



Big Data for Better Outcomes



BD4BO and ROADMAP: a collaborative approach to set new standards for the collation and evaluation of RWE in Alzheimer's Disease

Impact of Big Data Analytics on Healthcare

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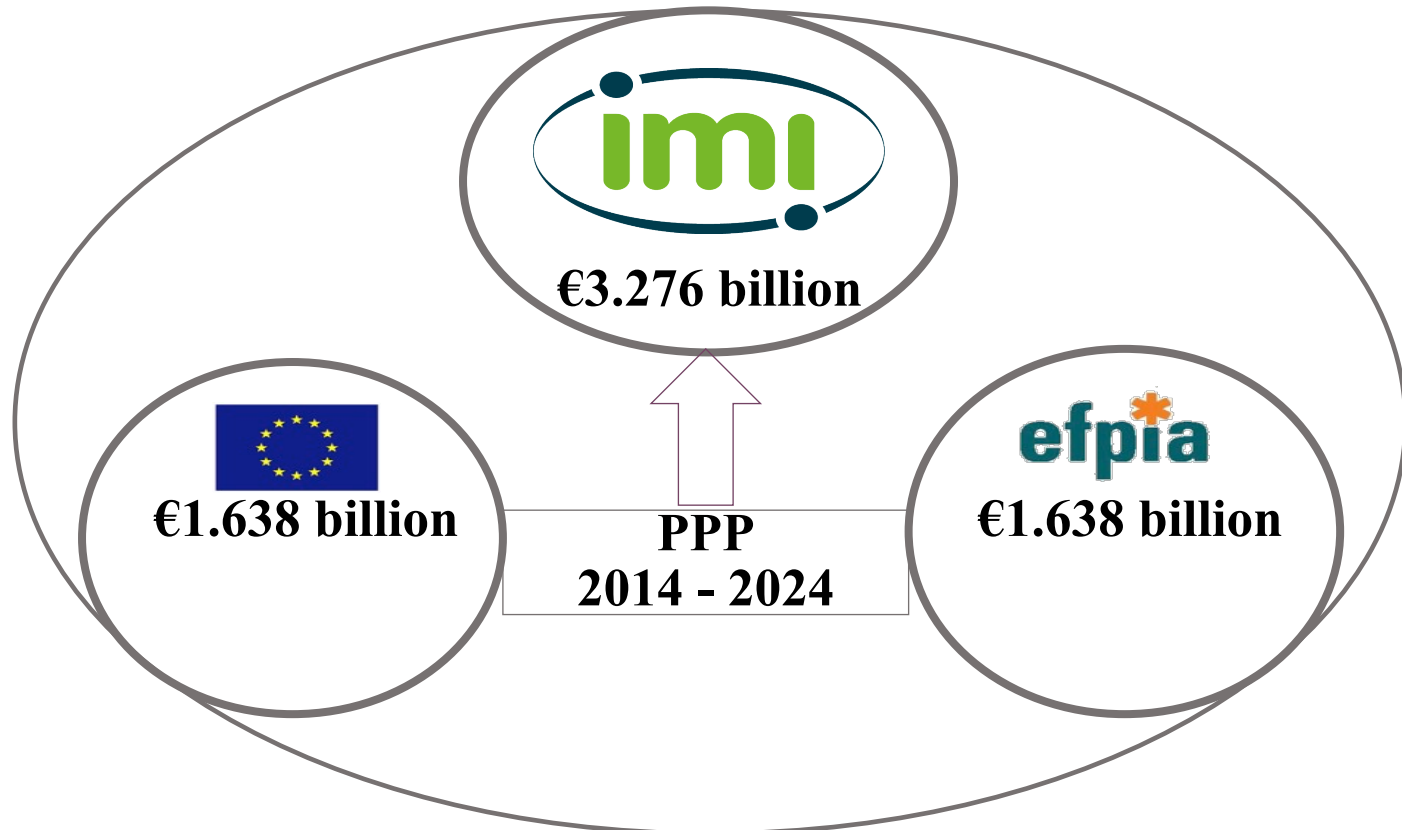
The Association of the British Pharmaceutical Industry



