

# IMI2 Big Data for Better Outcomes (BD4BO) Programme

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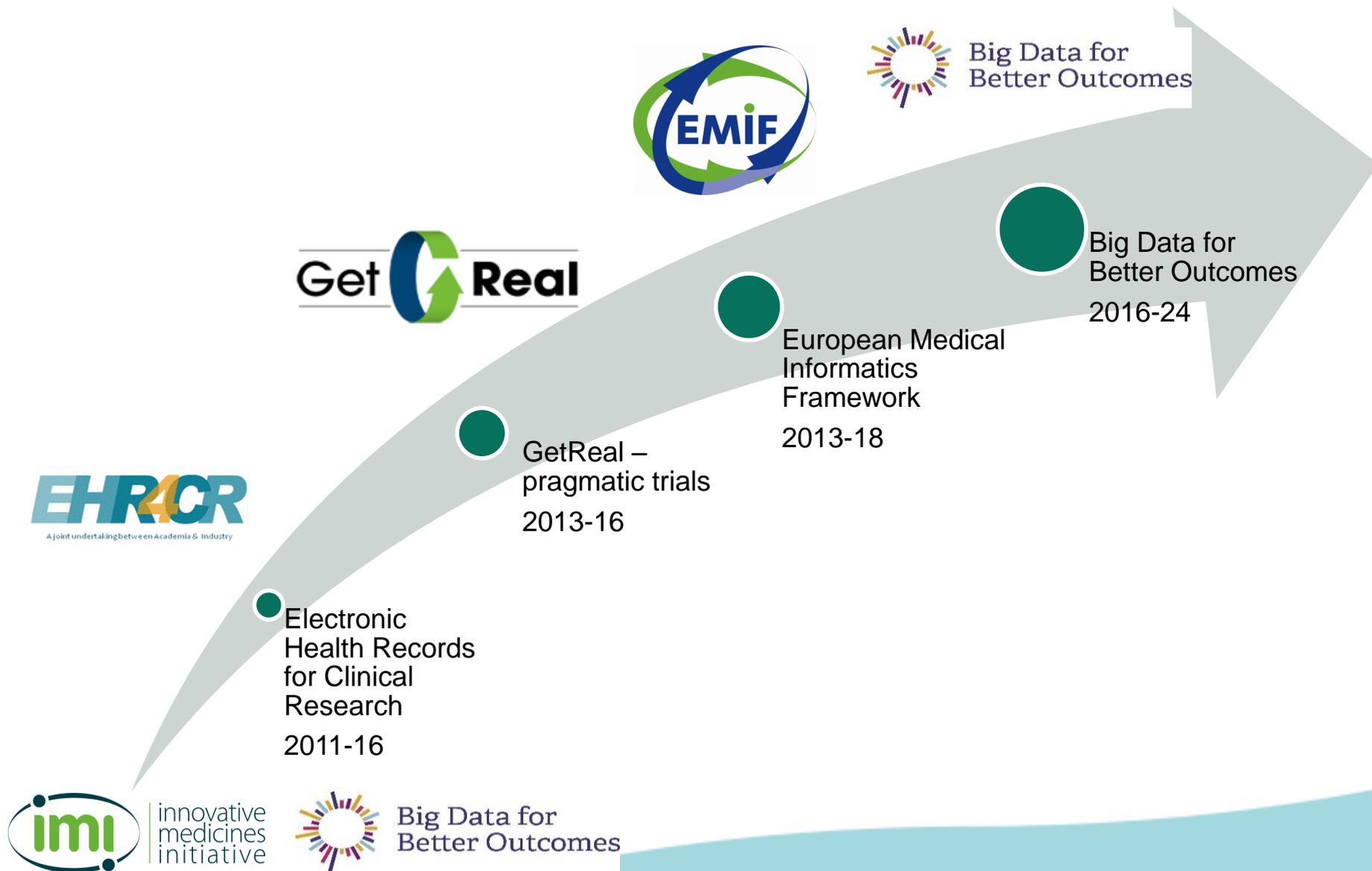
# BD4BO Mission

*Improve health outcomes and healthcare systems in Europe by maximising the potential of Big Data.*

