

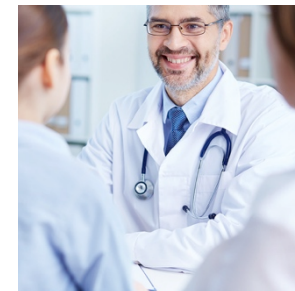
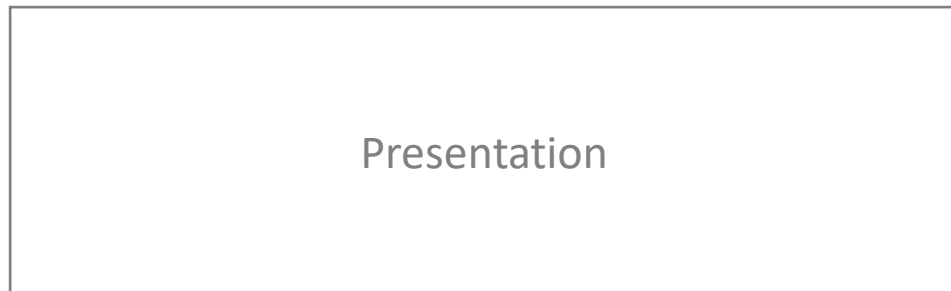


European Federation of Pharmaceutical
Industries and Associations



Translational research power - Health PPP today (IMI) and tomorrow

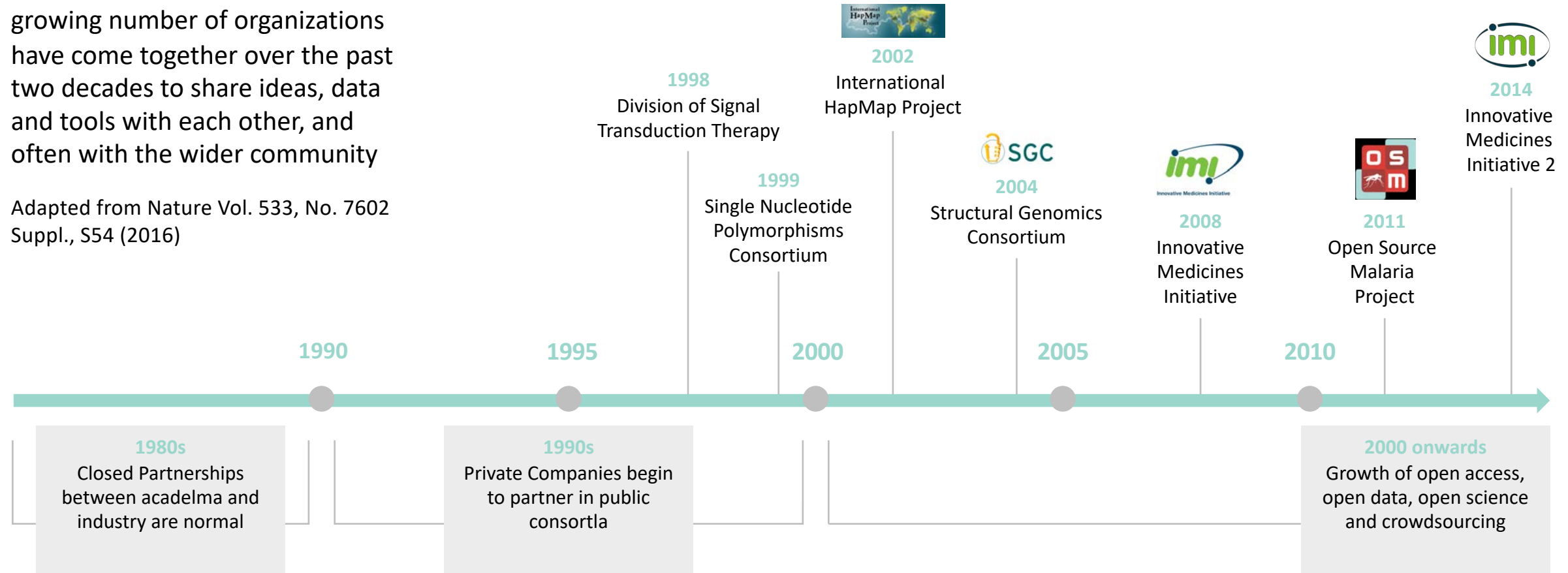
Magda Chlebus, Executive Director Science and Regulatory Policy | Budapest, 31 January 2019



