IMI2
Big Data for Better Outcomes (BD4BO) Programme
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

- Electronic Health Records for Clinical Research (EHR4CR) 2011-16
- GetReal – pragmatic trials 2013-16
- European Medical Informatics Framework (EMIF) 2013-18
- Big Data for Better Outcomes 2016-24
The Innovative Medicines Initiative 2 (IMI2)

1. The public contribution
   - 1,628 From H2020
     - CASH for grants for PUBLIC PARTNERS

2. The private Industry in-kind contribution
   - 1,425 EFPIA direct and indirect members
   - 213 Other sectors

3. Public Partners + Private Partners = in IMI2 consortia

What are the results?
- Improve outcomes & safety
- Improve R&D
- Speed up patient access

3,276 Billion € 2014 - 2024
BD4BO Overview

**Mission**

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

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
- EUROPEAN HEALTH DATA NETWORK (EHDN)

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
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
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
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

<table>
<thead>
<tr>
<th>System-level</th>
<th>Disease-level</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Monitoring of healthcare service delivery, incl. identification of overuse and under-use</td>
<td>• Enhancing our understanding of the natural progression of a disease and the target population for new medicines</td>
</tr>
<tr>
<td>• Capturing the diversity of Europe’s healthcare systems</td>
<td>• Enabling the detection of population-level effects</td>
</tr>
<tr>
<td></td>
<td>• Identifying high-value treatments</td>
</tr>
<tr>
<td>Patient-level</td>
<td>Trial/Product-level</td>
</tr>
<tr>
<td>• More effective healthcare</td>
<td>• Efficient and sensitive recruitment of patients for clinical trials</td>
</tr>
<tr>
<td>• Better health outcomes</td>
<td>• Real-time learning and monitoring</td>
</tr>
<tr>
<td>• Patient-centred care</td>
<td>• Re-use of existing data</td>
</tr>
<tr>
<td></td>
<td>• Provide source of pragmatic, real-world evidence on the effectiveness and cost-effectiveness of treatments</td>
</tr>
</tbody>
</table>
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

Thank you

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (IMI2) under grant agreement No. 116055. This Joint Undertaking receives support from the European Horizon 2020 research and innovation programme and European Federation of Pharmaceutical Industries and Associations (EFPIA).

www.imi.europa.eu

@IMI_JU