IMI2 Big Data for Better Outcomes

Supporting the evolution towards outcomes-focused, sustainable healthcare systems

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5th October 2018
Improve health outcomes and healthcare systems in Europe by maximising the potential of Big Data
Key Aspects

- ambitious
- transformative
- collaborative
- disease-specific
- patient-centric
Evolution of Big Data in IMI

- **2011-2016**: Electronic Health Records for Clinical Research
- **2013-2016**: GetReal
- **2013-2018**: European Medical Informatics Framework
- **2016-2024**: Big Data for Better Outcomes

IMI
What are the results?

- Improve R&D
- Improve outcomes and safety
- Speed up patient access

World’s largest life sciences PPP

€3,276 Billion 2014-2024
Mission: Improve health outcomes and healthcare systems in Europe by maximising the potential of Big Data

THEMES/ENABLERS:

- Design sets of standard outcomes and demonstrate value
- Increase access to high quality outcomes data
- Use data to improve value of HC delivery
- Increase patient engagement through digital solutions

DISEASE-SPECIFIC PROJECTS:

- ROADMAP: Alzheimer’s disease
- HARMONY: Haematologic malignancies
- BigData@Heart: Cardiovascular diseases
- PIONEER: Prostate cancer
- More to come....

CO-ORDINATING PROJECTS:

- European Health Data & Evidence Network (EHDEN)
- DO->IT: Coordination & Support Action

BD4BO Overview
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<th>Objective</th>
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| Provide the foundation for a Europe-wide, integrated data environment and framework for RWE across the spectrum of Alzheimer’s disease | • Minimum set of measurable real-world patient outcomes  
• Recommendations on RWE appropriate AD-related endpoints  
• Identification of data sources and outline a data integration strategy for RWE outcomes  
• Development of new methods for collecting RWE data to improve health care value for AD  
• Recommendations for disease progression and health economic modelling  
• Guiding principles and recommendations from HTA groups/payers/regulators for the development and incorporation of RWE into clinical and market access development plans for AD | 2016 - 2018    |
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| Improve the outcomes of patients with haematological malignancies through the use of Big Data sharing among all relevant stakeholders. | • A clinical data-sharing platform including Big Data series from patients with haematological malignancies  
• A community of European haematological malignancies stakeholders  
• Meaningful and harmonised clinical endpoints and outcome measures in haematological malignancies  
• Tools for analysing 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 | 2017 - 2021 |
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| Deliver clinically-relevant disease phenotypes, scalable insights from RWE and insights driving drug development and personalised medicine through advanced analytics | • Definitions of diseases and outcomes that are universal, computable and relevant for patients, clinicians, industry and regulators  
• Informatics platforms that link, visualise and harmonise data sources of varying types, completeness and structure  
• Data science techniques to identify new phenotypes and construct personalised predictive models  
• Guidelines that allow for cross-border usage of Big Data sources acknowledging ethical and legal constraints as well as data security | 2017 – 2022 |
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| To leverage the potential of Big Data and Big Data analytics to ensure the optimal, personalised care for all European men living with prostate cancer | • Meaningful and standardised clinical endpoints and outcome measures for localised, locally advanced, and metastatic prostate cancer  
• A single innovative data platform in which existing ‘big data’ from prostate cancer patients across different stages of the disease has been standardised and integrated  
• A community of all European prostate cancer stakeholders  
• Tools for analysing complex data sets including genomic data  
• A framework for legal, ethical and governance issues which will allow for cross-border usage of big data sources whilst acknowledging data security constraints | 2018 – 2023 |
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| As an enabling component of the BD4BO programme – to deliver the vision of large-scale medical outcomes research that develops a data network to enable other researchers to ‘find’ and safely ‘reuse’ data. | • An open, transparent call process for third party data providers, with financial support for mapping to OMOP common data model  
• Delivery of an operational, federated network equivalent to a representative 20% of the EU population, or approximately 100 million people (~200 data sets)  
• Data quality management framework, supportive of both validation and benchmarking  
• European SMEs with relevant experience in innovative services for data providers and/or consumers  
• Certification of these SMEs across the RWE technical continuum  
• EHDEN project governance for engagement of third party datasets, oversight of data harmonisation and interaction with BD4BO  
• Evolution of health outcomes research and incorporation of novel data sources | 2018 – 2023    |
**DO→IT**

The overarching coordination structure for all BD4BO projects

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| **Serve as the pivotal point of programme coordination providing expertise for communication, collaboration, dissemination and stakeholder engagement for some areas common for all BD4BO projects** | • Develop and coordinate the overall BD4BO programme strategy  
• Develop recommendations for new IMI2 scientific priorities  
• Identify best practice for data management & collection - the standardisation, selection and measurement of outcomes  
• Build an online repository to share knowledge and learning across the BD4BO programme  
• Lead communication activities of the BD4BO programme and provide coordination of communications with BD4BO projects  
• Facilitate stakeholder engagement with key healthcare system stakeholders to foster policy discussions and build consensus  
• Develop minimum data privacy standards for ICFs  
• Develop explanatory information and training material to improve awareness of data privacy issues and engage with stakeholders to ensure buy-in for ICF templates | 2017 – 2019 |
Benefits for Society
Improve health outcomes and healthcare systems in Europe by maximising the potential of Big Data

BD4BO Expected Impact
Coordinating Partner: London School of Economics and Political Science
Industry Lead: Novartis

PUBLIC PARTNERS
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
University of Liverpool
Norwegian Medicines Agency
Technology, Methods and Infrastructure for Networked Medical Research
Inserm Toulouse

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Eli Lilly and Company
Merck
MSD
Novo Nordisk
Pfizer
Roche
Sanofi
Servier
UCB
Association of Research-Based Pharmaceutical Companies

DO->IT Partners
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).