



IMI, Patients and Data

Pierre Meulien- Executive Director- Innovative Medicines Initiative (IMI)
Digital Citizen, Digital Patient – Tallinn, Estonia

What is driving the profound changes in the world of healthcare

- Science and technology (including digital technology)
- The epidemiology of disease (global trends- outbreaks etc)
- The role (and behaviour) of the consumer of healthcare- the patient
- Economics

All actors involved in the system from public or private spheres have to adapt to the outputs and impacts from these four drivers

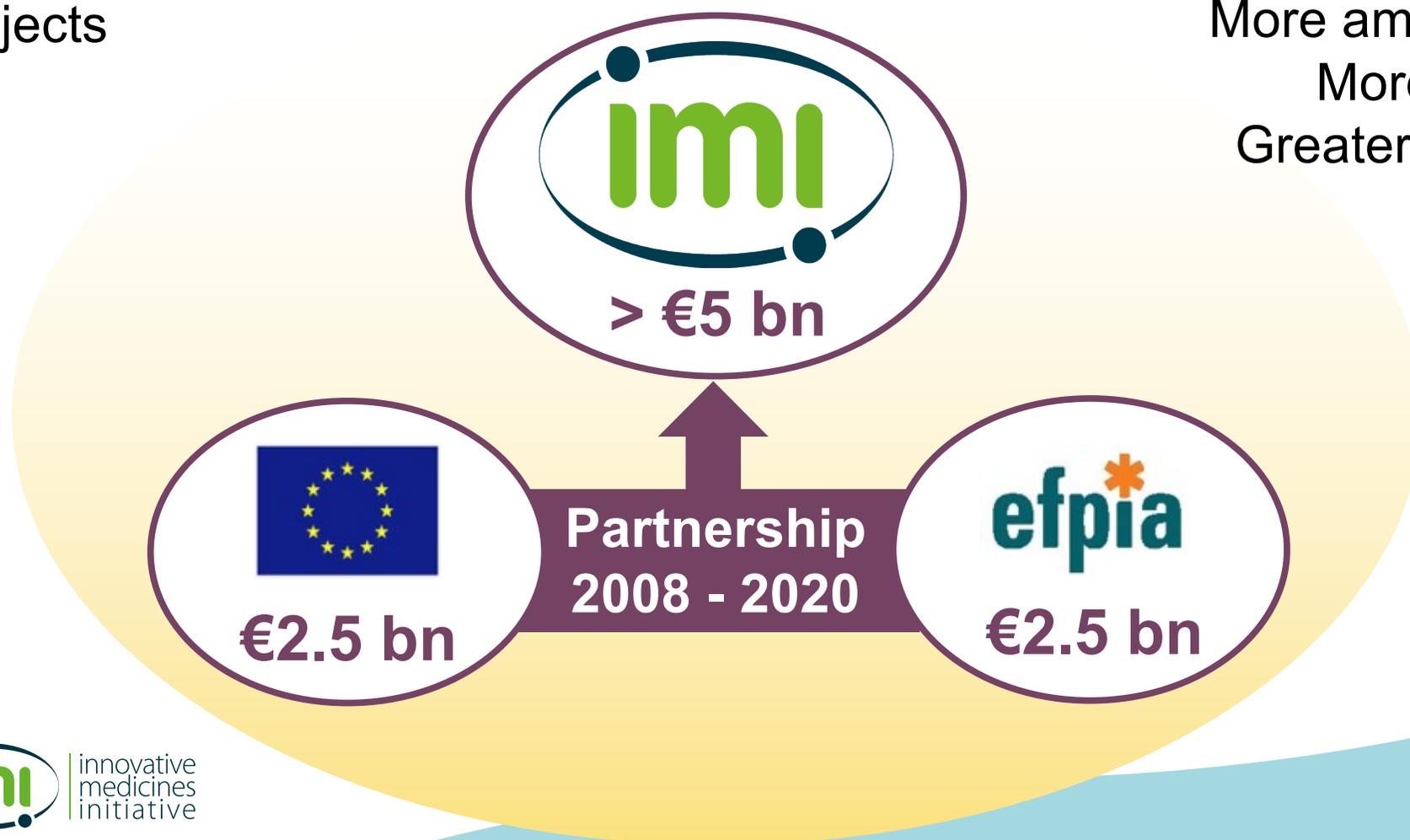
IMI – Europe's partnership for health

IMI1: 2008-2013

€2 bn budget
59 projects

IMI2: 2014-2020

€3.3 bn budget
More ambitious
More open
Greater scope

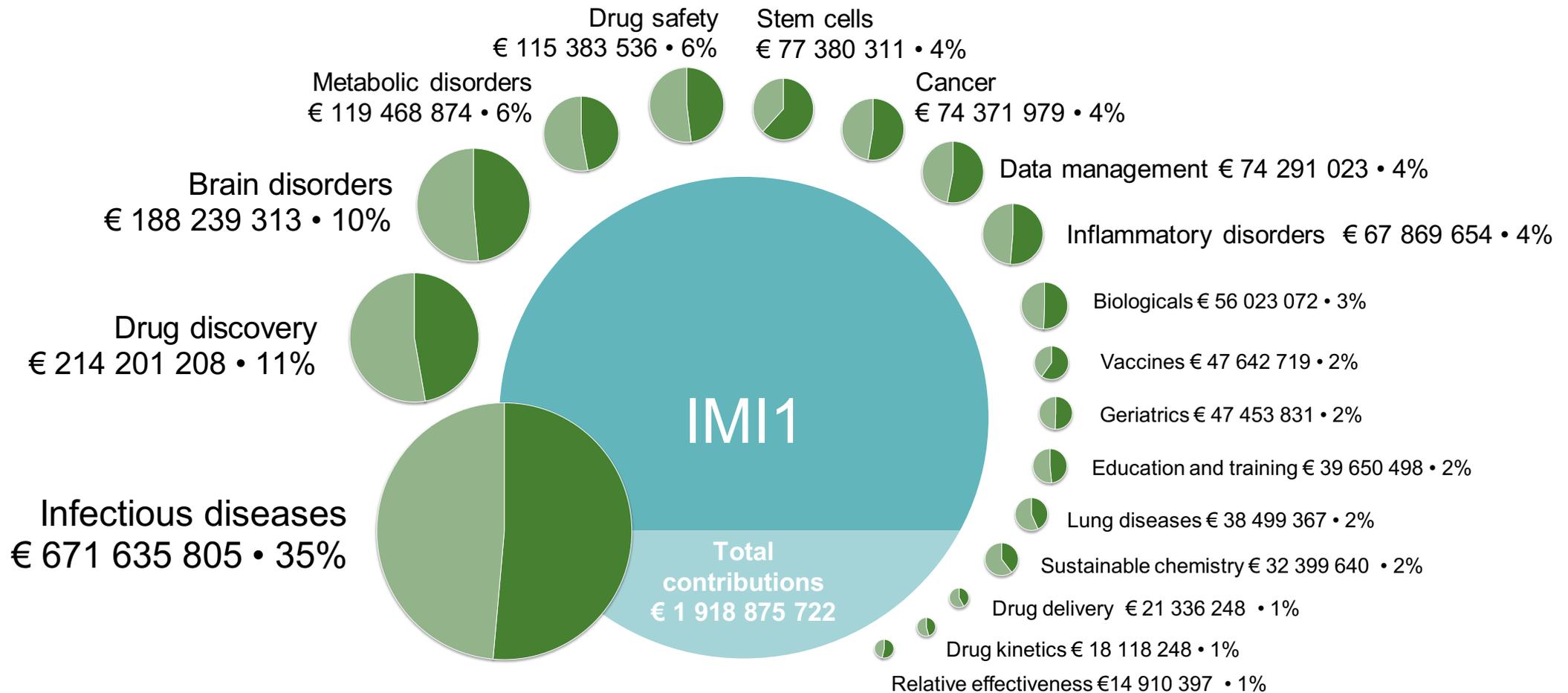


IMI – Europe's partnership for health

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.

