IMI2: public-private collaboration biomedical research

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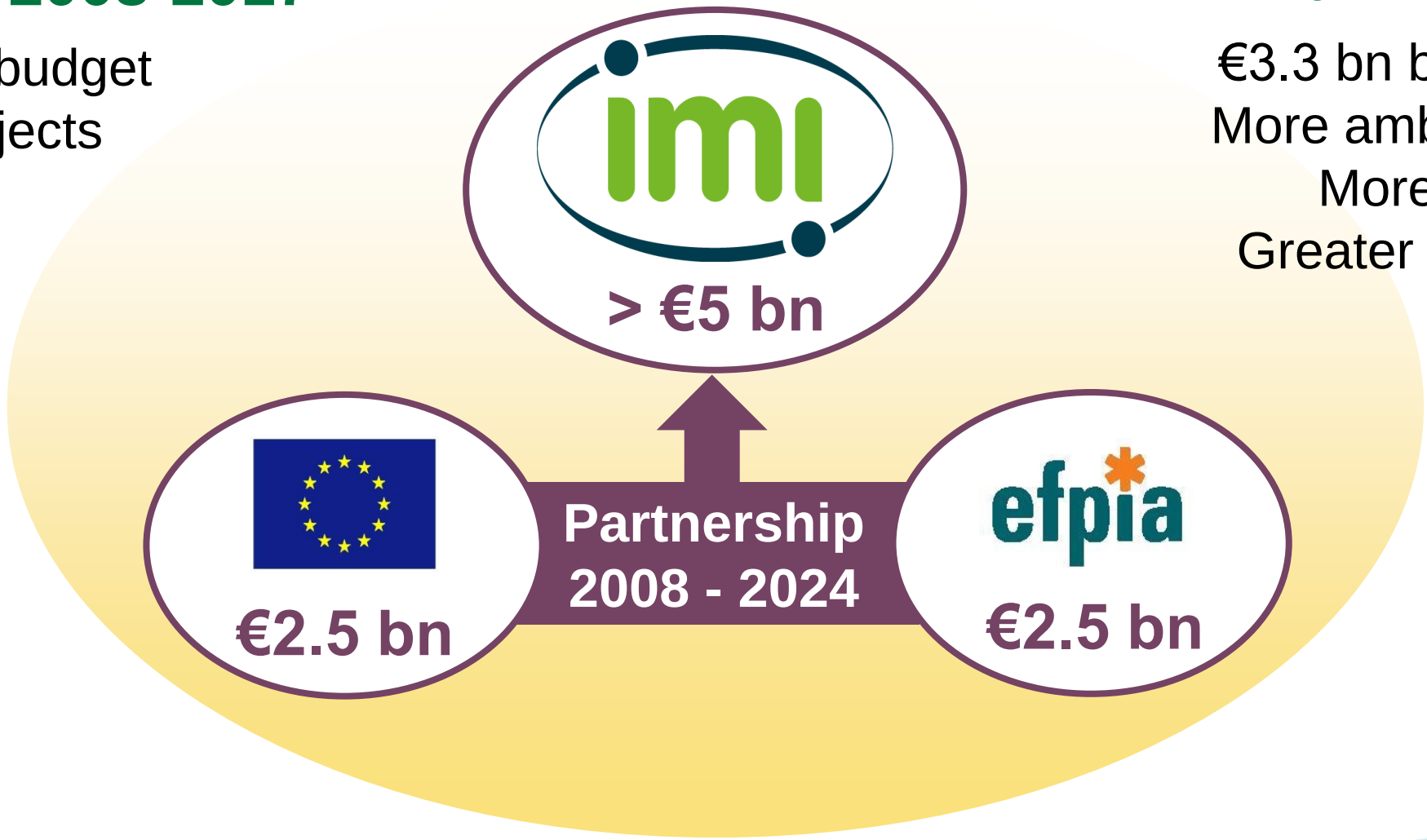
IMI – Europe's partnership for health

IMI1: 2008-2017

€2 bn budget
59 projects

IMI2: 2014-2024

€3.3 bn budget
More ambitious
More open
Greater scope



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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.

