

ROADMAP
***Real world Outcomes across the
Alzheimer's Disease spectrum:
a Multimodal data Access Platform***

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*Martin Pan MD
Biogen International GmbH*

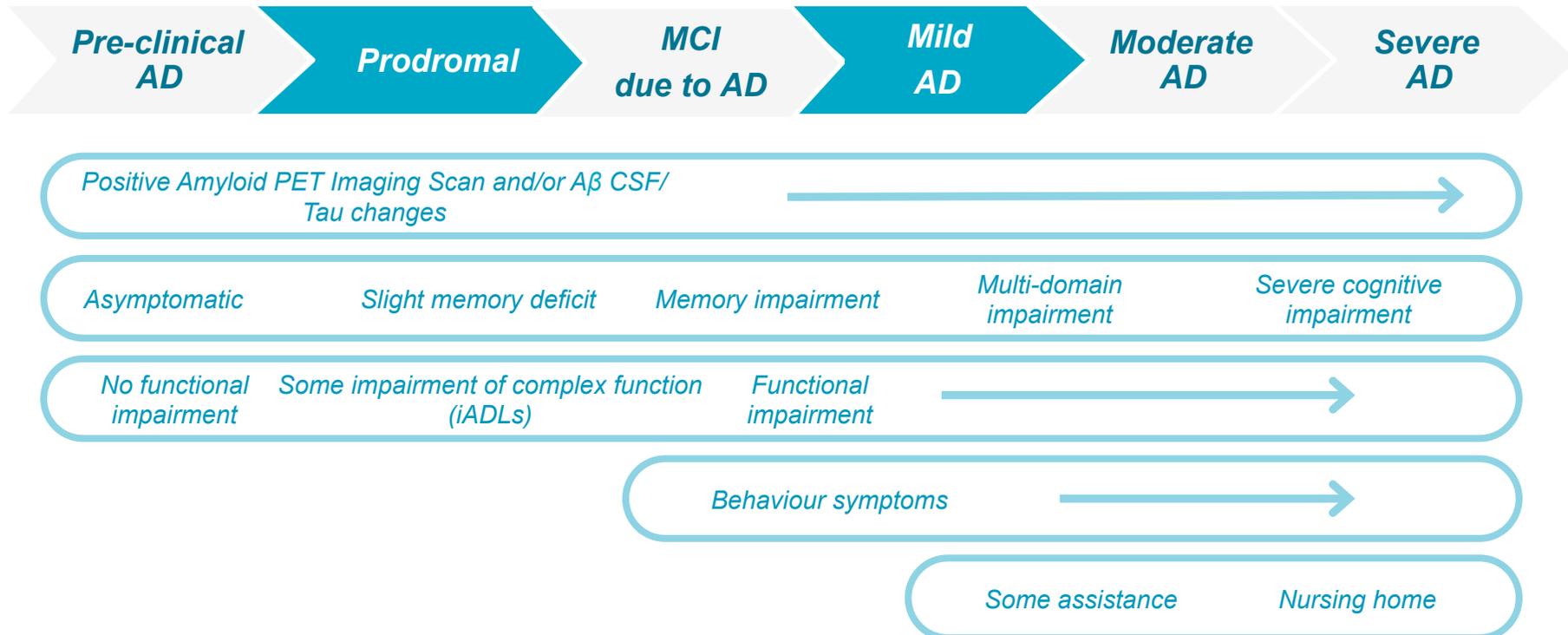


Current situation of Alzheimer's Disease (AD)

- Manufacturers invest in different interventions (nutrition, pharmaceutical, diagnostic tools, etc.)
- Disease starts 10-20 years before symptoms detected >> new trials target earlier stages of the disease
- Real world data and the care do not address the full spectrum of the disease
- Passive attitude towards care
- Not enough efforts on collection and analysis of high quality real world evidence

Available data sources to inform the real world trajectory and impact of AD are very limited

- Lack of consensus on appropriate study designs and endpoints in real world data sets
- Lack of measures transferable across studies and systems
- Lack of AD-related measures in medical records that are relevant across the spectrum of the disease
- Lack of clarity on how best to model the natural history of the disease using real world data sources



IMI-2 ROADMAP – Aims of Phase 1



- To deliver a series of data integration methods and tools for patient outcomes
- Ultimately this could provide the foundation for a Europe-wide real world evidence (RWE) platform on AD
- To develop tools for stakeholder engagement and understanding of the economic, legal and social implications
- To create an open collaboration among stakeholders that yields consensual, efficient uses of such RWE platform
- Benefit of AD patients and their caregivers

Industrial Consortium



Public Consortium



*HTA agencies/
payers from different
archetypes*



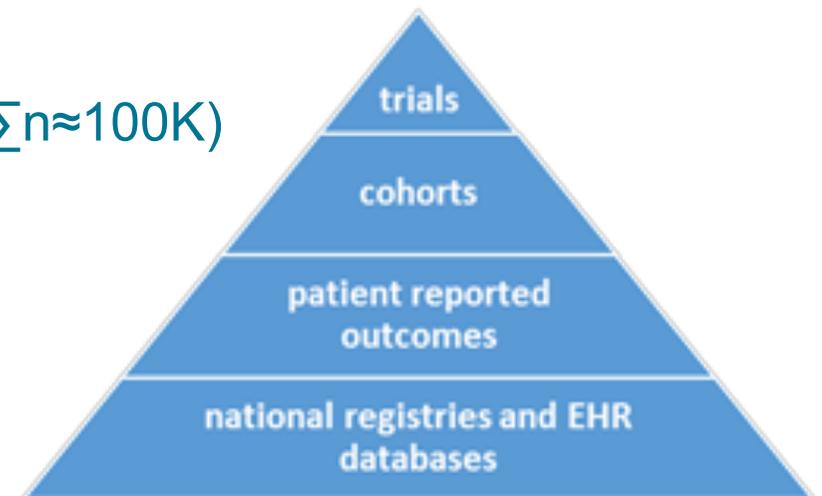
Public stakeholders

*National/Regional
Regulators*

*National/Regional
Health Authorities*

ROADMAP – Strong data corpus

- 6 EU Member States (Denmark, France, Netherlands, Spain, Sweden, UK)
- 75 national databases and clinical registries ($\sum n \approx 80M$)
- >40 cohorts ($\sum \approx 2M$)
- Studies using wearables and smart devices ($\sum n \approx 100K$)
- 4 dementia relevant trials ($n \approx 50K$).



ROADMAP - Deliverables

- Define a minimum set of measurable patient outcomes
- Develop recommendations on RWE appropriate AD related cognitive, functional, and behavioral endpoints
- Identify data sources and outline a data strategy for RWE outcomes
- Develop new methods for collecting RWE data to improve health care value
- Provide recommendations for disease progression modelling