ROADMAP

Challenges in Optimising Real World Evidence for Alzheimer's Disease

Real world Outcomes across the AD spectrum for better care: Multi-modal data Access Platform

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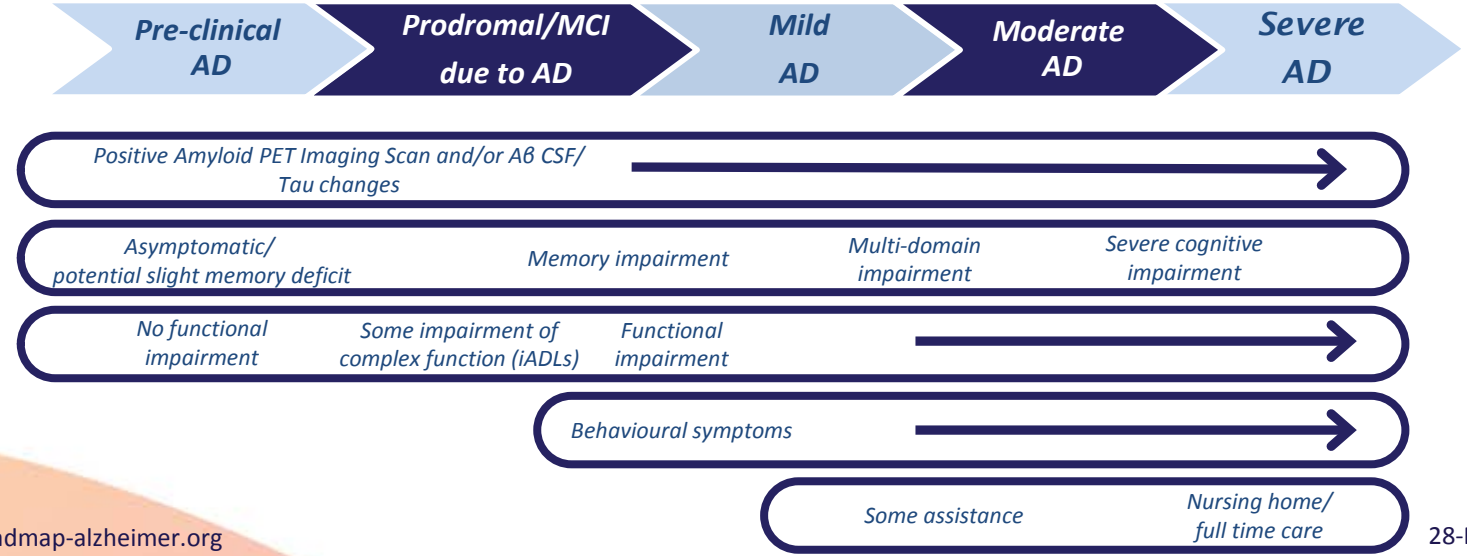
Background

- Need for innovative treatments in AD (economic, caregiver & societal impact of AD)
- challenges in the evaluation of early disease interventions within the current assessment systems have not changed
- precision medicine approach to health funding requires new models that encompass all the available evidence

Challenges for AD value proposition

- **Available data sources to inform the real world trajectory and impact of AD are limited**
  - **Lack of consensus on study design and endpoints in real world data sources**
  - **Lack of AD-related outcomes in medical records relevant across the spectrum of disease**
  - **Lack of clarity on how best to model of natural history of the disease using real world data sources**

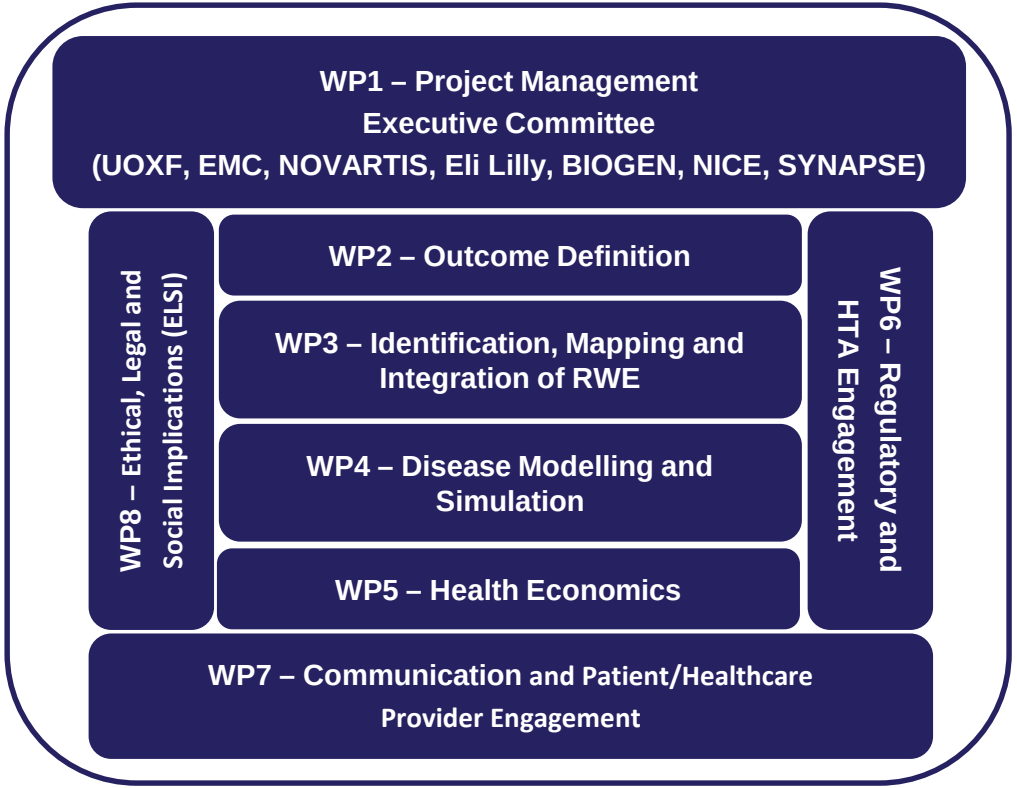


What is ROADMAP?

- Formed under the Innovative Medicines Initiative (IMI2) umbrella
- ROADMAP is a private-public partnership (PPP) to explore the usability of all data sources, in the decision-making process
- It's goal is to develop efficient uses of real world evidence (RWE) for the benefit of AD patients and their caregivers

ROADMAP Consortium

ROADMAP Structure



Aims

The aim of ROADMAP is 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

In parallel, we will develop tools for **stakeholder engagement, understanding the ELSI context and health economics impact** of a RWE approach in AD.

In doing so, ROADMAP aims 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**.

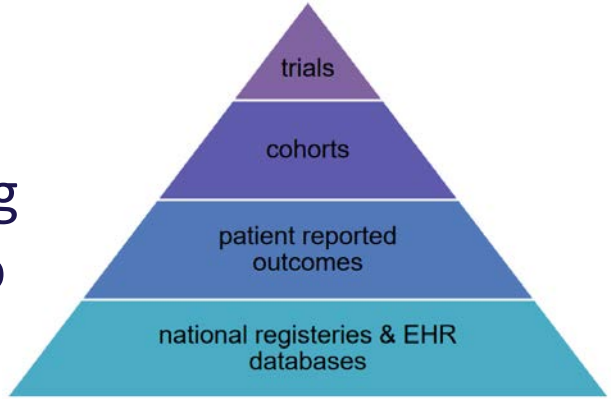
Methods

- 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

ROADMAP – Strong data corpus

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

Leverage existing large data set to perform pilots



*n refers to number of patients

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

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

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