

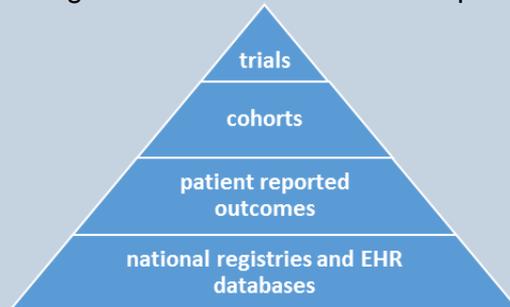
# Overcoming ethical issues in sharing real world evidence in Alzheimer's disease: The ROADMAP Project

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*“ROADMAP addresses the challenge of how to best inform clinical and health-policy decisions by conceptualising the entire population as the decision-making laboratory, and building a population-based integrated data environment which is optimised for precision and personalised medicine.” (ROADMAP)*

## **Project objective:**

To provide the foundation for an integrated data environment and framework for real world evidence in Alzheimer's disease through a multi-modal data access platform.



*The ROADMAP Data Pyramid*

For further information on ROADMAP, please visit: [www.roadmap-alzheimer.org](http://www.roadmap-alzheimer.org)

## **Key challenge:**

To ensure ethical principles are respected without unnecessarily hindering the sharing, linking and aggregating of sensitive medical data in so far as is required for the scientific progress in researching Alzheimer's disease.

## **Approach:**

Combining academic, clinical and industry expertise with comprehensive stakeholder input from both patients and their carers to identify the most pressing ethical issues to be addressed before such a platform can be developed.

## **Ethical issues identified:**

(1) informed consent; (2) autonomy and participation; (3) transparency; (4) ownership; (5) data provenance; (6) privacy; (7) group harms and discrimination.

## **Additional challenge:**

Prioritise the outcomes across the stakeholder spectrum: patient community, HTA/regulators, payers and policy makers, as well as industry.

## **Open questions:**

- Pending legal changes: How will the General Data Protection Regulation (GDPR) affect the project?
- Social implications of findings
- Technical challenges: Keeping data safe but accessible
- Additional data sources: How will decisions be reached about the inclusion of additional RWE data sources, such as data from wearables and mobile devices?
- Transparency and communication: Maintaining engagement of relevant stakeholder groups, esp. patients and carers
- Broader epistemological questions regarding data integration (RWE and clinical data)

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