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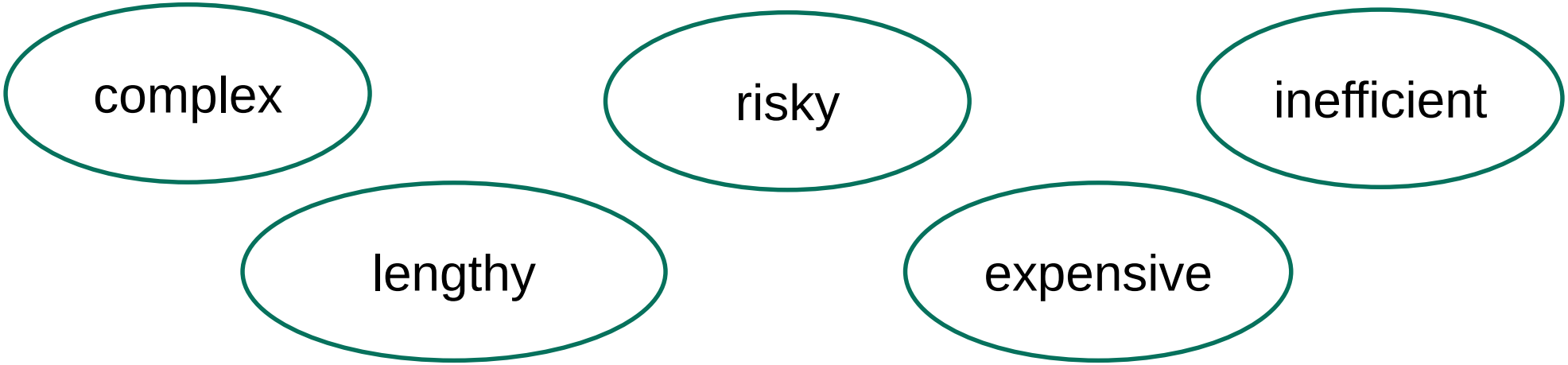
IMI – Why Europe's partnership for health?

Because drug development is very…



Because…

- Biological mechanisms underlying disease are complex
- Clinical trial designs need to be adapted to scientific knowledge
- Regulatory pathways should be adapted due to scientific drivers

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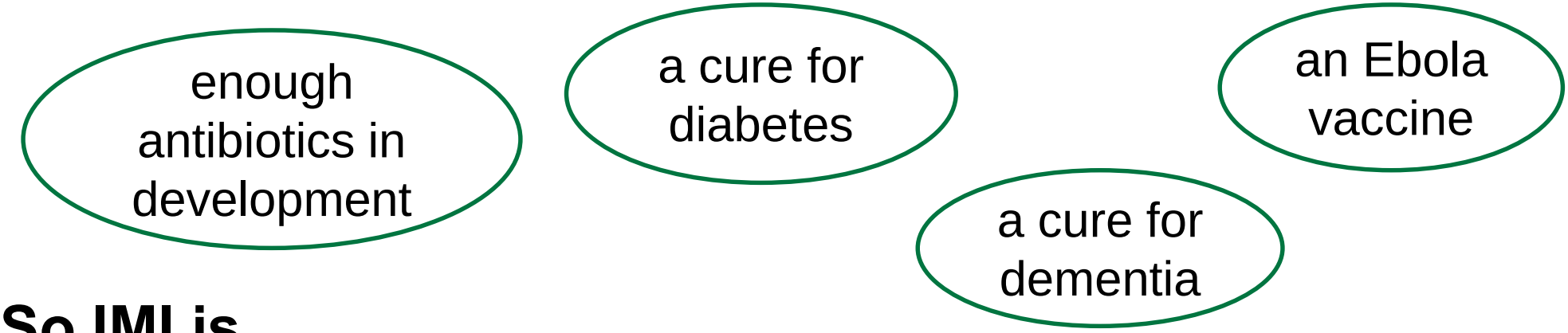
IMI – Why Europe's partnership for health?

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



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...

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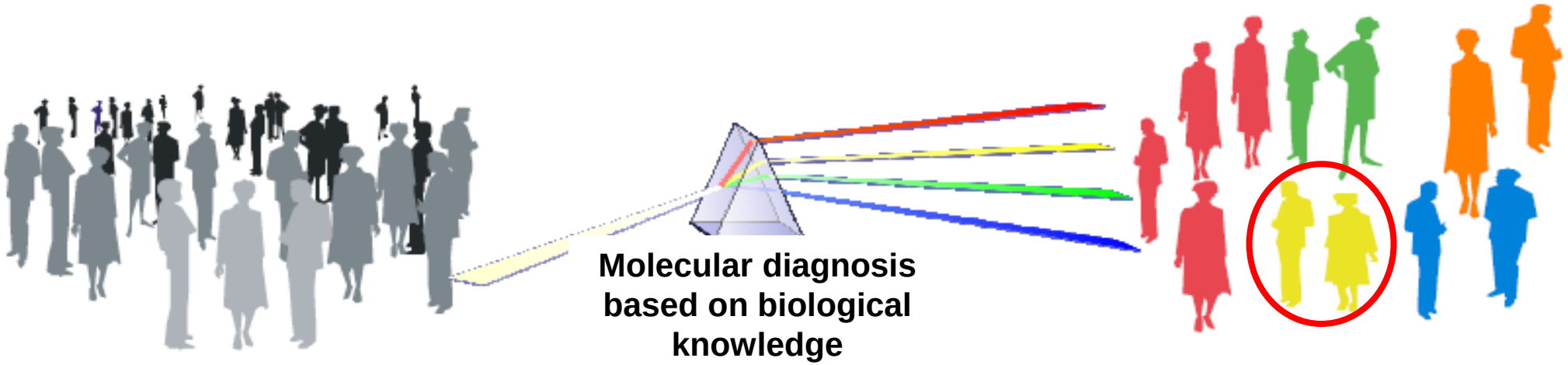
The Vision for IMI2

