



ROADMAP

Outcome definition Scope and methods

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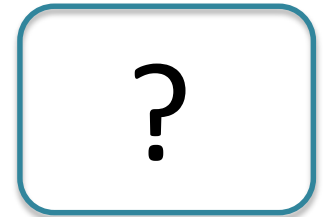
Alzheimer's Disease (AD)

- Most common cause of dementia
- Affects 50M individuals worldwide
- Prevalence projected to double over the next 20 years

- Effective treatments remain elusive
- Evaluating new treatments & interventions is challenging
 - **Difficult to access** reliable, meaningful data
 - Outcomes of relevance to people most affected often **not measured**

ROADMAP aims to tackle this:

- identify **priority outcomes**
- enable **data access**
- guide use of **real-world evidence**



Outcome

= any impact of a disease which a treatment or intervention could potentially change



Health

memory

cognitive ability

Practical & personal

ability to perform
daily activities

quality of life



Social & community

impact on supporter &
family

access to information or
services

Financial

cost of required drugs

loss of income due to
inability to work



WP1	Project Management and Coordination
WP2	Outcome Definition
WP3	Identification, mapping and integration of RWE
WP4	Disease Modelling and Simulation
WP5	Health Economics
WP6	Regulatory and HTA Engagement
WP7	Communication and Patient/Healthcare Provider Engagement
WP8	Ethical, Legal and Social Implication (ELSI)

Timeline

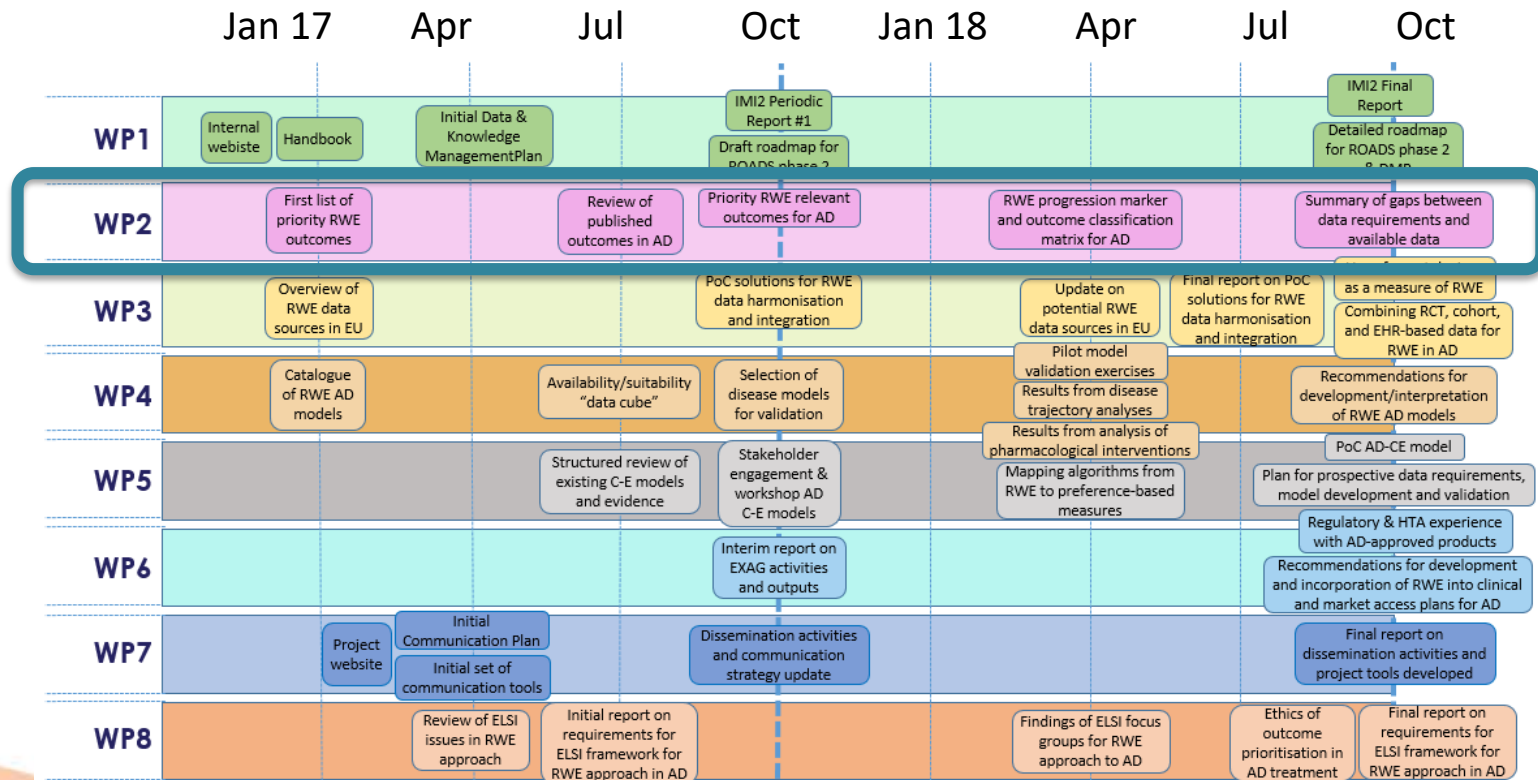
2 years:

Nov 2016 – Oct 2018

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Non-governmental
organisation



Non-departmental
public body

NICE National Institute for
Health and Care Excellence

Pharmaceutical
industry



Academic
organisations



1. Review the literature

What has already been done?