Distribution of funding per scientific area – IMI1

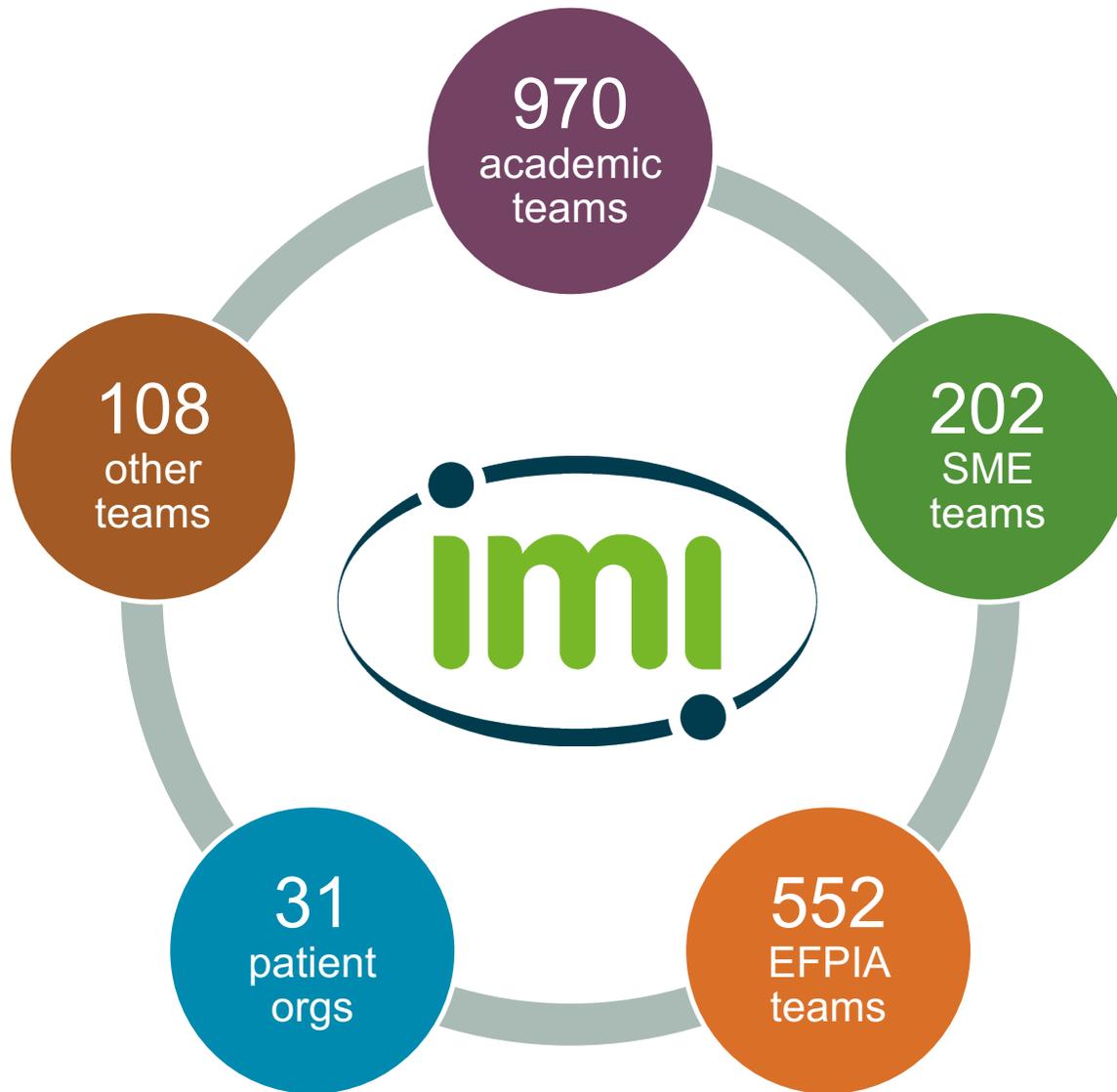


EFPIA contributions



IMI contributions

An international, cross-sector community



Over 9 000 researchers working for:

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

IMI 2 Strategic Research Agenda

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegenerative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan Diseases
- Vaccines