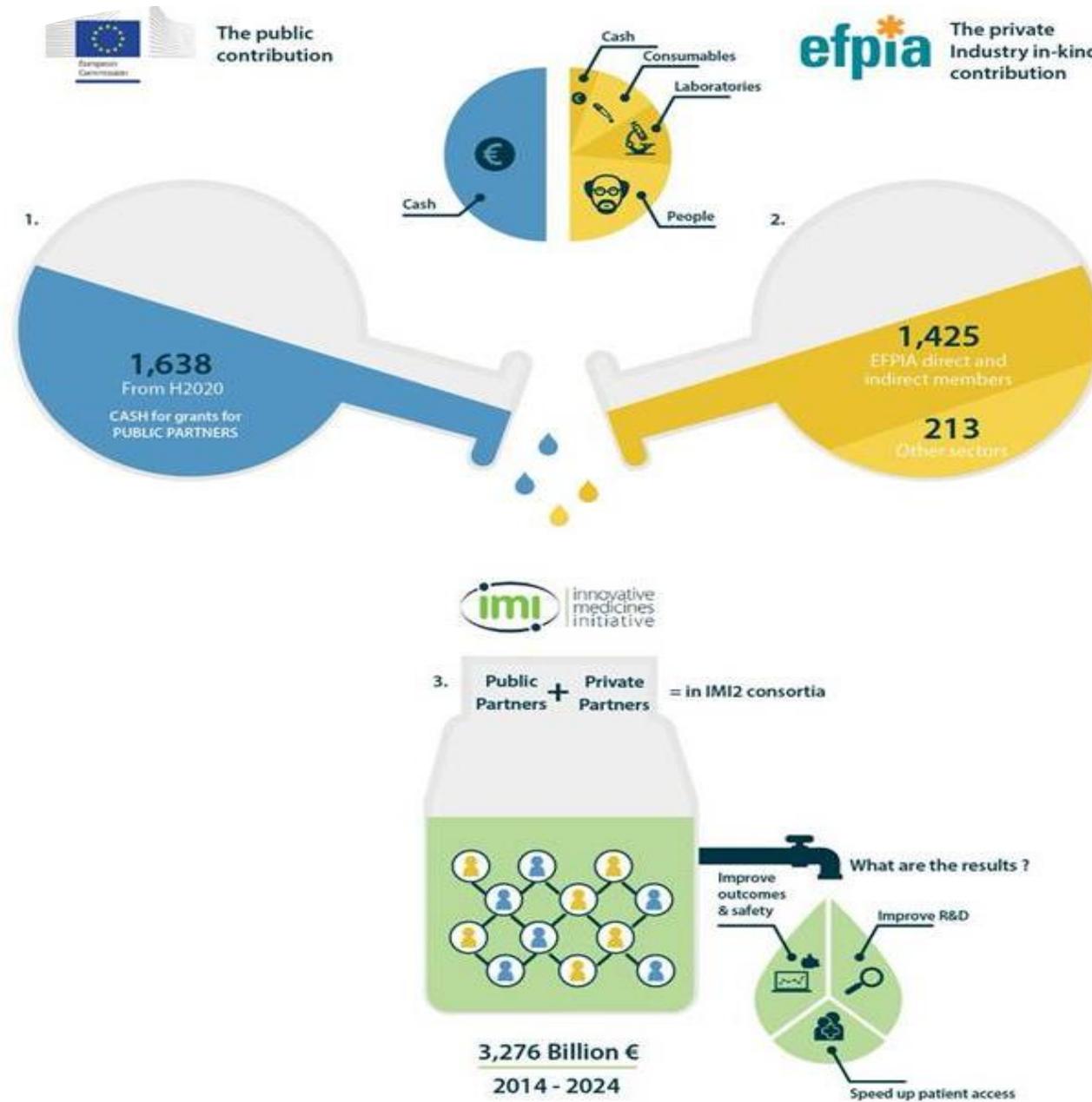
# Key aspects

- **Ambitious:** Leverage Big Data's power for healthcare systems, including improved access, analysis and harmonisation of Big Data.
- **Transformational:** Big Data has the potential to transform healthcare across the entire pathway for every stakeholder, with the ultimate outcome of improved patient care and value.
- **Collaborative:** BD4BO provides a framework for PPPs to combine and expand new/existing data sources, build analytic capabilities and establish common standards.
- **Disease-specific:** cardiovascular diseases, haematological malignancies, Alzheimer's disease and prostate cancer.
- **Patient-centric:** Patients play a key role as consortium members and contributors, and are the ultimate beneficiaries of improved outcomes delivered by BD4BO.

# Evolution of Real World Data in IMI



# The Innovative Medicines Initiative 2 (IMI2)



# BD4BO Overview

*Improve health outcomes and healthcare systems in Europe  
by maximising the potential of Big Data.*

Mission

1

Design sets  
of standard  
outcomes and  
demonstrate value

2

Increase access  
to high quality  
outcomes data

3

Use data  
to improve value  
of HC delivery

4

Increase patient  
engagement  
through digital  
solutions

Themes /  
Enablers



ROADMAP: ALZHEIMER'S DISEASE



HARMONY: HAEMATOLOGIC MALIGNANCIES



BigData@Heart: CARDIOVASCULAR



PROSTATE CANCER

Disease-  
specific  
topics



EUROPEAN HEALTH DATA NETWORK (EHDN)

Coordination  
and  
operational  
topics

Better Outcomes, Policy Innovation and Healthcare System Transformation

# Disease-specific projects



**Objective:** provide the foundation for a Europe-wide, integrated data environment and framework for RWE across the spectrum of Alzheimer's disease.