- *what has been published & is accessible?*

2. Gather new data

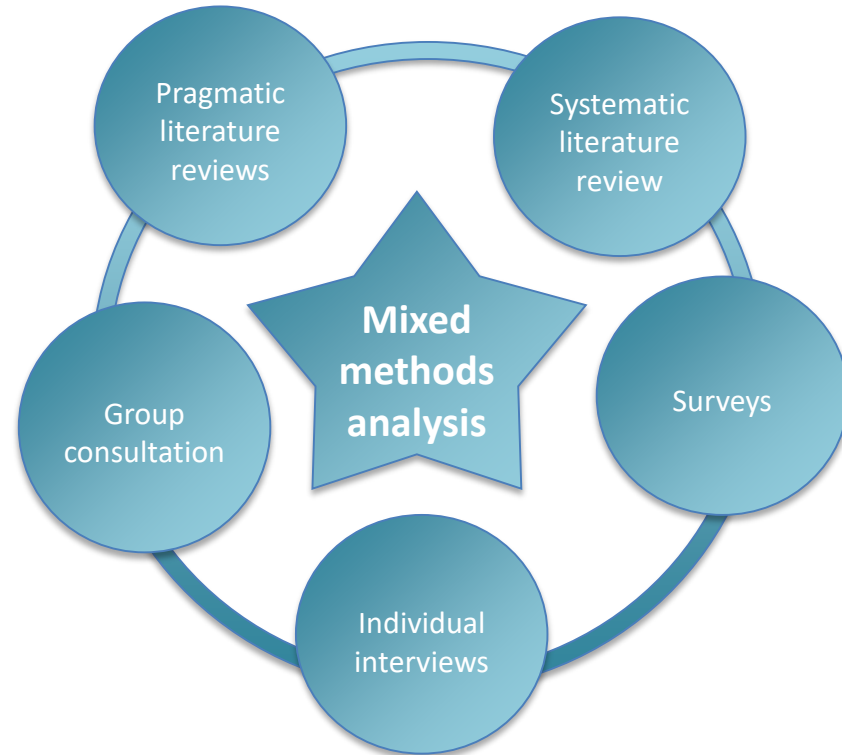
What new, reliable information would we like?

- *what do we need & have resources to gather?*

3. Analyse & interpret

What does this evidence tell us?

- *analyse appropriately*
- *establish consensus*
- *place in real world context*



Pragmatic reviews

1. quick trawl of published evidence on the outcomes of AD
Set the scene, defined terms for the systematic review & other work packages -> early publication.
2. review of outcomes used by Health Technology Assessment organisations from 3 European countries
Added context on how decisions are made around funding AD treatments.

Systematic review

1. comprehensive, replicable and unbiased collation of all available information on specific question: what outcomes matter to people with AD, supporters & healthcare professionals?
Provided robust & objective platform for priority outcomes list, informed & complemented primary data collection methods.



Qualitative evidence

1. Consultations with the European Working Group of People with Dementia and their supporters
2. Individual interviews with professionals working in dementia

Allowed identification of different priorities and to add depth & understanding of prioritisation to existing outcomes lists




Quantitative evidence

1. Surveys (professionals, people with dementia & supporters)

Allowed direct comparison of relative importance by stage of disease.

Methods 3: analyse & interpret

Data collection	<i>Literature review data</i>	<i>Qualitative data</i>	<i>Quantitative data</i>
Data analysis	Identify outcomes by ranking or thematic analysis	Identify outcomes by frequency of appearance or consistency of agreement	Identify outcomes by relative ranking or votes for top three
Synthesis & triangulation	Define outcomes & merge related Develop structure for grouping outcomes into overarching categories 		
Expert review	Core team discussions Group data synthesis meetings WP2 consensus ROADMAP consortium Expert advisory group Executive committee		

Outcome = specific, focussed component

Category = umbrella term used to group related outcomes

Challenges:

- Two year timeline
- Multiple work packages, cross-cutting & interlinked work
- Mostly remote working with colleagues
- Unanswered questions & gaps in the data: some stakeholder voices not represented

Opportunities:

- Broad expertise in Alzheimer's Disease
 - clinical, patient-focussed, economic, industry, research methodology, policy making
- Pan-European representation
- Connect voice of people with dementia to policy & strategy
- Robust basis for findings -> can support future research & development

ROADMAP aims to:

- identify **priority outcomes** ✓
- enable **data access**
- guide use of **real-world evidence**



Work Package 3

- gather information on real world data sources
- map against priority outcomes list

Work Package 4

- build an infrastructure that facilitates data access