



# ROADMAP

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

**@IMI2\_ROADMAP**  
**[www.roadmap-alzheimer.org](http://www.roadmap-alzheimer.org)**

- 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

- 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

### EFPIA partners



### Public partners



### Associated Data Providers



### Related projects



EMA-NICE/HTA/payers Qualification Pilot use of RWE in AD

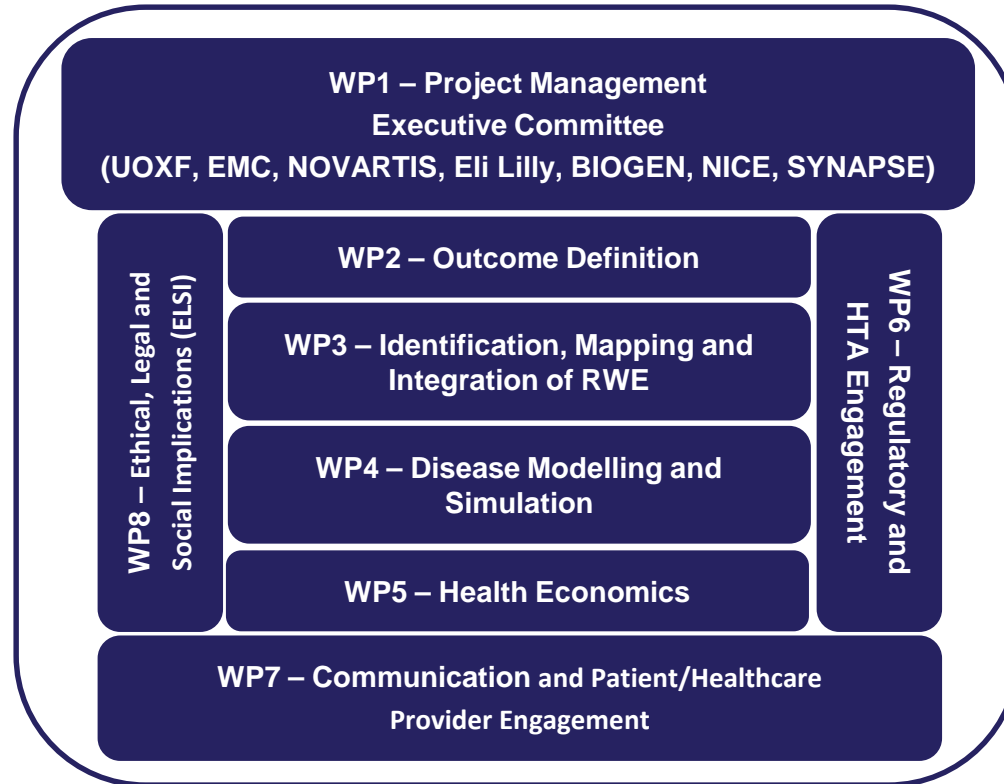
**NICE** National Institute for Health and Care Excellence

**MEB** Medicines Evaluation Board

**Alzheimer Europe**

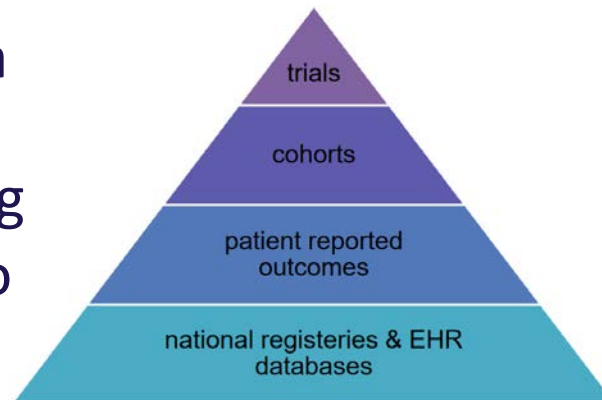
National/Regional Health Authorities to comprise an Expert Advisory Group (EXAG led by NICE):

- (1) HTA bodies/payers from different archetypes
- (2) Regulators
- (3) Patient Associations



- **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 trials** n≈100K

Leverage existing large data set to perform pilots



\*n refers to number of patients

- Define a **minimum set of** measurable **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



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