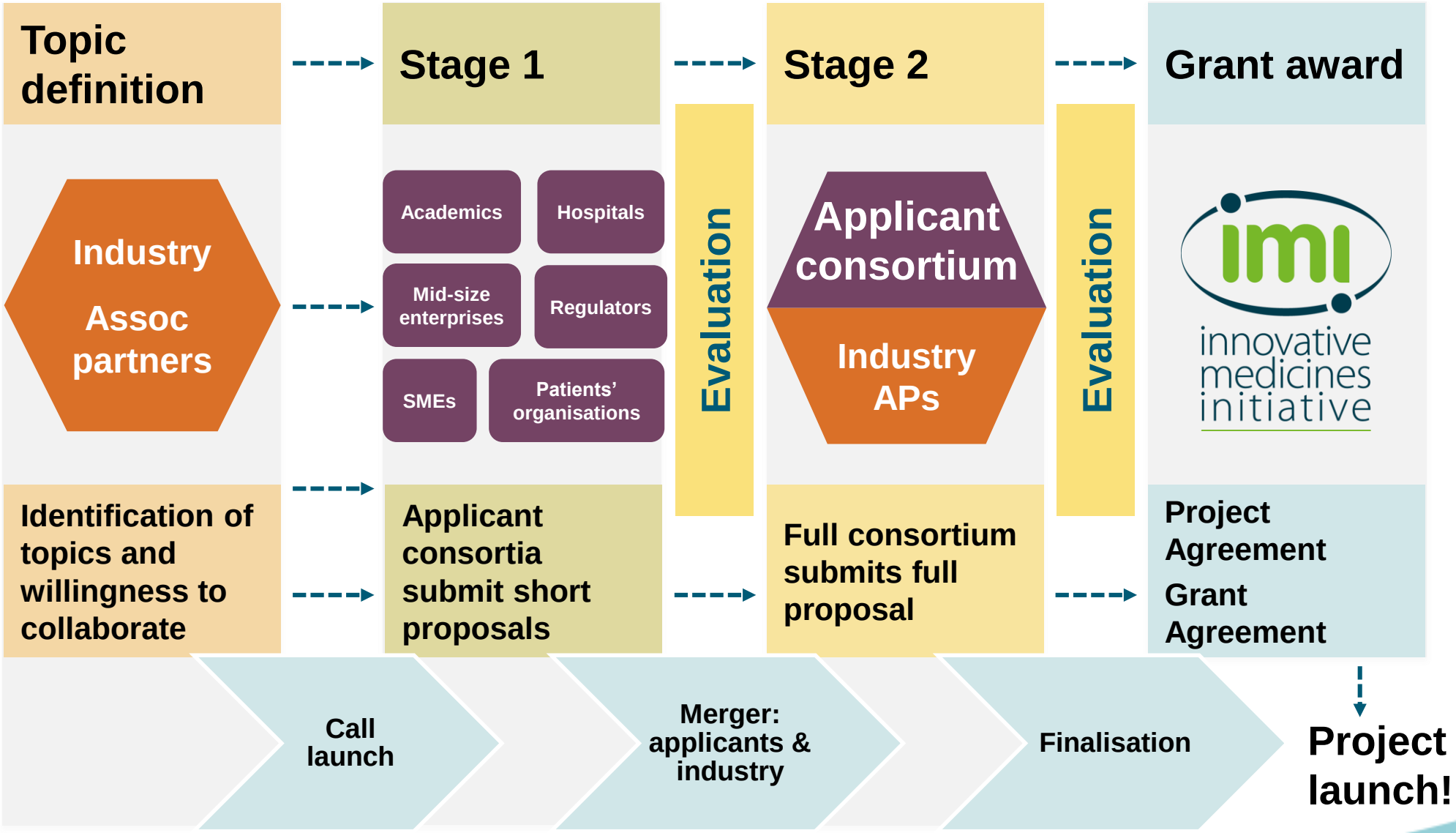
How IMI works

Typical IMI project life cycle



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A single set of rules

- **Covering all H2020 research and innovation actions**
- **Adaptability where needed:**
  - Entities eligible for funding
  - IP
  - Evaluation process (criteria, template, …)