Science is driving the manner in which we view disease

Population ⟷ **Individual**



**We "treat" a population.
Some respond and some don't**

**We "treat" a *targeted* population
They all respond**

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IMI 2 budget (2014 – 2020)

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc…

€1.638 bn

efpia

€1.425 bn

EFPIA companies

receive no funding

contribute to projects ‘in kind’

Other €213 m

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

IMI 2 total budget €3.276 billion

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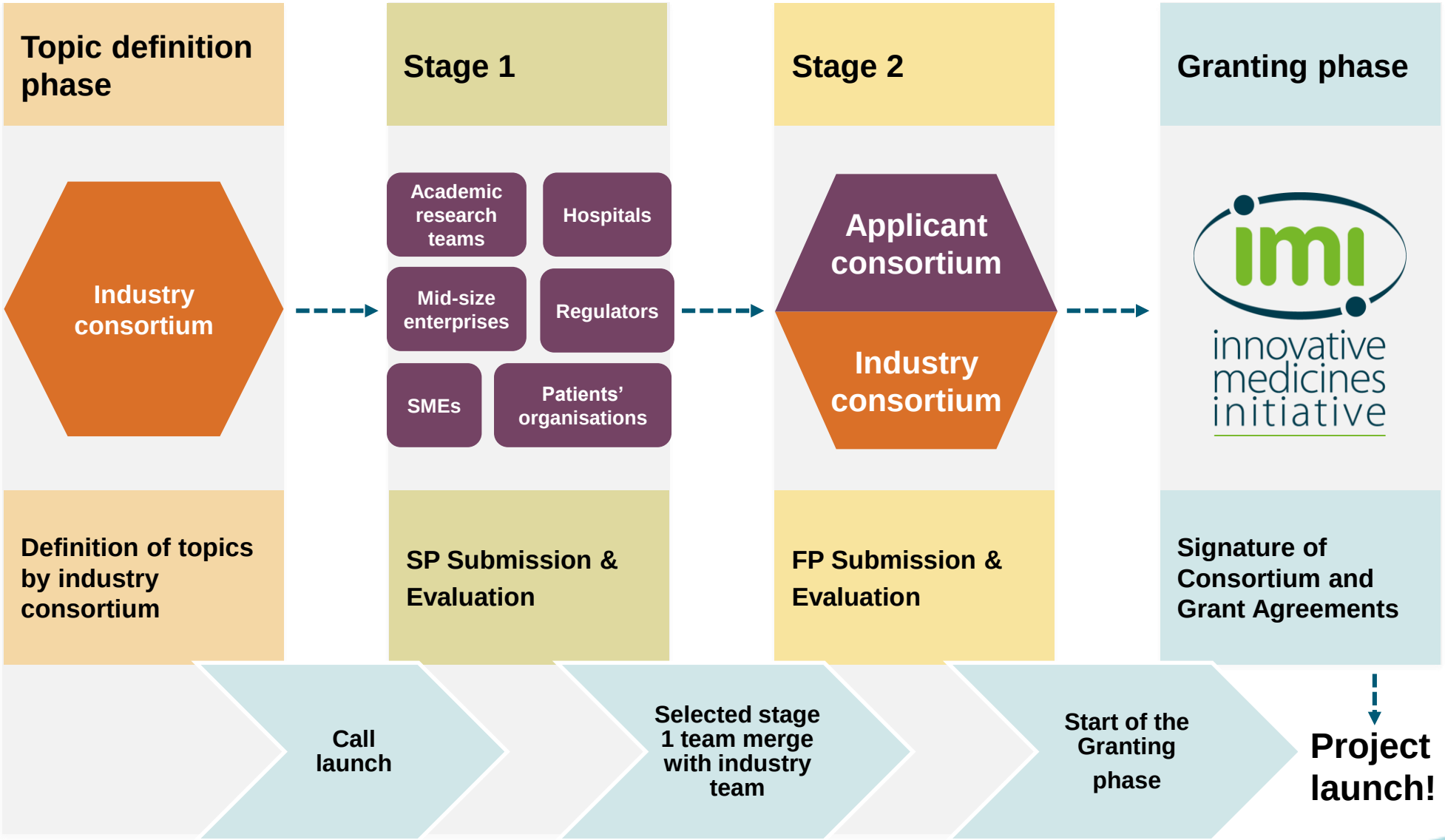
IMI2 calls: Two stage procedure