The Innovative Medicines Initiatives

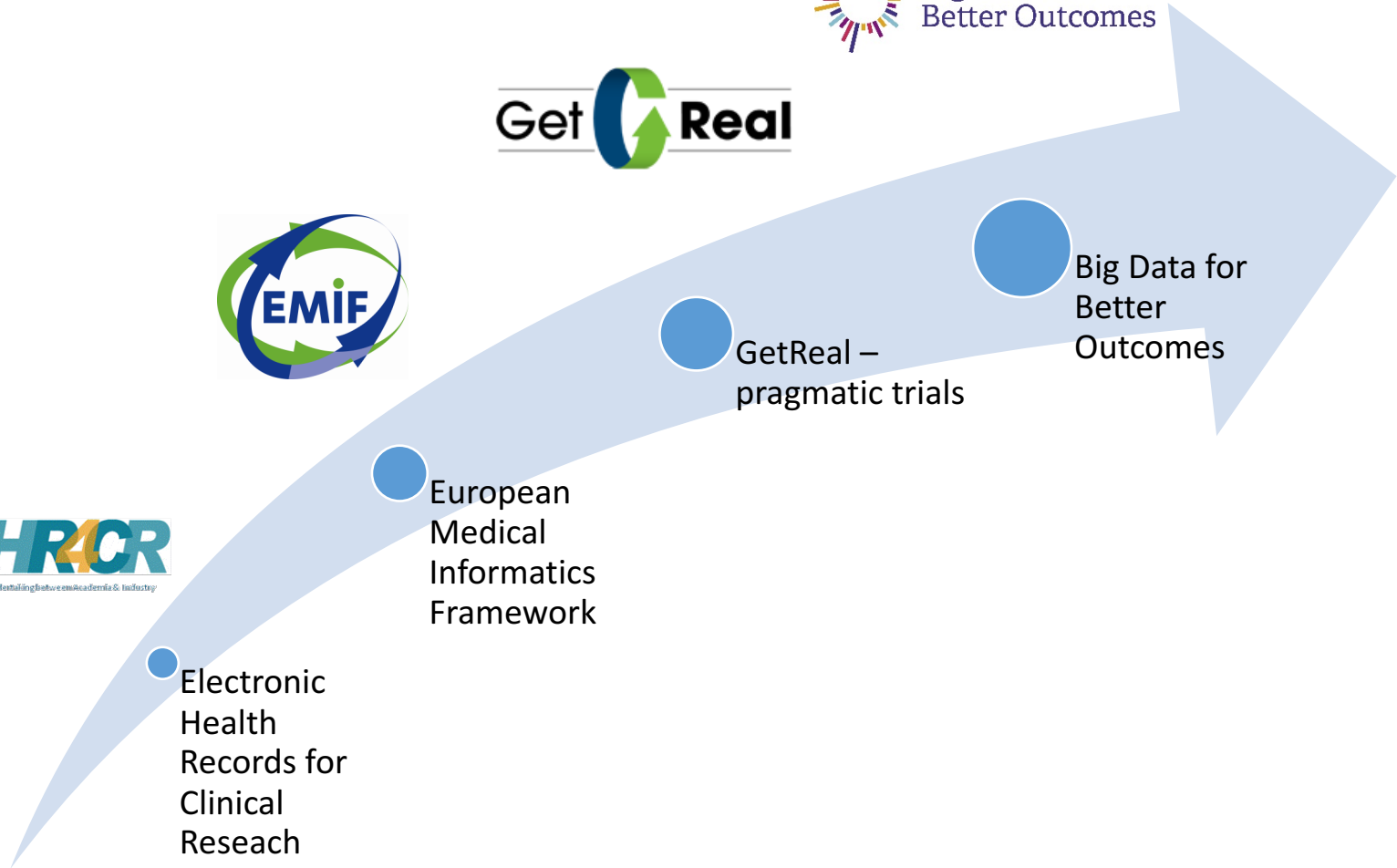


IMI2 is the largest PPP in Europe, and the world's biggest PPP in life sciences





Evolution of Real World Data in IMI



Electronic Health Records for Clinical Research

European Medical Informatics Framework

GetReal – pragmatic trials

Big Data for Better Outcomes



Mission of BD4BO



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



Key aspects



- ***Ambition:*** 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.
- ***Collaboration:*** 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.