A Growing Movement

In response to the limitations of the closed model of innovation, a growing number of organizations have come together over the past two decades to share ideas, data and tools with each other, and often with the wider community

Adapted from Nature Vol. 533, No. 7602 Suppl., S54 (2016)



IMI Accelerates Innovation

Multiple companies join force and

Identify **missing or weak** links in medicines pathways that hold progress

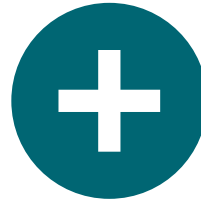
Combine (often) **proprietary knowledge, data and assets**

Open them up for challenge by and **collaboration with public partners**

Validate proposed solutions during project lifetime in R&D practice



Solutions for diseases with high burden and cost for patients and society

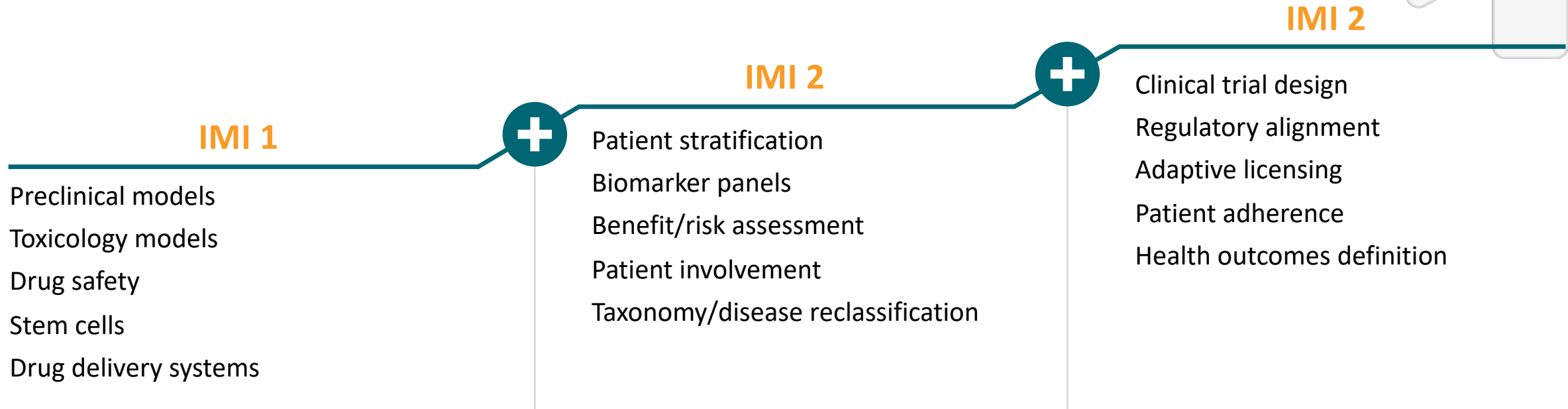


Solutions that challenge current business models and focus on value for patients and sustainable healthcare

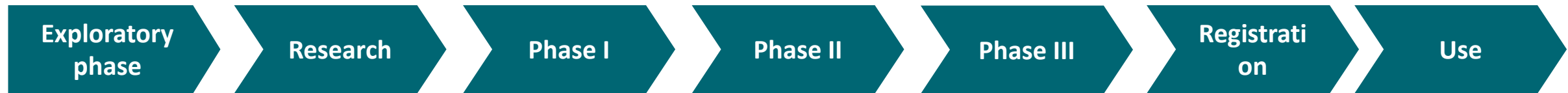


Tracking and addressing science gaps and inefficiencies from discovery to disease management

