

# 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**

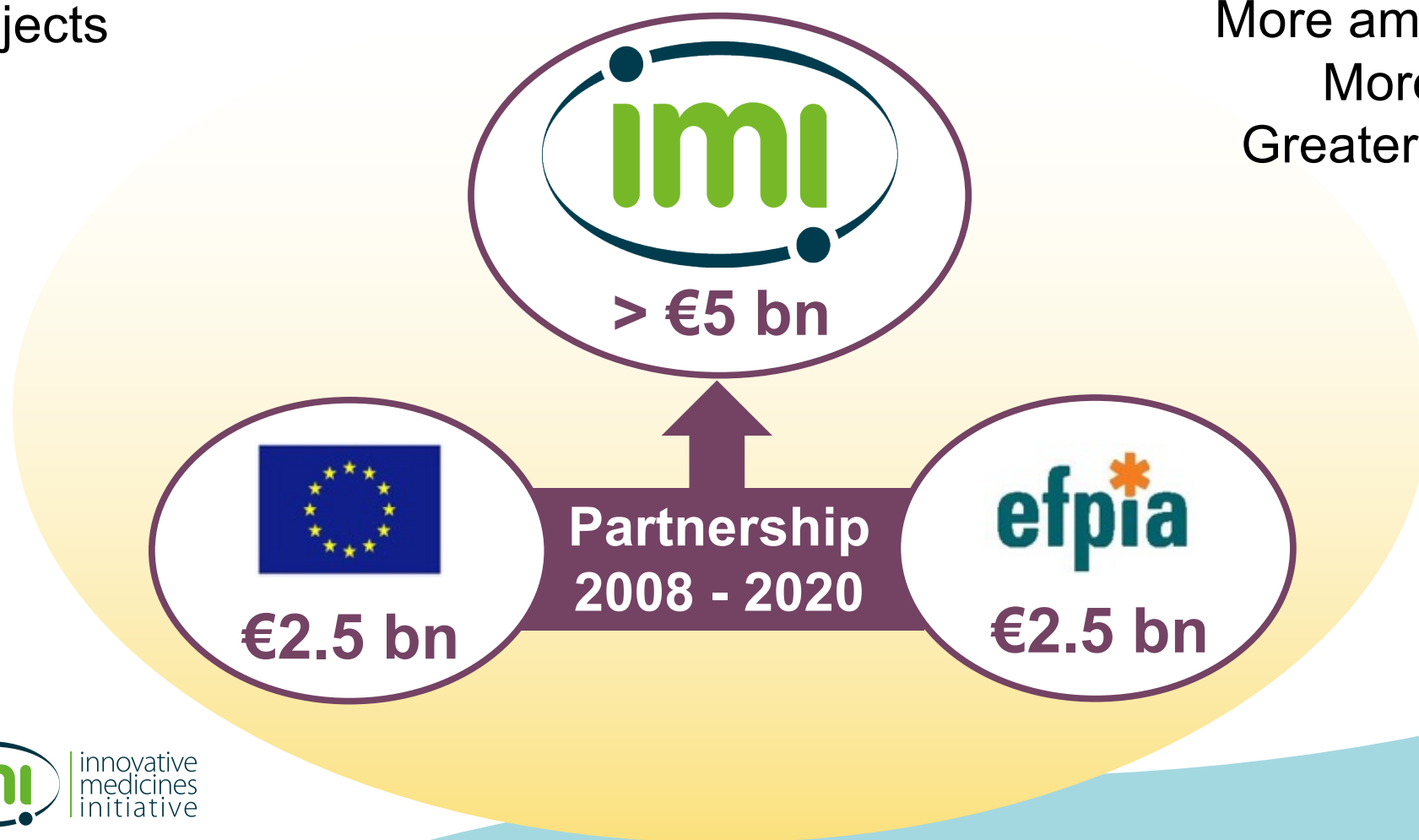
# IMI – Europe's partnership for health

## IMI1: 2008-2013

€2 bn budget  
59 projects

## IMI2: 2014-2020

€3.3 bn budget  
More ambitious  
More open  