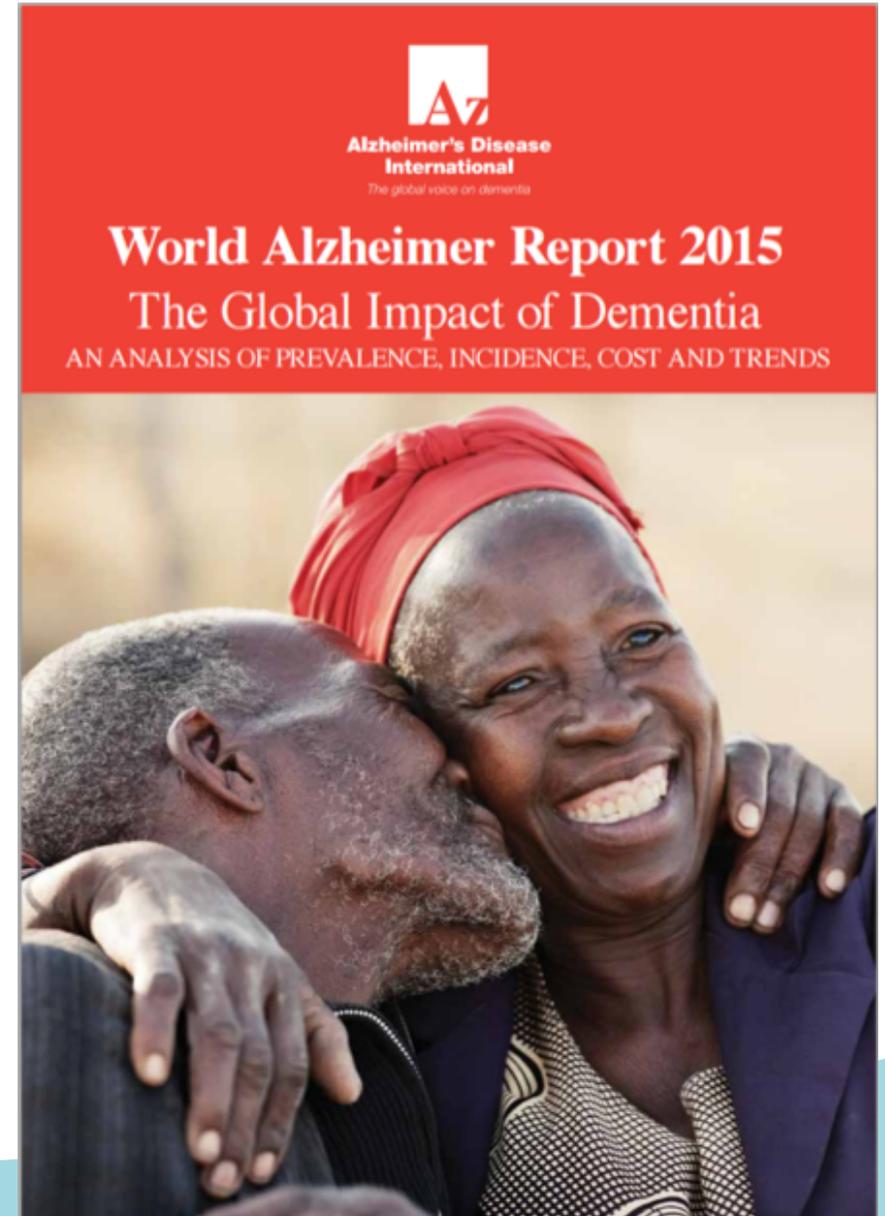
The right prevention and treatment
for the right patient at the right time
Strategic Research Agenda for
Innovative Medicines Initiative 2

**Aligned with
WHO priorities**

Alzheimer's disease – a major unmet need

Alzheimer's disease in numbers...