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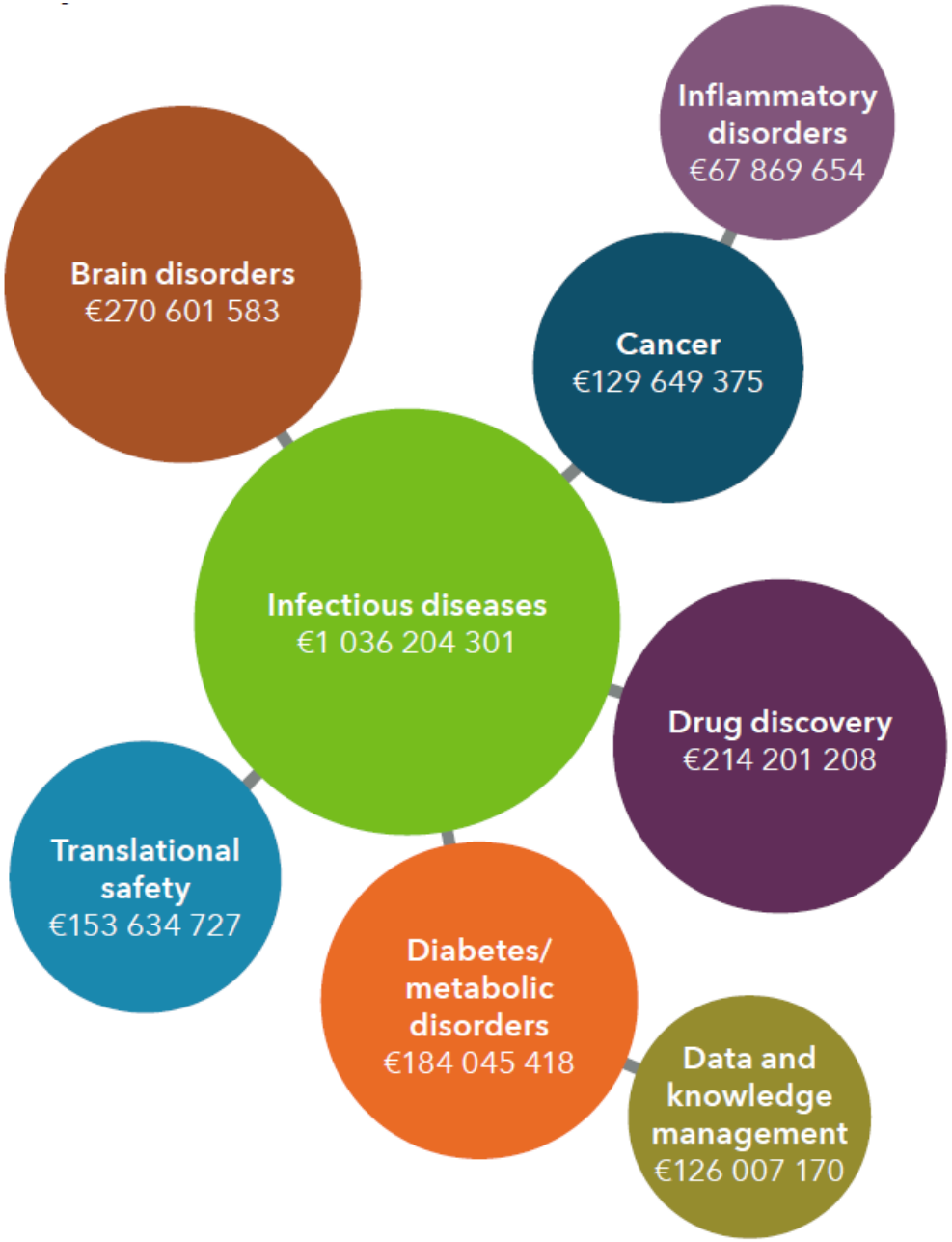
IMI investment in major research areas