Greater scope

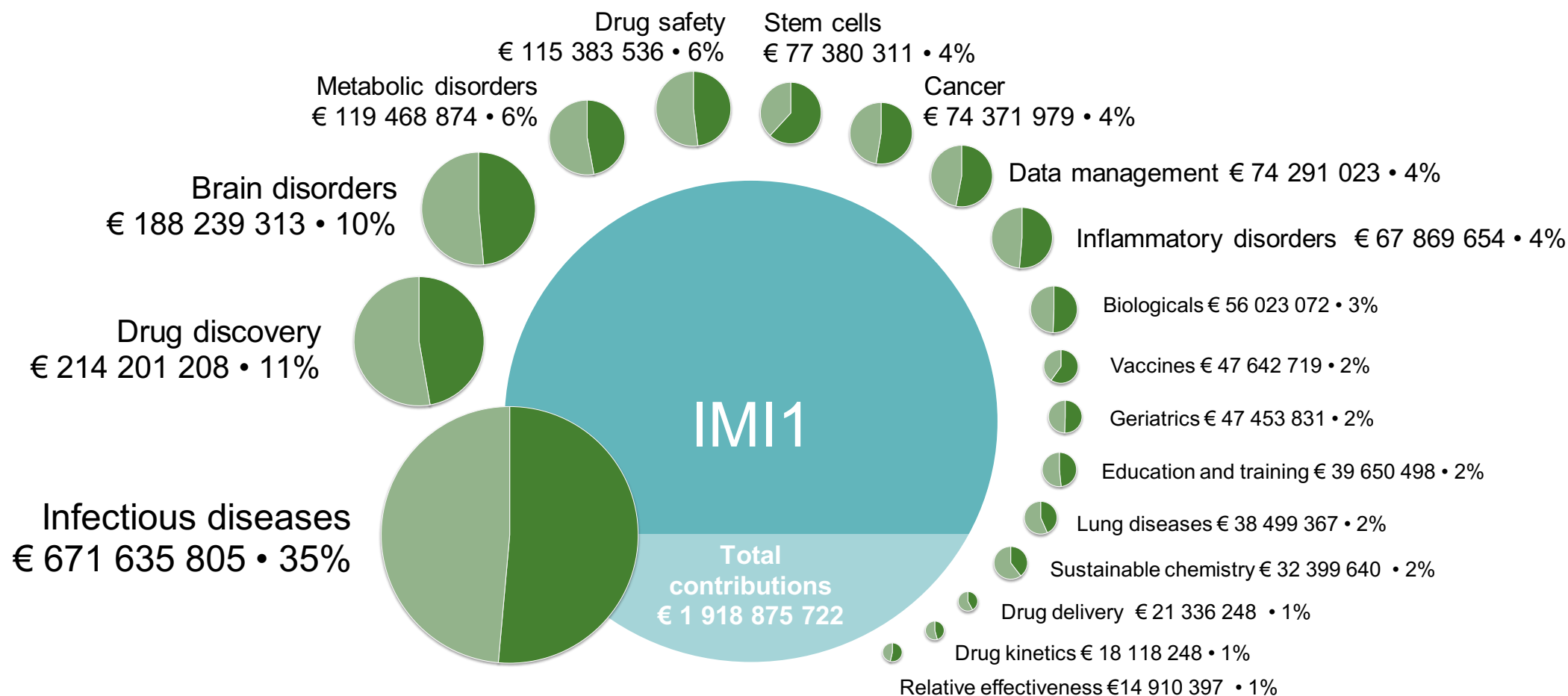


# IMI – Europe's partnership for health

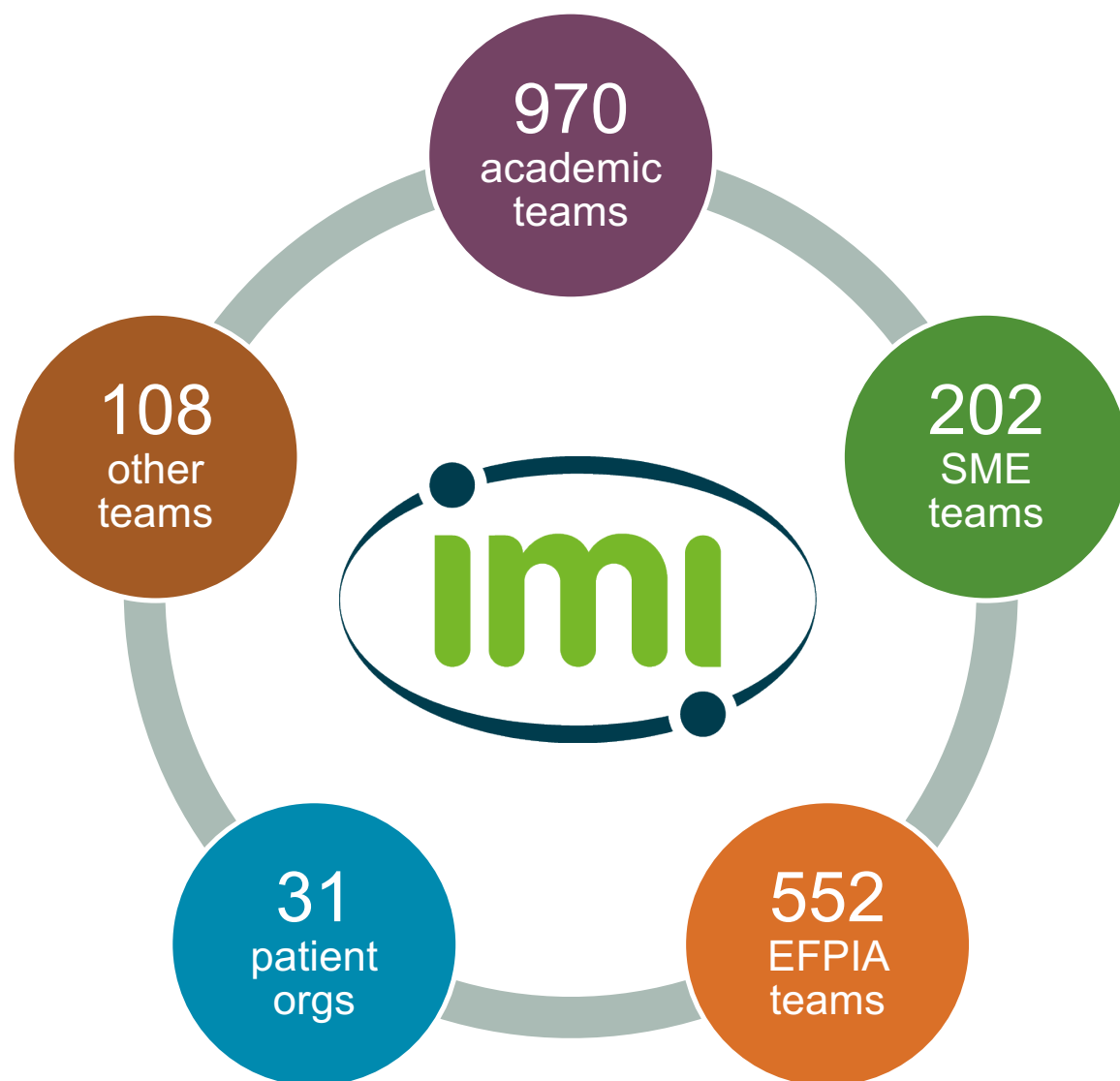
## IMI mission

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



# 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