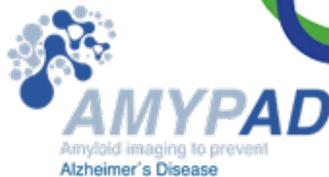
- **46.8 million** affected globally
- **10.5 million** in Europe
- **Global cost** USD 818 billion (EUR 732 billion)



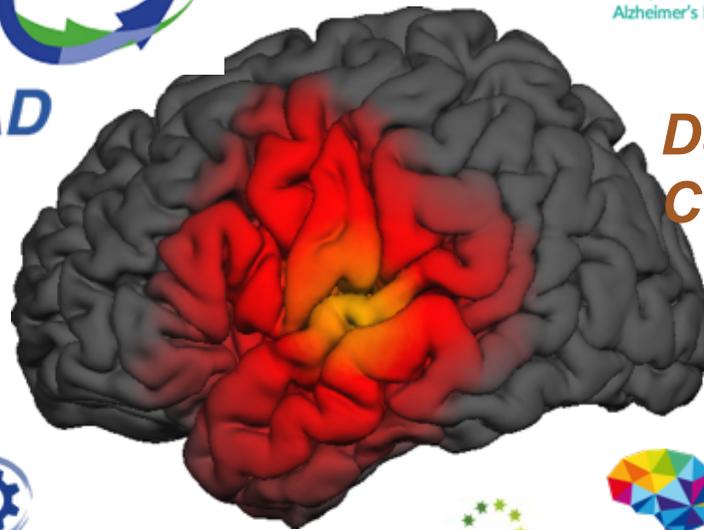
IMI action on Neurodegeneration

Remote Assessment of Disease and Relapse Programme (RADAR)

Big Data for Better Outcomes Programme (BD4BO)



IMPRiND



Data Quality Consortium



IMI dementia portfolio highlights

Challenge 1: What are the underlying causes of dementia?

AETIONOMY: Identifying subgroups of dementia, based on underlying genetic / molecular causes, to allow tailored treatments

Challenge 2: Who is at greatest risk of developing dementia?

EMIF: Linking & analysing data from many studies to identify markers of risk

Patients involved

Challenge 3: How can we improve clinical trial design?

EPAD: Setting up innovative clinical trials that allow multiple treatments to be tested at same time

Challenge 4: Can brain scans aid research & treatment?

AMYPAD: Studying how brain scans of 'amyloid plaques' could aid diagnosis, treatment & research

A convergence of opportunity

Clinical Research

Optimise clinical research processes

- achieve faster and more accurate patient identification
- identify sites that have access to the most suitable patients
- reduce protocol amendments

Enhance access to Real World Data

- study the use of new medicines in real populations
- conduct comparative effectiveness studies
- monitor long term safety
- gather evidence for adaptive licensing

Healthcare

Improve quality and safety of care

- enhance care co-ordination
- increase adherence to clinical evidence
- reduce medical errors and treatment delays

Support patients in self-care and health maintenance

Improve efficiency of care

- optimise care pathways to improve outcomes
- collate evidence for public health strategy and decision-making

Need to scale up trustworthy access to combined health data from diverse sources across Europe