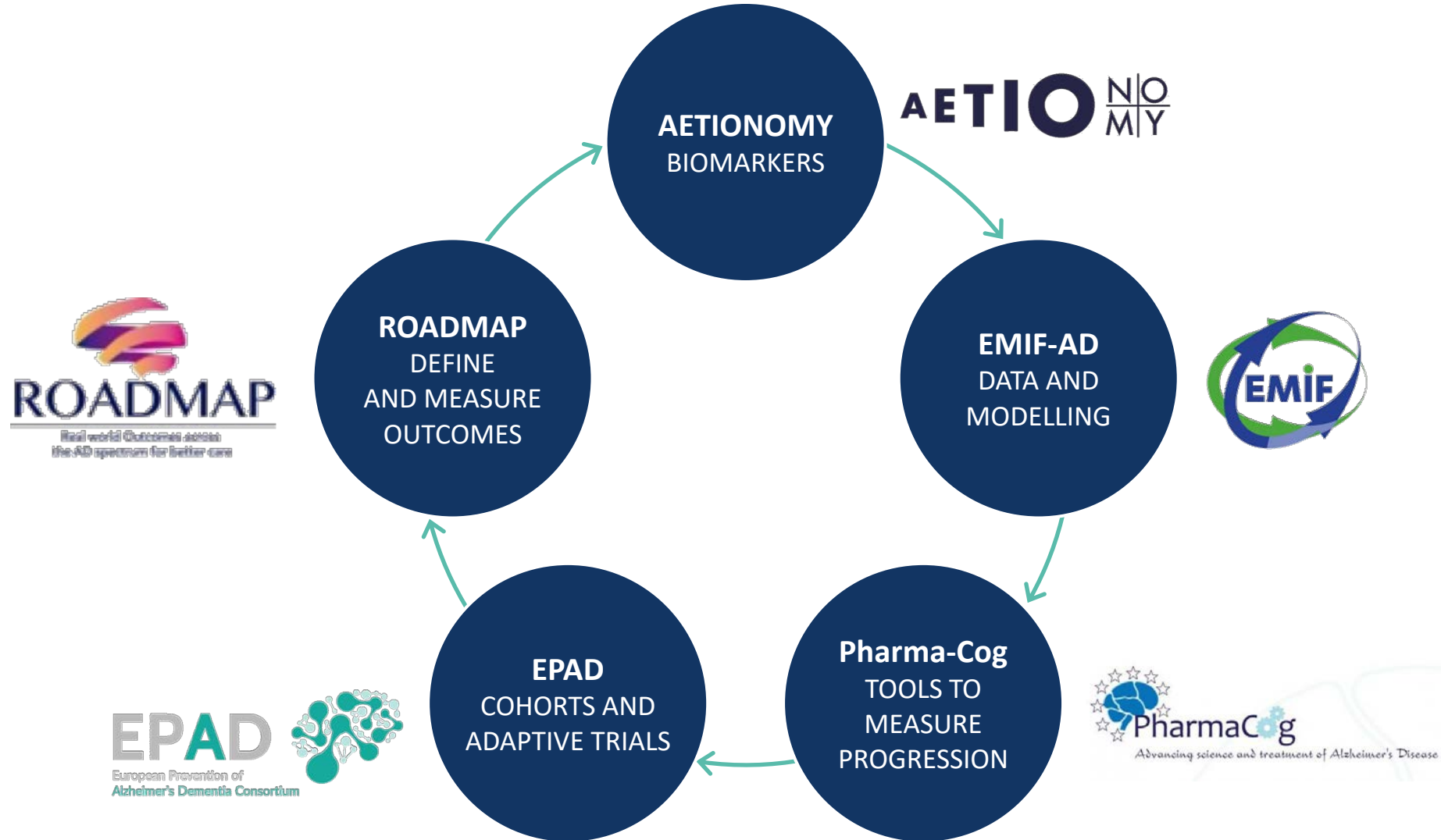
IMI Accelerates Research and Development to Strengthen Competitiveness