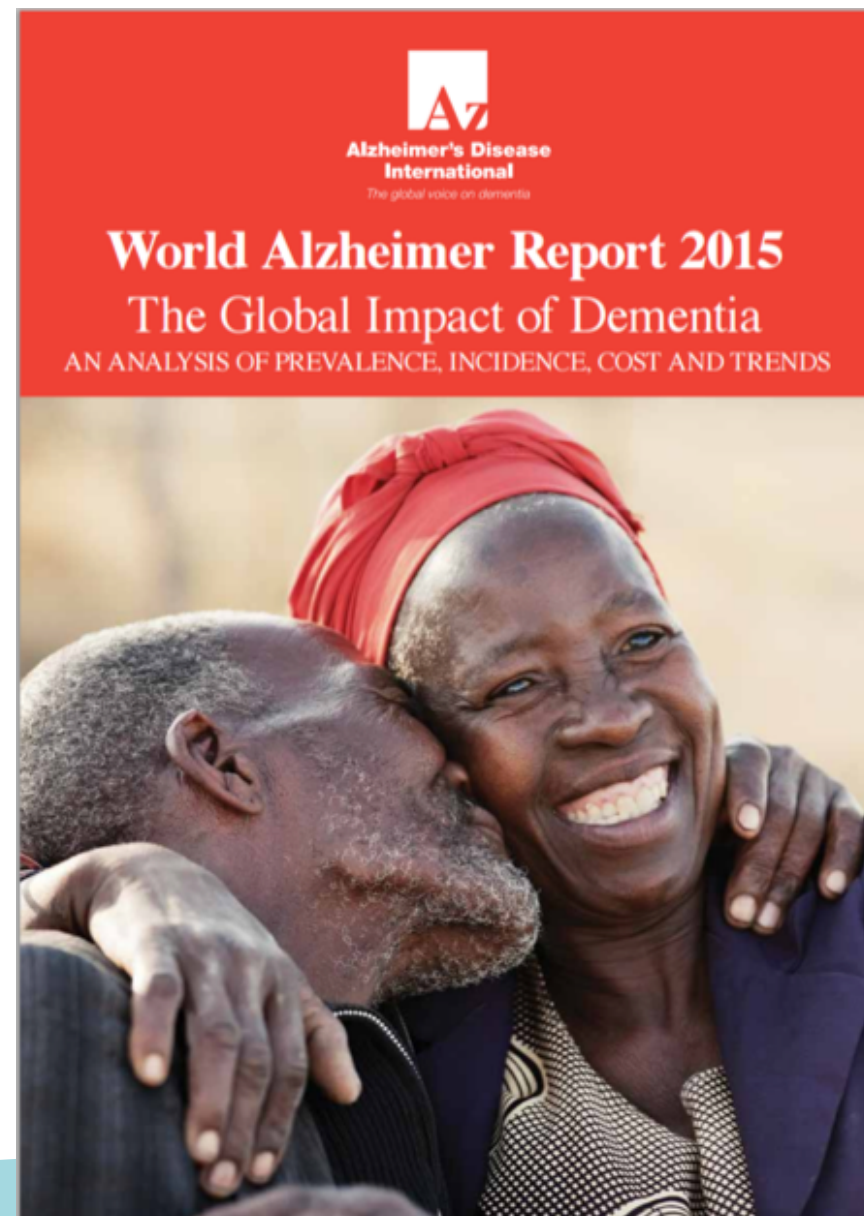
The right prevention and treatment  
for the right patient at the right time  
Strategic Research Agenda for  
Innovative Medicines Initiative 2

**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)