***Expected outputs:***

- First list of priority, RWE-relevant outcomes for AD
- Overview of potential data sources with RWE data in Europe
- Catalogue of RWE-relevant AD models and simplistic disease stage framework
- Review of ELSI issues in RWE approach

**Duration:** Nov. 2016 – Oct. 2018

[www.roadmap-alzheimer.org](http://www.roadmap-alzheimer.org)

# Disease-specific projects



**Objective:** improve the outcomes of patients with hematological malignancies through the use of big data sharing among all relevant stakeholders involved.

**Expected outputs:**

- A clinical data-sharing platform including Big Data series from patients with hematological malignancies
- A community of European hematological malignancies stakeholders
- Meaningful and harmonized clinical endpoints and outcome measures in hematological malignancies
- Tools for analyzing complex data sets including genomic data
- Biomarkers that will contribute to timely patient access to more effective and better tolerated innovative therapies
- A framework for legal, ethical and governance issues

**Duration:** Jan. 2017-Dec. 2021

[www.harmony-alliance.eu](http://www.harmony-alliance.eu)

# Disease-specific projects



**Objective:** deliver clinically-relevant disease phenotypes, scalable insights from RWE and insights driving drug development and personalised medicine through advanced analytics.

**Expected outputs:**

- Standardised operational disease and outcome definitions
- Improved trial design and drug development
- Better response to therapy

**Duration:** March 2017-March 2022

[www.ehnheart.org](http://www.ehnheart.org)

# Coordinating projects

**European Health Data Network (EHDN):** a federated network of relevant and high quality data sources.

- **Objective:** to improve Europe's technical capabilities to undertake systematic health outcomes research at an unprecedented scale across the entire region.
- **Expected output:** an increased use of outcomes-based models in an actual healthcare delivery and regulatory/HTA decision making

**DO->IT:** the over-arching coordination structure for all BD4BO projects.

- **Objective:** serve as the pivotal point of collaboration, stakeholder engagement and communication for all BD4BO projects.

# Potential Big Data Benefits

## System-level

- Monitoring of healthcare service delivery, incl. identification of overuse and under-use
- Capturing the diversity of Europe's healthcare systems

## Disease-level

- Enhancing our understanding of the natural progression of a disease and the target population for new medicines
- Enabling the detection of population-level effects
- Identifying high-value treatments

## Patient-level

- More effective healthcare
- Better health outcomes
- Patient-centred care

## Trial/Product-level

- Efficient and sensitive recruitment of patients for clinical trials
- Real-time learning and monitoring
- Re-use of existing data
- Provide source of pragmatic, real-world evidence on the effectiveness and cost-effectiveness of treatments

# BD4BO expected impact

To improve health outcomes and healthcare systems in Europe by maximising the potential of Big Data by:

- Identifying, standardising and validating outcomes
- Making data accessible to all stakeholders in the research and innovation cycle
- Engaging patients to play a more active role as data owners/contributors
- Providing data privacy guidance
- Translating outcomes into actionable policy levers to promote value-based and outcomes-focused healthcare systems.

# BD4BO Partners

**Coordinating Partner:** London School of Economics and Political Science

**Industry Lead:** Novartis

National Institute for Health and Care Excellence

Dental and Pharmaceutical Benefits Agency

European Cancer Patient Coalition

European Multiple Sclerosis Platform

Semmelweis University

Imperial College London

Swedish Institute for Health Economics

Centre for Research in Healthcare Management– Università Bocconi

Norwegian Institute of Public Health

The Association of the British Pharmaceutical Industry

Amgen

Bayer

Boehringer Ingelheim

Celgene

EFPIA - European Federation of Pharmaceutical Industries and Associations

Farmaindustria

GlaxoSmithKline

Health iQ

Intersystems

Janssen Pharmaceutica NV

Eli Lilly and Company

Merck

MSD Sharp & Dohme

Novo Nordisk

Pfizer

Roche

Sanofi

Servier

UCB

Association of Research-Based  
Pharmaceutical Companies

Norwegian Medicines Agency

Technology, Methods and Infrastructure  
for Networked Medical Research

Inserm Toulouse





For more information about BD4BO visit  
[www.bd4bo.eu](http://www.bd4bo.eu)

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[www.imi.europa.eu](http://www.imi.europa.eu)

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