Pharmaceutical Value Chain



End-to-End and Combination: Data, Samples, Registries, CT Networks



European Lead Factory – R&D structural change



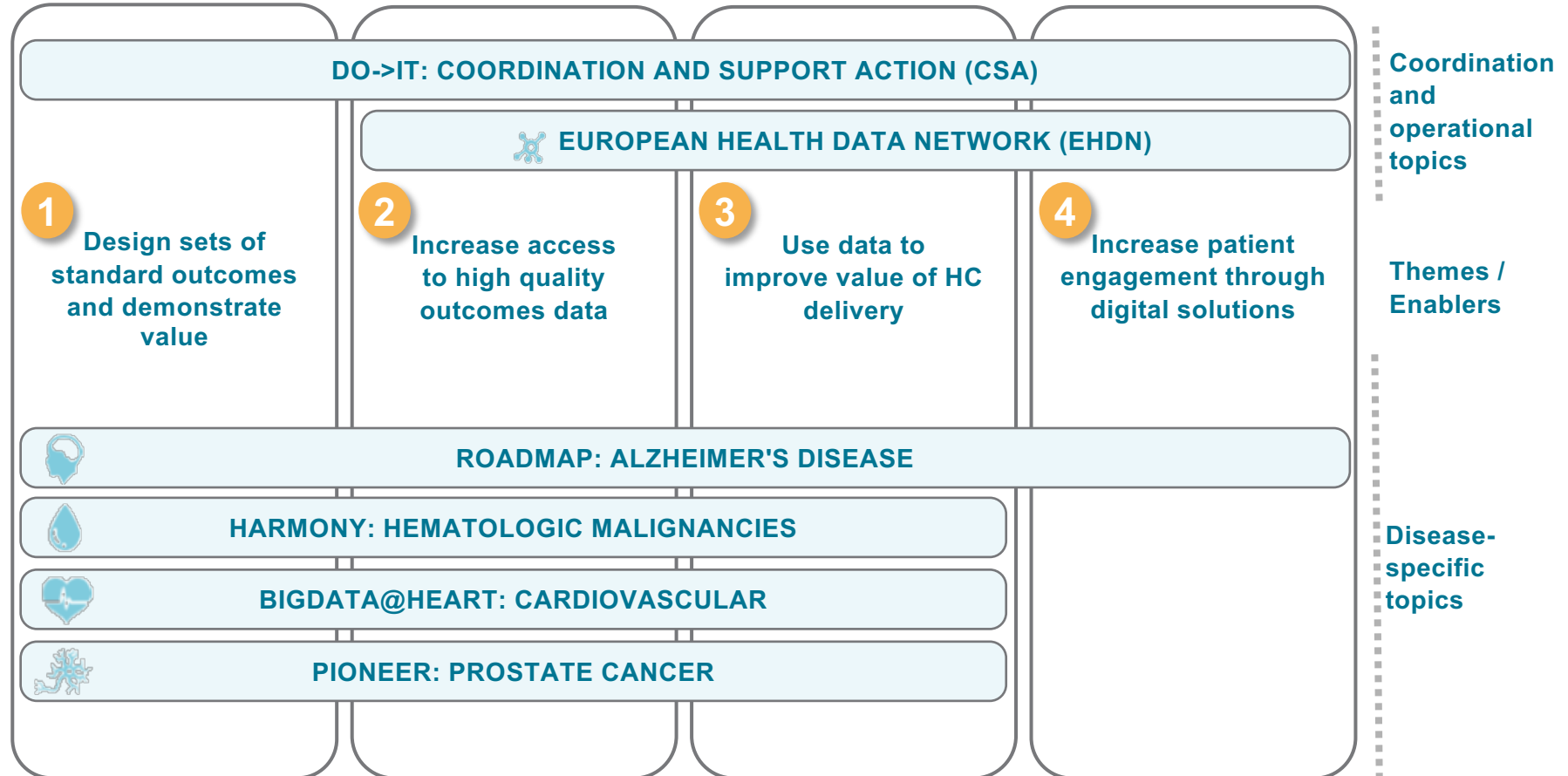


Medicines Adaptive Pathways to Patients (MAPPs) seek to foster access to **beneficial treatments** for the **right patient groups** with **high unmet medical needs** at the **earliest appropriate time** in the product life-span in a **sustainable fashion**. A key component of MAPPs is **stakeholder collaboration**.