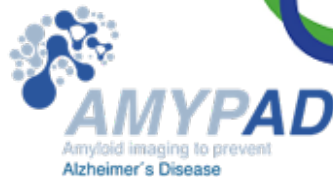
# IMI action on Neurodegeneration

Remote  
Assessment  
of Disease  
and Relapse  
Programme  
(RADAR)

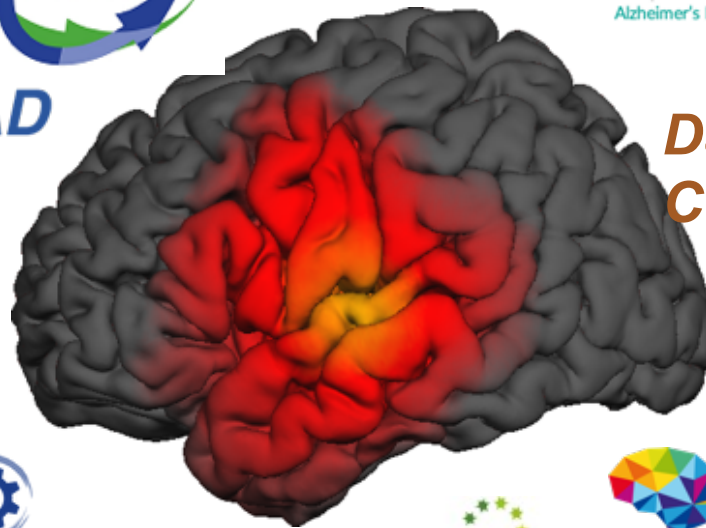
Big Data for  
Better  
Outcomes  
Programme  
(BD4BO)