Patients
Health Care
Hospital
Physician
Clinical Research
Service Providers

“Big” Health Data

Patients
Health Care
Hospital
Physician
Clinical Research
Service Providers

Population registries,
Clinical trials databases

Care pathways,
decision support,
trends and alerts

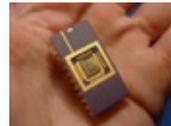
Genomic data



Environmental data



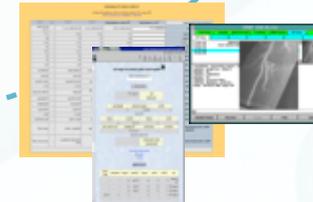
Mobile devices



Bio-sensors

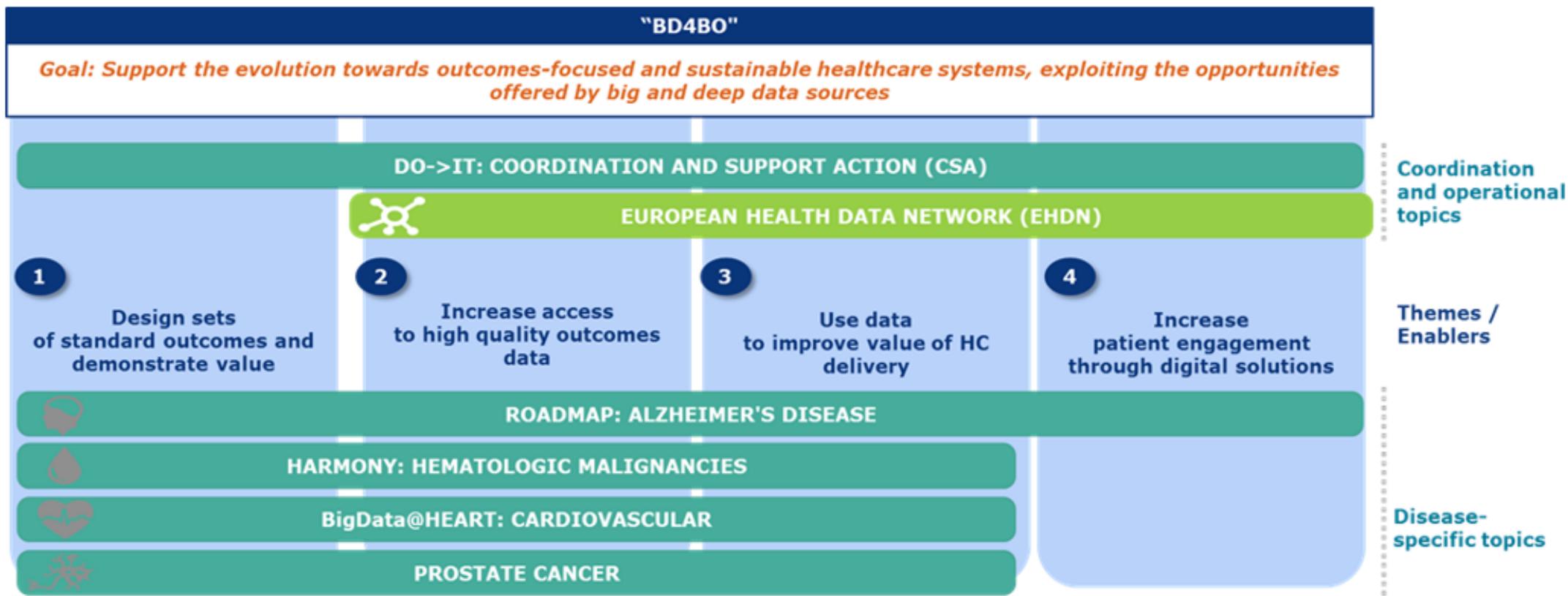


Social networks



Clinical applications

The Big Data for Better Outcomes programme at IMI



Patient Reported Outcomes and COPD

- IMI Project – PROACTIVE - main goal
 - To **develop** and **validate** a new Patient Reported Outcome (PRO) capturing the COPD patients' experience with physical activity as a meaningful measure to patients and doctors.
 - Two PROs tools successfully developed as “hybrid” tools (i.e questionnaires combined with wearables - activity monitor readouts) available electronic and pencil version.
 - Developed simultaneously in four EU languages /cultures /patient populations (50+ culturally sensitive translations available for global use in research)



Achievements

- Tools tested in 6 clinical studies (with and without drugs) in thousands of patients with stable moderate to severe COPD
- Presented for Qualification opinion to EMA after previous advice consultation



- Draft Qualification Opinion issued in May 2017

A successful consortium..

Collaborative spirit amongst partners with a willingness to deliver

8 companies

10 Public partners incl 2 patients organisations + European Respiratory society

1 SME

+ links with COPD foundation



RADAR- CNS

Remote Assessment of Disease and Relapse- Central Nervous System

- Collaborative Research to explore wearable devices to help prevent and treat depression, MS and epilepsy
- €25 million budget
- Leads: Kinds College London and Janssen

This is just the beginning and there are many questions

- How do these technologies scale?
- There is currently no regulatory environment for this technology
 - Basis for validation?
 - Determination of data quality?
 - Who has stewardship?
 - Who develops standards?
- How does the public differentiate between good and bad quality products?
 - no guidance documents – no consumer reports
- What is the business model?



infodesk@imi.europa.eu

<http://www.imi.europa.eu>

www.imi.europa.eu

 @IMI_JU