Big Data for Better Outcomes programme



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

Mission

Better Outcomes, Policy Innovation and Healthcare system Transformation

Coordination and operational topics



EUROPEAN HEALTH DATA NETWORK (EHDN)

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: HEMATOLOGIC MALIGNANCIES



BigData@Heart: CARDIOVASCULAR



PROSTATE CANCER



OUTCOMES IN BIG 5 TUMORS

Disease- specific topics



Promise of big data in health care



<u>System Level</u>	<u>Disease Level</u>
<ul style="list-style-type: none">• Monitoring of healthcare service delivery, including identification of overuse and under-use• Capturing the diversity of Europe's healthcare system	<ul style="list-style-type: none">• 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
<u>Patient Level</u>	<u>Trial/Product Level</u>
<ul style="list-style-type: none">• More effective healthcare• Better health outcomes• Patient-centred care	<ul style="list-style-type: none">• 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



Expected impact of BD4BO



To achieve real-world impact by:

- Identifying, standardising and validating outcomes,
- Making data accessible to all stakeholders in the research and innovation cycle,
- Engaging patients,
- Translating outcomes into actionable policy levers to promote value-based and outcomes-focused healthcare systems.



ROADMAP Aims



- To deliver a **series of data integration methods and tools for patient outcomes, developed and tested through pilot projects**, which are scalable and transferable, and which will provide the foundation for a future Europe-wide RWE platform on AD
- To develop tools for **stakeholder engagement, understanding the ELSI context and health economics impact** of a RWE approach in AD
- To create the **conditions for an open collaboration among stakeholders that yields consensual, efficient uses of this RWE platform for the ultimate benefit of AD patients and their caregivers**



ROADMAP Methods



- ROADMAP brings together two major informatics infrastructures: IMI European Medical Informatics Framework (EMIF) and the MRC Dementias Platform UK (DPUK)
- Access cohorts, AD patient registries and electronic health records (EHR's) from throughout Europe
- Data pyramid approach (patient reported outcome, EHRs, and cohorts through trials)
- Evaluation of linking RWE with RCT data
- Pilot studies to develop scalable and transferable tools/methods to support disease progression and economic modelling

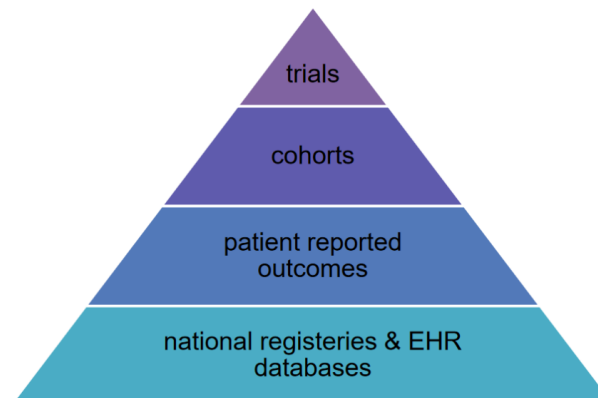


Strong data corpus



- **6 European countries** (Denmark, France, Netherlands, Spain, Sweden, UK)
- **75 national databases and clinical registries** n \approx 80M*
- **more than 40 cohorts** n \approx 2M
- **several studies using wearables and smart devices** n \approx 100K
- **5 dementia relevant trials** n \approx 100K

Leverage existing large data set to perform pilots



*n refers to number of patients



ROADMAP Expected Key Deliverables



- Define a **minimum set of measureable real-world patient outcomes**
- Develop **recommendations on RWE** appropriate AD-related cognitive, functional, and behavioural **endpoints**
- **Identify data sources** and outline a data **integration strategy** for RWE outcomes
- Develop **new methods for collecting RWE data** to improve health care value for AD
- Provide **recommendations for disease progression and health economic modelling**
- Under the leadership of UK NICE and the Dutch Regulator (MEB), deliver **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



ROADMAP Achievements



Outstanding expertise and resources available from core partners

Leveraging and maximising synergy with existing initiatives/projects with which partners have direct links

Project outputs:

- [First list of priority real world evidence 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
- Initial report on requirements for an ELSI framework for a RWE approach in AD



Expected impact and timelines



ROADMAP aims to provide the foundation for a Europe-wide integrated data environment and framework for RWE across the spectrum of Alzheimer's disease

- Phase 1 runs over 2 years from November 2016 - October 2018.
- Key findings from Phase 1 of ROADMAP will likely determine a further Phase 2 project for the prospective collection of key clinical and health economic outcomes in AD



Thank you

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