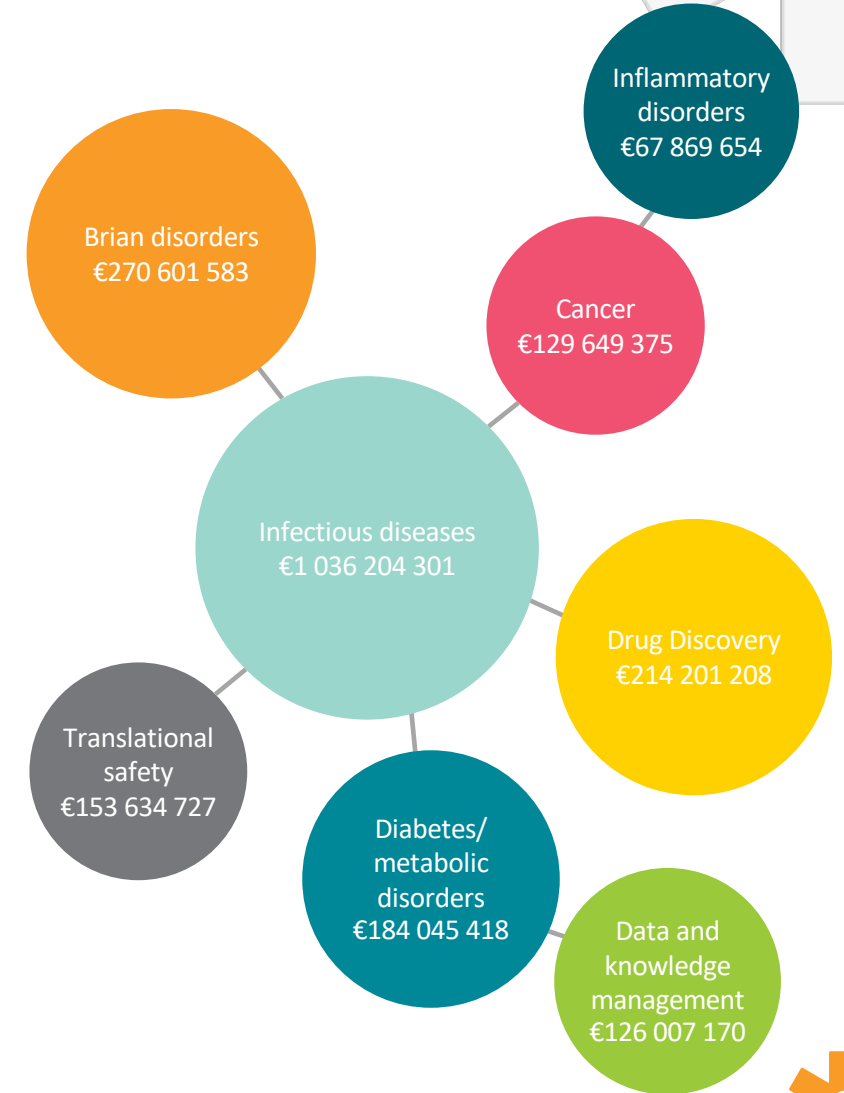
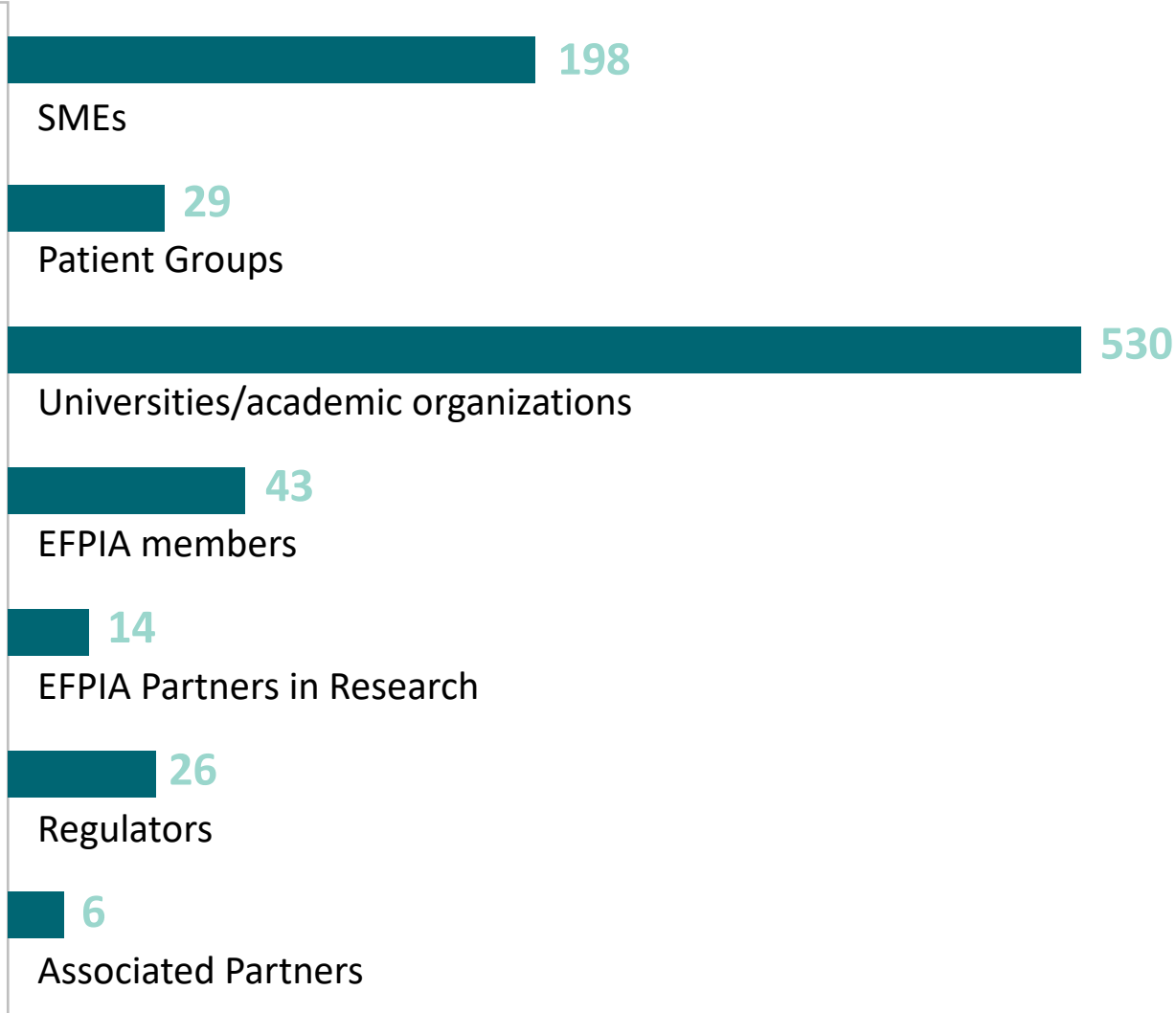