AETIO N/O  
M/Y



IMPRiND



Data Quality  
Consortium



MOPEAD



ADAPTED



Dementias  
Platform UK  
Medical Research Council



# 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

Patients  
Health Care  
Hospital  
Physician  
Clinical Research  
Service Providers

## 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

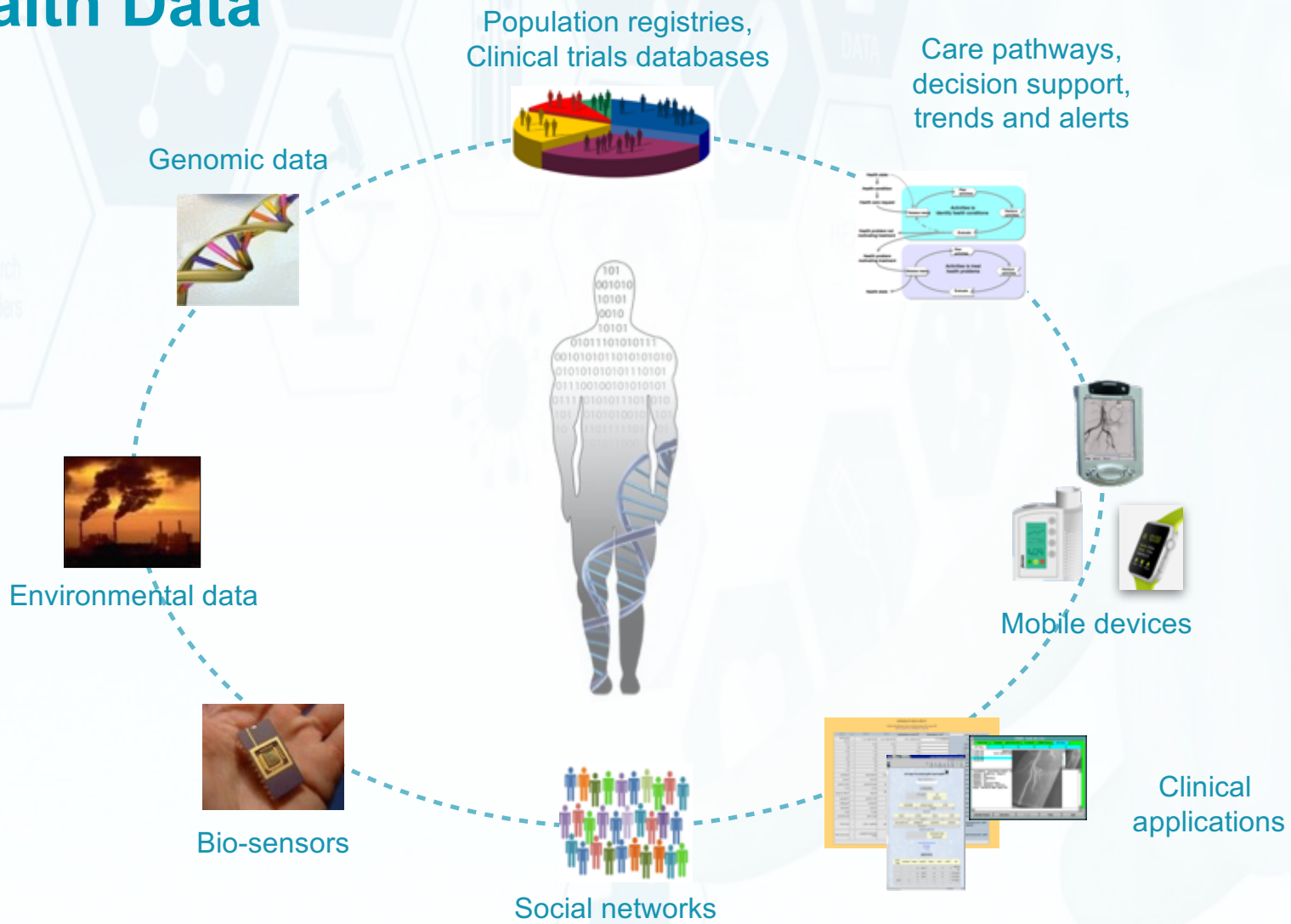
Improve efficiency of care