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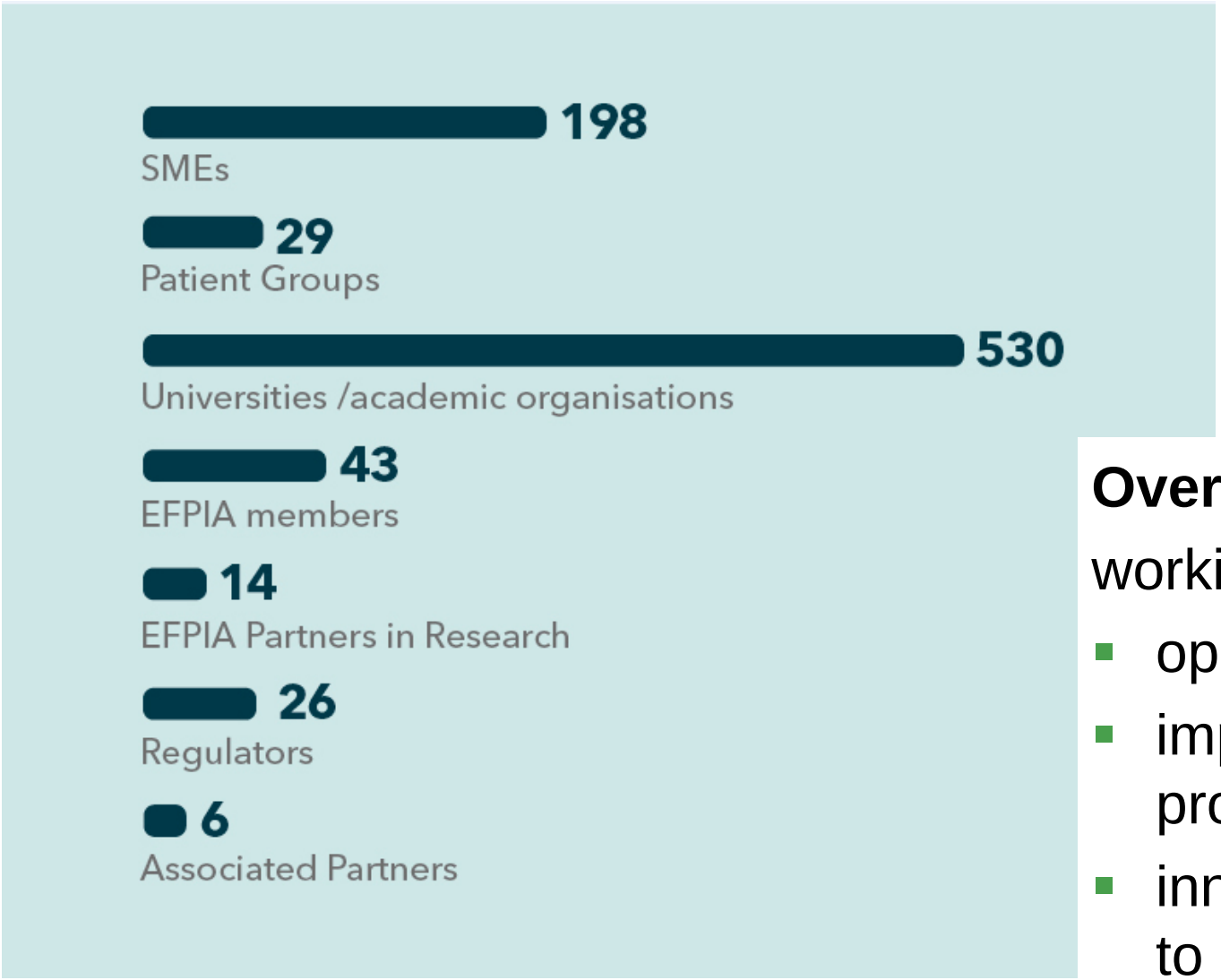
An international, cross-sector community



Over 11 500 researchers

working for:

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

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What does an IMI project look like?

Non-competitive collaborative research

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 by IMI funding and the outcomes should be transformative for the industry as well as having a clear “public” value

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Incentives to collaborate and create a partnership

- Different industry sectors, e.g., food and pharma, have complementary experience and expertise, tools and methods that could be shared and leveraged to common benefit
- There is significant new knowledge and important assets (databases, biobanks, standards) in the public space that could be taken to the next level by the interaction with industry
- Regulators need data to move regulatory science in order to enable new products reaching the market
- Create an open innovation space to de-risk biotech activities in the field
- Patients need new treatments that have been developed in partnership with them to ensure these will have a real impact on quality of life

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In the pipeline:

- Challenging to align different sectors on a common goal
- Concrete discussions between EFPIA companies and other industries (food, pharma, med-tech, diagnostics, etc.)
- Future calls planned for Jun 2019 / Jan 2020

Goals of IMI 2 programme

- **Improve the drug development process** by creating tools to assess the efficacy, safety and quality of medicines
- **Increase the success rate** of **clinical trials** of new medicines & vaccines
- **Speed up** the **earlier stages** of drug development
- **Develop** new **treatments** for areas of **unmet need**
- **Develop** new **biological markers** to **diagnose** diseases and **assess** treatments