BD4BO: enabling outcomes based models

Goal: Support the evolution towards outcomes-focused and sustainable healthcare systems, exploiting the opportunities offered by big and deep data sources



Types of Organizations Participating in IMI and Major Funding Areas



IMI DELIVERS

Examples from a decade of successes

- Ebola vaccines and diagnostics,
- New candidate antibiotics,
- Tools to predict toxicity approved by regulators,
- Standards that opened the path to autism medicines research,
- 70 novel drug targets, 35 validated drug targets
- Several clinical trials networks (1800 sites across Europe) and 39 cohorts and registries to optimise clinical trials
- Developed manufacturing method of flucytosine that dramatically cuts production cost
- Outcomes (real world data) data infrastructure and governance
- First ever human beta cell line culture which changed the way diabetes research is done
- Etc.

Diabetes	Optimising obesity treatment (Jan 2109)
Neuro	Digital transformation of CT endpoints in pain Placebo effect in pain PRISM2 - psychiatric ratings
Immuno	Psoriatic arthritis
Infections	New topics under the AMR accelerator
Translational safety	Dosing in specific populations Digital pathology
Digital health	Big Data for Better Outcomes/Alzheimer's Disease: ROADMAP2 Patient-led observatories of PROs
Onco	Patient reported outcomes – quality of life
ATMPs	Regulatory standards for gene therapies Real world evidence CAR-T cell therapies Manufacturing of ATMPs
Other enablers	Chemogenomic library (Jan 2019) Pharmaceuticals in the environment (Jan 2019) Handling biological products