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IMI2 IP main peculiarities

- Access rights on background/results for action implementation on royalty-free basis
- Possibility to transfer background/results without prior notification to other beneficiaries
- Access rights to Affiliates under the same conditions than beneficiaries
- Definition of Sideground
- Research Use vs. Direct Exploitation
- Access rights for third parties after the end of the action for research use purposes
- Time-limits on access rights to be agreed
- Consortium agreement before the action starts

Based on previous experience

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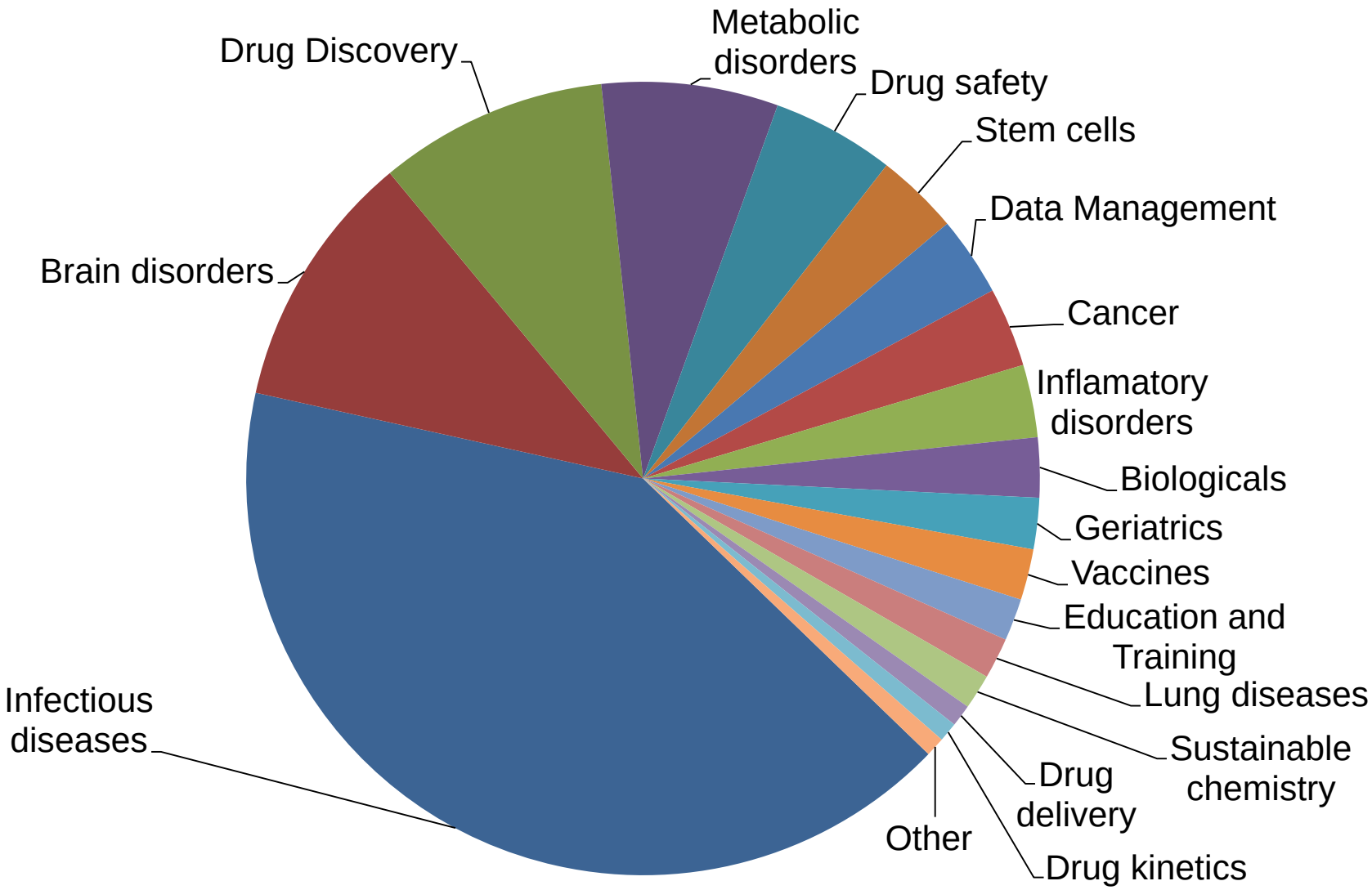
IMI and infectious diseases