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IMI Governance

Governing Board
Overall strategic orientation & operations

States Representatives Group
Consultation, opinions

Scientific Committee
Advice on scientific issues

Stakeholder Forum
Information & feedback

Strategic Governing Groups
Advice on specific subjects

Associated Partners
Input on specific Calls / projects

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

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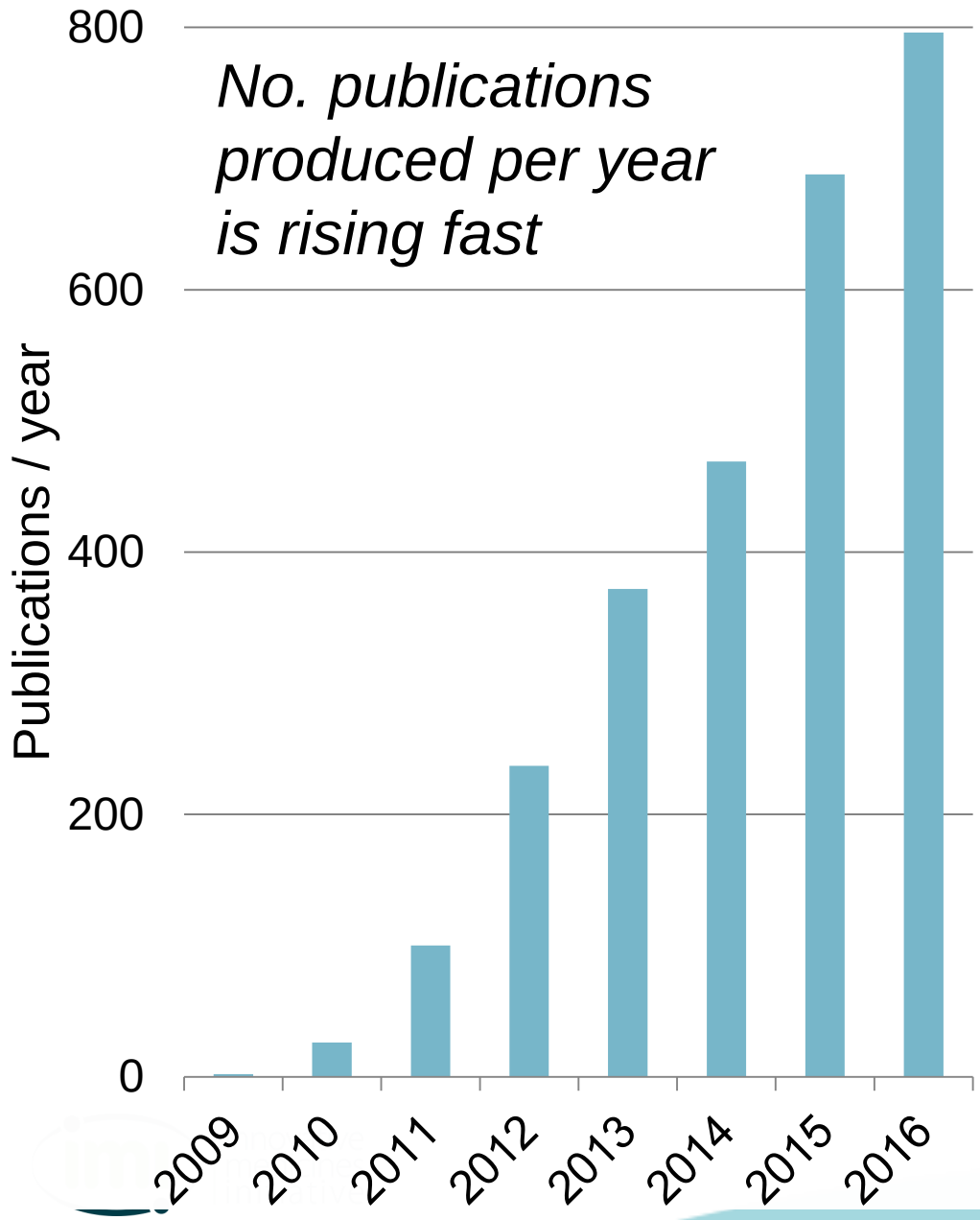
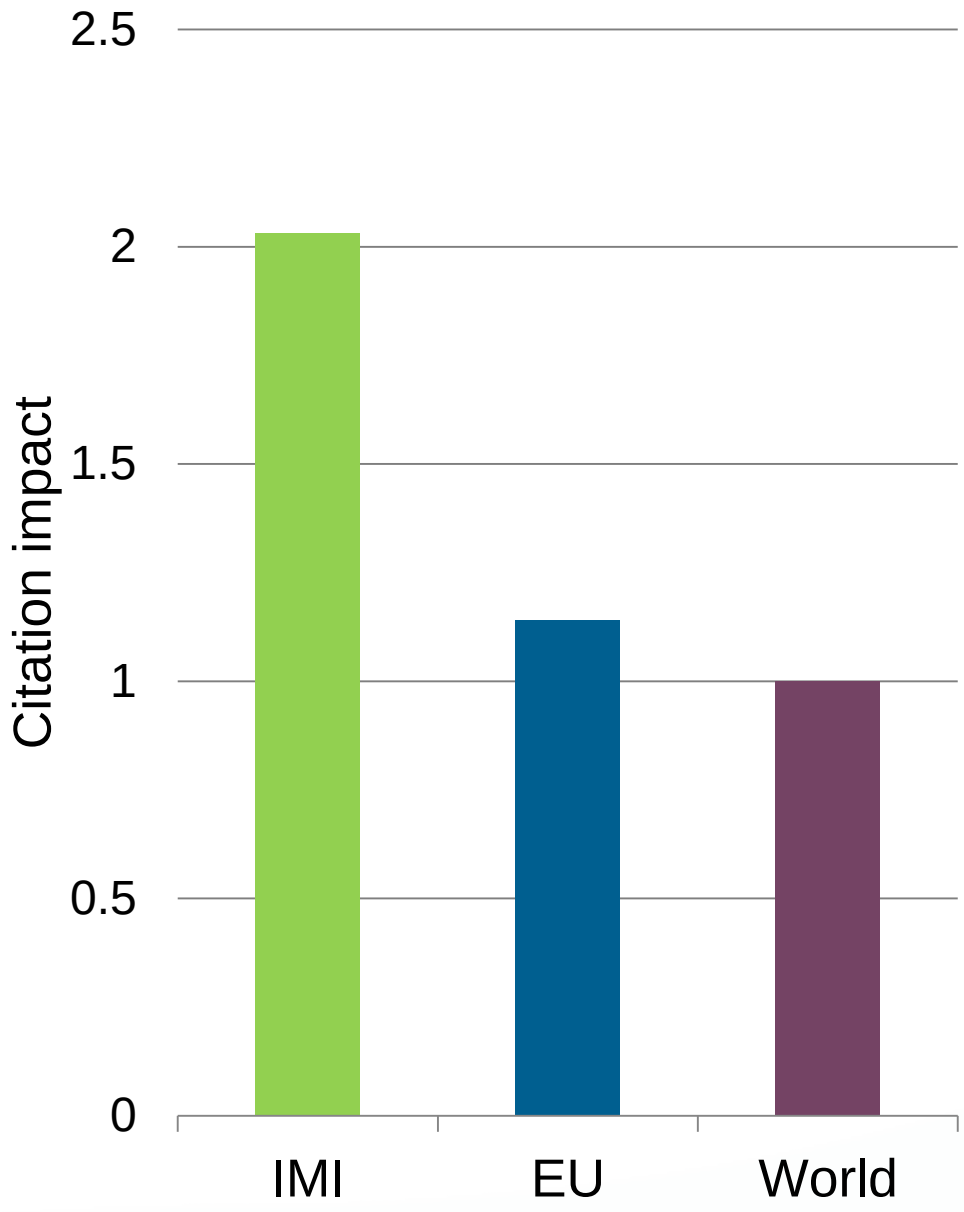
IMI and scientific excellence