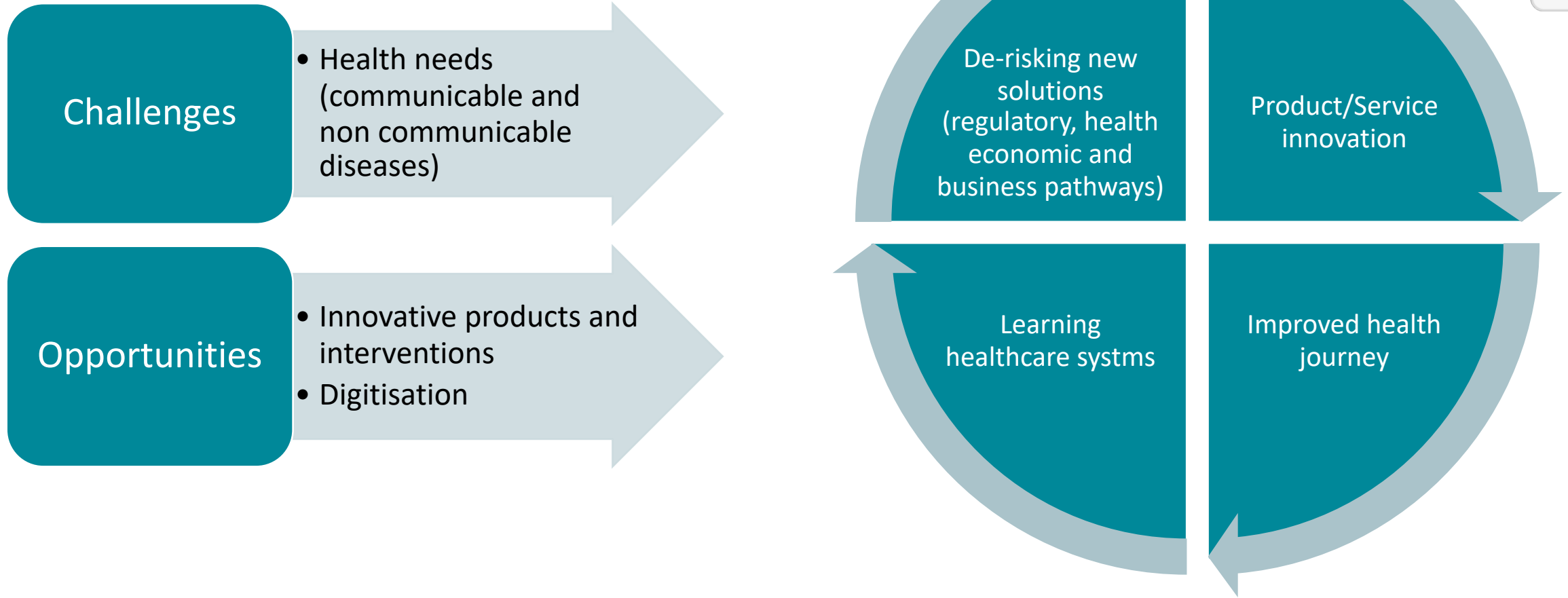
Topics planned for 2019
Visit IMI website for
more information

Cross-sector and technology integration

The whole is greater than the sum of its parts...

- * **Integration of technologies and know-how to deliver better and safer products and services**
- * **Integration of these products and ancillary services to create innovative health and care solutions**
- * **Integration of clinical, community, social and informal care workflows**
- * **Integration of business models for these innovations involving different sectors in the healthcare industry.**

Cross-sectorial and technology integration



The whole is greater than the sum of its parts!

IMI started a new model of collaboration and breaking silos

- **Across the value chain** from discovery to delivery, from prevention to health management, including access, healthcare systems and business models
- **Within and between sectors:** IMI supports evolution of collaborative research and pushes boundaries of precompetitive collaborations
- **Between regulated/regulators:** IMI has been a preferred (or unique) mechanism of collaboration with industry for regulatory and other health authorities
- **Between public/private:** IMI addresses healthcare, R&D productivity and healthcare systems challenges and impacts on both simultaneously



The industry is ready for the next level integration challenge.

Public-private partnership: translational research power



**10 YEARS OF
BREAKTHROUGHS**
A HEALTHIER
FUTURE



innovative
medicines
initiative