IMI budget breakdown



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May 2016

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 networks; clinical studies

Challenge 4: Low return on investment

DRIVE-AB: new economic model of antibiotic development & stewardship.

ND4BB - Facts

Total budget: > € 650 million

7 public-private partnership projects up and running

Network of >**700 hospitals** in over 400 cities across 40 countries in Europe/associated countries and **> 400 laboratories**

>10 early discovery programmes from academia and SMEs accepted to date, of which 5 have been terminated on scientific grounds

6 clinical development programmes active

- 3 Phase II studies + 1 about to start
- Observational studies, epidemiology of disease
- EMBARC: EU-wide bronchiectasis patient registry

Joint Information Centre

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Current IMI vaccine projects

Total budget:
> €340 million

BIOVACSAFE

Biomarkers to boost vaccine safety

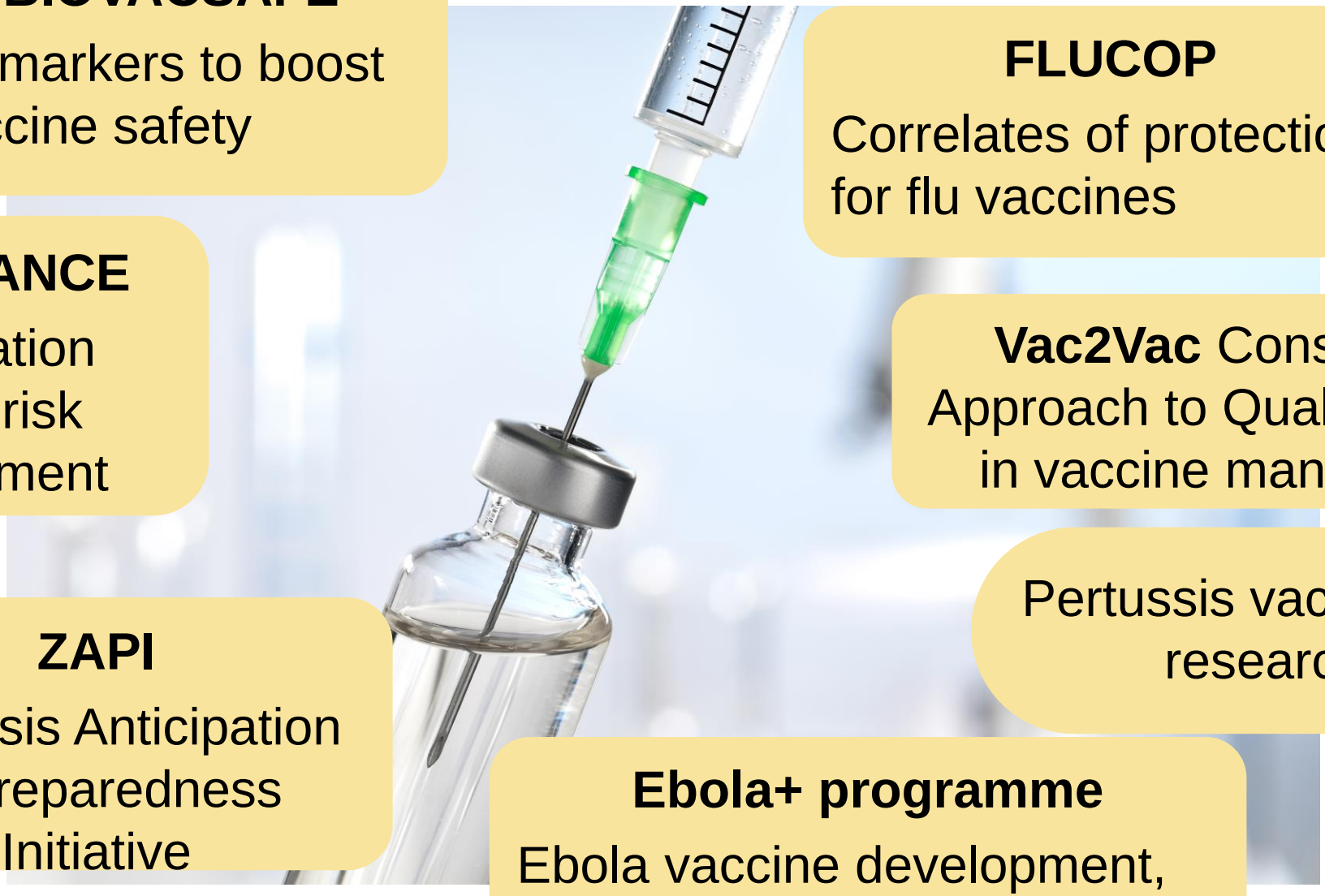
FLUCOP

Correlates of protection for flu vaccines

ADVANCE

Vaccination benefit risk assessment

Vac2Vac Consistency Approach to Quality Control in vaccine manufacture



Pertussis vaccination research

ZAPI

Zoonosis Anticipation & Preparedness Initiative

Ebola+ programme

Ebola vaccine development, manufacture & compliance

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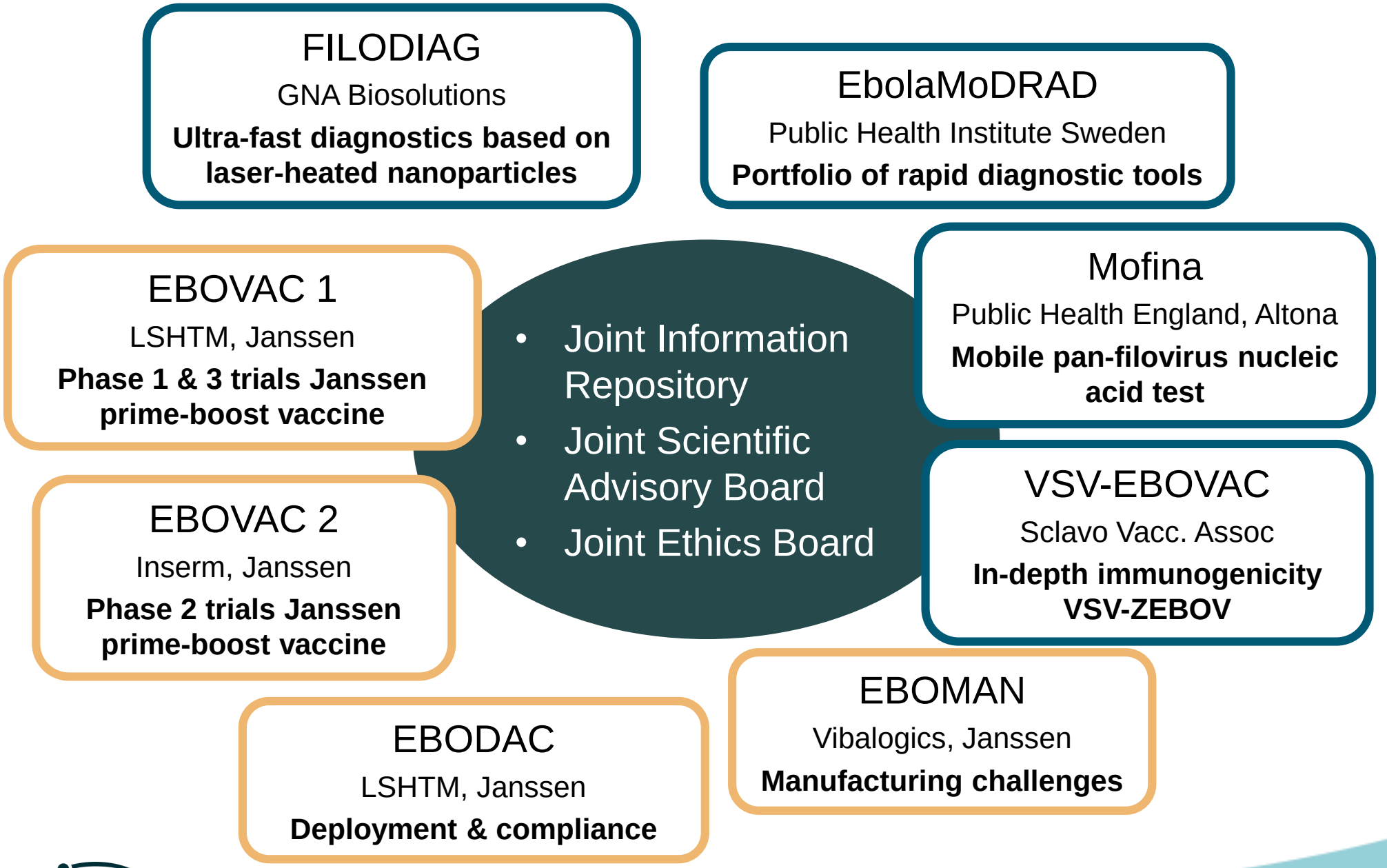
The family of Ebola+ projects