- In 2016 IMI projects produced 796 publications, bringing the total number of publications to 2 690.
- Almost two thirds of all IMI project papers are co-authored by people from different sectors.
- These cross-sector papers have a higher citation index (2.17) than papers where all authors are from the same sector (1.80).

IMI and scientific excellence

- The citation impact for all IMI papers is 2.03.
- IMI's citation impact is comparable to UK's Medical Research Council (2.01), the Wellcome Trust (2.05) and the FNIH (1.96).
- 26.1% of papers from IMI projects are 'highly cited', meaning they are in the top 10 % of papers by journal category and year of publication.



Why get involved? Why apply?

- *Key research challenges can only be addressed through collaboration of all relevant stakeholders*

- *Funding*
- *Scientifically excellence*
- *Develop your network of international collaborators*
- *Benefit from access to industry data, researchers and resources*
- *Boost the impact of your research, publications, future grants etc*
- *Work in areas with a direct impact on the drug discovery and development process addressing key societal challenges*

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Priorities for 2020

Neurodegeneration and other neuroscience priorities

- Digital endpoints and placebo effect in chronic pain

- The primary aim of this call is to progress digital endpoint(s) to Health Authority acceptance as primary / surrogate endpoints or key secondary endpoints for evaluation of chronic pain in pivotal clinical trials.

