# Leading the path towards a general agreement on payment and care models for Alzheimer's disease

## Introduction

One of the primary goals of healthcare is to improve the overall health of the population. Efficient allocation of funds for purchasing care is a key factor, and it is crucial that scarce resources are spent wisely on interventions that offer the most benefits for patients. Therefore, a value-based approach to healthcare would ensure that the health system receives the greatest benefit from investment of public funds when deciding between alternatives for health interventions.

The ROADMAP communications team carried out an interview with one the leaders of Work Package 6 (WP6), Robin Thompson (Director, EU+ Value and Market Access for Alzheimer's disease (AD) at Biogen).

He will introduce us to the function of the Expert Advisory Group, his expectations and an industry perspective on the value of using real-world evidence (RWE) in AD research.

## Meet the industry co-leader of ROADMAP's Regulatory and HTA Engagement team

*Robin Thompson is health economist and market access specialist with a PhD in Economics from the University of York, UK. He has over 20 years' experience of working in a range of academic, commercial and government settings. He is the Director, EU+ Value and Market Access for Alzheimer's disease (AD) at Biogen.*

## How does your work package contribute to the ROADMAP project?

A pivotal activity for our team was the establishment of the Expert Advisory Group (EXAG). The EXAG is an important window into the project from an HTA, payer and regulator perspective. This bilateral engagement mechanism is a critical way of ensuring that ROADMAP activities are going to be fit for the end purpose both for regulators and payers.

The EXAG works in two ways:

- On the one hand, we present them the ongoing work across the work packages (WPs) at strategic phases.
- On the other hand, they provide us with an external stakeholder view of what we are doing from an end user perspective.

This feedback is meaningful for decisions how WPs could be taken forward.

We will be looking at aspects like relative effectiveness and cost-effectiveness. Because of that, it is important to identify which outcomes regulatory agencies and HTA bodies such as NICE use when it comes to using real-world evidence (RWE) in AD.



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One goal is to ensure that these outcomes are aligned with the ones the Outcome Definition team (WP2) is working on and that they are important to these organisations for their work in assessing products for an AD indication. In this context, we aim to align the set of outcomes that are relevant for these organisations and what they are looking for in terms of RWE.

WP6 contributes to other important elements as well. In collaboration with medical regulators, our WP conducts a literature review of past regulatory and health technology assessments of AD medicines. Through this, we evaluate experiences of regulatory and HTA bodies with AD approved medicines.

In doing so, we intend to learn from past experiences and contribute to a more harmonised approach of medicine licensing and reimbursement in the near future.

In addition to this, we explore innovative mechanisms for engagement with regulatory bodies that relate to endpoints of the disease progression model (WP4). Through engagement with the EMA's Innovation Task Force we specifically focus on potential novel endpoints or ways in which we can measure AD at specific stages, in terms of robust instruments.



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## What are your expectations regarding your impact of work in ROADMAP?

A key part of our work during ROADMAP phase 1 is to gain the understanding of the current landscape and key regulatory, HTA and payer issues in relation to real-world evidence (RWE).

The aim is to obtain insights from regulators, payers and HTA bodies on RWE requirements to ensure stakeholders prepare appropriately for the anticipated introduction of disease modifying therapies and ensuring that what we have in place from a data collection perspective will be fit for purpose.

In addition to the specific requirements, we will also identify potential gaps that currently exist. This will help us inform a potential second stage of the project. In this context, our engagement mechanism with the EXAG will play an important role in informing a phase 2 of the project.



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## What potential value do you see in using RWE in AD research?

RWE plays an important role in understanding the natural history of the disease as new medicines become available. It will enable us to compare long-term effectiveness.

Form a payer perspective RWE is hugely important, typically in clinical trials data is of limited duration and there will be a need for understanding real-world effectiveness across various countries. The accumulation and collection of robust RWE will be hugely important from patient access, reimbursement and reassessment perspectives.

There hasn't been success in bringing forward new medicines for AD in more than 10 years. At the same time there are a number of medicines in development and hopefully in the next couple of years we will see a potential disease modifying therapy making it to the market. Once active disease modifying therapies are available we need a real-world disease progression model to compare with.



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