IMI2 Big Data for Better Outcomes

Supporting the evolution towards outcomes-focused sustainable healthcare systems in Europe

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BD4BO DO→IT WP3 Lead – Communications and Outreach

7th EMWA Symposium
Real-World Evidence: A Central Role for Medical Communicators
9 May 2019
1,638 from H2020 cash for grants from public partners

1,425 EFPIA direct and indirect members

213 other sectors

What are the results?

Improve R&D

Speed up patient access

Improve outcomes and safety

€3,276 Billion 2014-2024

Public partners

Private partners

€ in IMI2 consortia

What are the results?

World’s largest life sciences PPP
Evolution of Big Data in IMI

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

IMI
BD4BO Mission

Improve health outcomes and healthcare systems in Europe by maximising the potential of Big Data
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 Network (EHDN)
- DO->IT: Coordination & support actions

BD4BO Overview
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<th>Objective</th>
<th>Expected outputs</th>
<th>Timeline</th>
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<td>Provide the foundation for a Europe-wide, integrated data environment and framework for RWE across the spectrum of Alzheimer’s disease</td>
<td>• Minimum set of measurable real-world patient outcomes</td>
<td>2016 - 2018</td>
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<td>• Identification of data sources and outline a data integration strategy for RWE outcomes</td>
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<td>• Development of new methods for collecting RWE data to improve health care value for Alzheimer’s Disease</td>
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<td>• Recommendations for disease progression and health economic modelling</td>
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<td>• Guiding principles and recommendations from regulators, HTA bodies and payers for the development and incorporation of RWE</td>
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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 hematological malignancies  
• A community of European hematological malignancies stakeholders  
• Meaningful and harmonised clinical endpoints and outcome measures in hematological 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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<td>• To improve stratification of patients throughout the course of the disease</td>
<td>• Definitions of diseases, outcomes and DPFs for different stages of PCa that are universal, computable and relevant for patients, clinicians, industry and regulators</td>
<td>2018 – 2023</td>
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<td>• To improve individualisation of treatments for patients to achieve better disease outcomes</td>
<td>• Data access agreements</td>
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<td>• To improve harmonisation of care across EU member states reducing inequality</td>
<td>• Informatics platforms that link, visualise and harmonise data sources of varying types, completeness and structure</td>
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<td>• To improve real world evidence-based shared decision making</td>
<td>• Data science techniques to identify new phenotypes and construct personalised predictive models and nomograms</td>
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<td>• Research results and policy papers</td>
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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  
  • Certification of SMEs across the RWE technical continuum with relevant experience in innovative services for data providers and/or consumers  
  • Evolution of health outcomes research and incorporation of novel data sources | 2018 – 2023      |
### Objective

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

### Expected outputs

- Develop and coordinate the BD4BO programme strategy
- Identify best practice for data management & collection
- Build an online repository to share knowledge and learning
- Lead and coordinate communication activities of the BD4BO programme and related projects
- Facilitate stakeholder engagement with key healthcare system stakeholders to foster discussion and build consensus
- Develop minimum data privacy standards, explanatory information and training material for Informed Consent Forms

### Timeline

2017 – 2019
Stakeholder Engagement
Benefits for Society

System-level | Patient-level | Disease-level | Trial/product-level
Improve health outcomes and healthcare systems in Europe by maximising the potential of Big Data
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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European Federation of Pharmaceutical Industries and Associations
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GlaxoSmithKline
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Intersystems
Janssen Pharmaceutica NV
Eli Lilly and Company
Merck
MSD
Novo Nordisk
Pfizer
Roche
Sanofi
Servier
UCB
Association of Research-Based Pharmaceutical Companies
Thank you!

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