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

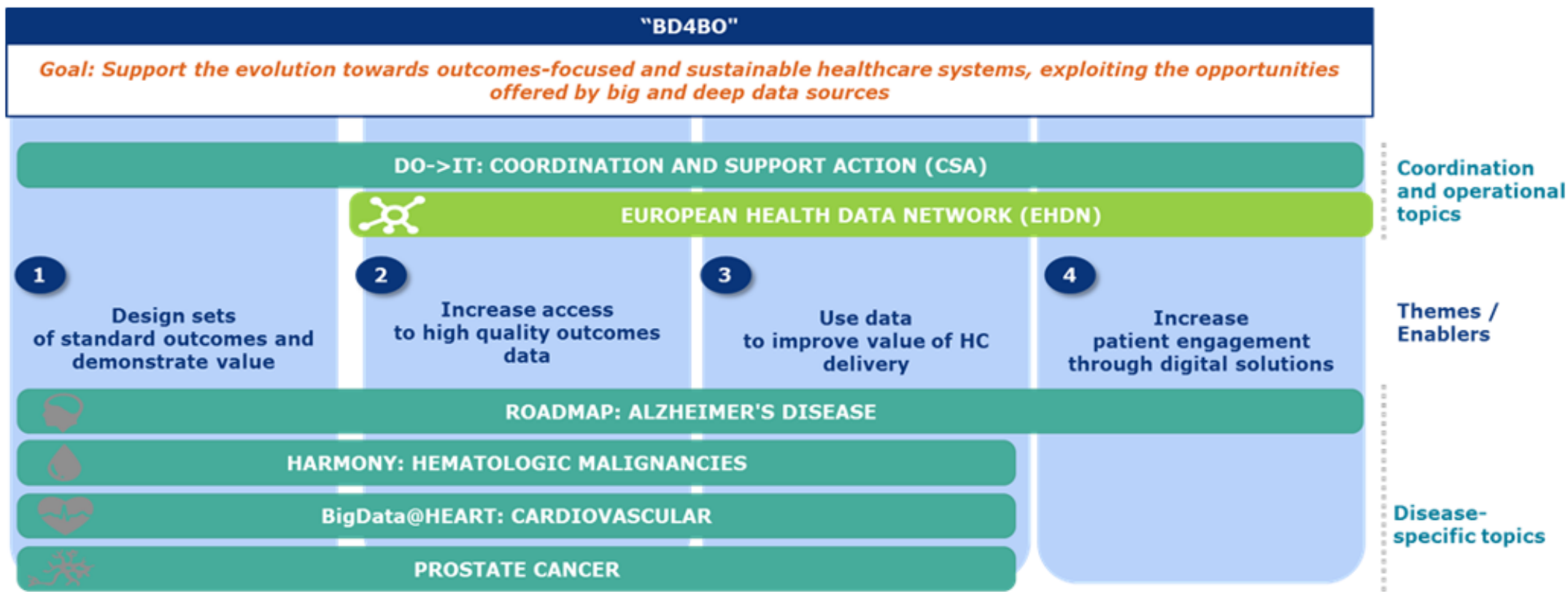
**Need to scale up trustworthy access to combined health data from diverse sources across Europe**

# “Big” Health Data

Patients  
Health Care  
Hospital  
Physician  
Clinical Research  
Service Providers



# 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](mailto:infodesk@imi.europa.eu)

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