- The intention of this call is not to simply explore digital endpoint space in chronic pain, but to deliver endpoints ultimately via medical grade devices that can subsequently be used for regulatory approval.
- As the placebo effect in pain clinical trials is substantial, an additional aim is to assess new methods to better understand and control placebo effects to determine the real treatment advantage offered by analgesic agents.

Priorities for 2020

- **Infection control including vaccines**
- Development of innovative personalized diagnostics and patient-guided therapies for the management of sepsis-induced immune suppression
- The proposed topic is addressing **Sepsis**, a global health priority being targeted by many countries and the WHO. If not recognized early and managed promptly, sepsis can lead to septic shock, multiple organ failure and serious consequences including death. There are approximately 30 million sepsis patients per year worldwide.
- Reduce mortality and decrease secondary HAI through diagnostic and therapeutic approaches including
- (i) implementation of an **immune-based personalized diagnostic test to clearly identify sepsis patients in an immune-suppressed state** and
- (ii) introduction of **innovative immuno-modulators in order to restore immune homeostasis.**

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Priorities for 2020

- **Big data, digital health, clinical trials and regulatory research**
- **Data lakes**
- Many pharma and life sciences companies are currently creating data lakes to bring together internal data to apply analytics and create insights. However, these data often need to be complemented with other data sources.
- Most health data are generated outside the life sciences, e.g. electronic health records, claims,biobanks etc. In addition, control over health data is starting to shift towards the patient; **initiatives and healthcare technology companies already signal a future where the patient will be in control of data and can decide how and with who to share**. To improve our ability to combine data from multiple sources and
- maximize insights generation from these data, we need a common approach to enable quick and efficient connectivity of data to use for diverse purposes.

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Priorities for 2020

- A fundamental requirement for this to work is to make data **findable**, **accessible**, **interoperable** and **reusable** (the underlying concepts are known as the **FAIR principles**).
- Therefore, we propose a project to create (1) a common set of tooling for managing and FAIRifying data lakes, i.e. the agreement or development of a common and potentially open source toolset, (2) agreement on
- the necessary key ontologies and standards and (3) to create a market place for datasets or individual-level data to further enhance data fluidity.
- With a successful implementation, users would be able to find, access
- and use data which data owner decides to share, and leverage them for different purposes.
- Data owners could do this at the individual level

Priorities for 2020

- **Oncology**
- Prospective real-world clinical implementation **of liquid biopsies**
- **Liquid Biopsy is a promising concept for patient selection and disease monitoring in drug development and in clinical practice.** However, as of today, few clinical studies used Liquid Biopsies to systematically and prospectively identify eligible patients for clinical studies, therapy selection, therapy monitoring or detection of first signs of efficacy.
- Based on outputs from **IMI CANCER-ID** the project will use prospective clinical trials to
- investigate the efficacy and robustness of the method and its ability to guide recruitment to trials and therapeutic choices
- **Tumour plasticity**
- **Drug resistance** in cancer is one of the greatest causes of mortality and despite increasing success with targeted therapies in the clinic (including immunotherapy) the mechanisms by which cancer cells evade cell death are still not well understood. Drug combinations are likely to be critical to overcoming drug resistance but are dependent on identifying the cellular programs that cancer cells use to resist therapeutic agents.

Priorities for 2020

Facilitating the translation of advanced therapies to patients in Europe

Optimising patient access to new therapies for rare diseases

Payers and manufacturers recognise the challenges in delivering innovative medicines to Rare Diseases patients and the need to address reimbursement hurdles which will demand new models of reimbursement based on value based agreements and performance guarantees.

However determining the appropriate outcomes, data and standards required to make these decisions efficiently across the **many healthcare systems** requires transparency and alignment across all stakeholders, including patients, payers, regulators, industry and other experts. Additionally, there is **a paucity of registries and databases** that capture long term outcomes including patients' Quality of Life and functional data, coupled with general uncertainty regarding variability & durability of outcomes for new and novel treatment options including

Priorities for 2020

Advanced Therapy Medicinal Products (ATMPs).

To facilitate the health economic evaluation of such new and novel treatments, the project will aim to build an ecosystem involving relevant stakeholders to identify and capture appropriate long term outcomes required by HTA bodies and assess how these may align with regulatory requirements (continued evidence generation).
This project will aim to capture and demonstrate improved health outcomes important to patients and for payer reimbursement and regulatory decisions, providing patients more rapid access to new therapies

- Σας ευχαριστώ για την προσοχή σας!

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