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Other projects

- **RAPP-ID -** rapid point-of-care test platforms
- **Predict-TB -** modeling to predict drug combination
- Call 6 currently under stage 2

Establishing impact of RSV (**respiratory syncytial virus**) infection, resultant disease and public health approach to reducing the consequences

How to get involved

IMI2 – Call 8:

IMI 2 Ebola and other filoviral haemorrhagic fevers (EBOLA+) Programme: Future Outbreaks

- **Broad scope**
- **Single stage, open call, with multiple submission deadlines:**

  - ~~16 March 2016~~
  - 16 September 2016 ← currently open
  - 16 March 2017
  - 18 September 2017
  - 16 March 2018

- Total budget: up to EUR 70 million IMI financial contribution
- Expectation for contributing partner contributing at least 40% of total budget
- **Available budget for next cut-off date: EUR 55 256 680**

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IMI2 – Call 9

Currently open for submission of short proposal – submission deadline **26 July 2016** – 17:00:00 Brussels time

1. Addressing the **clinical burden of *Clostridium difficile* infection** (CDI): Evaluation of the burden, current practices and set-up of a European research platform (part of the **IMI New Drugs for Bad Bugs (ND4BB) programme**)
2. Development of **immune tolerance therapies** for the treatment of **rheumatic diseases**
3. **Data quality** in preclinical research and development
4. Next generation of **electronic translational safety**
5. Identification and validation of biomarkers for **non-alcoholic steatohepatitis (NASH)** and across the spectrum of **non-alcoholic fatty liver disease (NAFLD)**
6. Joint **influenza vaccine effectiveness** studies

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Future Calls

IMI2 – Call 10 | Autumn 2016:

Topics – indicative info likely available late summer

- More info at our Stakeholder Forum (28-29 September, Brussels)
- More info at our webinars

Areas under discussion:

- Oncology, Paediatric, Advanced Therapies, One Health Initiatives, Patient Engagement, …

Tips for applicants

- Start working early (on your proposal & finding partners)
- Read and understand the Call documents
- Use the templates
- Make sure you address the requirements of the topic
- Each proposal evaluated ‘as it is’
- Don’t forget to address any ethical issues
- Unsure?: ask questions

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