The ROADMAP project an EU consortium to improve care in Alzheimer's disease

Introduction

Data has been attributed as having "transformative potential" in healthcare systems, with benefits across the entire pathway of care delivery for all stakeholders. Access to large data sets gives a more comprehensive picture of patients, allows patient-related outcomes to be measured more accurately, and supports decision-makers in shaping healthcare systems.

The ROADMAP communications team carried out an interview with one the leaders of Work Package 3 (WP3), Pieter Jelle Visser (Associate Professor at VU University medical Center Amsterdam and Senior clinical researcher at Maastricht University).

Meet the ROADMAP WP3 co-leaders

Pieter Jelle Visser is a clinical epidemiologist who has coordinated large-scale European Alzheimer's disease (AD) studies on early diagnosis and prognosis in which data harmonisation was central (DESCRIPA, EDAR, BIOMARKAPD). Visser's leadership brings expertise through a broad portfolio of studies in which they integrated biomarker and health data including a 10-year follow-up of mild cognitive impairment (MCI) subjects. Visser leads data harmonisation for EMIF-AD and works on data harmonisation for EPAD.

Antje Hottgenroth is a biologist with a doctorate in Natural Sciences. She held several positions within the German affiliate, the regional and currently corporate company organisation Eli Lilly. During her recent Data Scientist role, she contributed to several company projects for optimisation of real-world evidence (RWE) research and build of a RWE/real-world data (RWD) knowledge repository.

What is your team doing within ROADMAP?

In Work Package 3 (WP3) we work on the identification, mapping and integration of real-world evidence (RWE). I am academic co-leader together with Antje Hottgenroth, who represents the industry side of the collaboration.

At this stage we are creating the environment for the analysation of data within ROADMAP. We use existing cohort data and existing infrastructures and develop the work flows. We identify sources of RWE data in different countries. This will lead to an overview of available RWE data.

So, our WP supports the project and several WP's in finding the data that they need for their analysis. This work is driven by research questions. Once we receive a research question (as defined consensually by members of this public-private collaboration), we reflect which data we can use for it and search for suitable sources. In some cases this means that we need to start negotiations to obtain the data (for example when sources are not part of the ROADMAP consortium) then we harmonise and provide it to the team(s).

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A big challenge in this context is, that the type of data from electronic health records (EHR's) often lacks consent for re-use. Our WP is particularly well placed to help tackle the challenges in access procedures, which are completely different to those for data from conventional clinical trial sources. In the case of EHR's for example, the data is often only accessible through other platforms to ensure that the data is not directly accessible on a civic level. Something we do not do is anonymise data, which is an initial task of the data provider to ensure the anonymity of patients. ROADMAP and specifically our WP does only work with data that is already coded/ anonymous.

But many other things to do with, for example, patient pathways through the health and social care system, the levels of quality of life the people affected may experience in different health states, the resource use generally that they require at different stages of disease progression, are probably best sourced in a more naturalistic way because that gives us the best measure of what happens in real world practice.

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What is real-world evidence (RWE) data and why is it so important to leverage from many different sources?

There are many different positions on RWE. In general, I have more of a philosophical point of view on this. Data is collected in a specific context, for example as part of a research study with specific questions. Data from trials comes from a highly selected population and therefore cannot be fully representative of the general public.

Every source of data provides a different view on the specific disease and patient population, but there is no real gold standard. Data collected outside of clinical trials, for example from general practitioners, is considered "real-world data" because the population it is collected from is not so well "standardised", it has for example multiple different diseases at the same time.

Through RWE from different sources, we can potentially acquire data that helps us to better reflect the natural course of the disease in a world-like situation throughout different patient populations in different countries. Knowing how the disease develops (for example its incidence and progression rate in the real world) could serve as a reference against which potential treatment effects can be compared.

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Using RWE and learning from it is particularly important because it helps understand to how a potential treatment may change the disease course in a real world setting.

I think ROADMAP is very well positioned to help create a fuller picture of the so to say "real disease". Bringing together all available evidence, we will be able to better identify the impact of AD, including impairments patients experience and costs associated with it. In this case, RWE could be considered as the observable burden of the disease and this is what ROADMAP also aims to uncover to a fuller extend.

What challenges do you see?

From a scientific point of view, a specific challenge in AD is that on one hand, a portion of people remain undiagnosed and are therefore invisible to us in capturing the real disease model. This means that the information from the general practitioner leaves white spots because people with AD which don't visit the general practitioner don't get a diagnosis and potential data remains uncaptured.

On the other hand, if the burden of disease remains uncaptured it can't be used as RWE for science. A challenge for the treatment is that RWE in the early developmental stage of the disease is hard to capture because symptoms remain almost invisible for a long time until they start to measurably burden the person.

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What impact do you expect from your WP's work within ROADMAP on the design of a 2nd phase of the project, how will it inform it?

Apart from the development of a preliminary workflow for partners to receive access to relevant data sources, we help to identify novel cohorts that are not in ROADMAP phase 1. Within our WP we identified novel sources and at the same time we have identified some regional gaps. The identification and mapping of those unused EHR datasets across Europe are an asset we can deliver.

In addition to this, we also have a small subtask exploring the utility of technical devices in AD. These encompass wearables (such as smart watches) and similar technologies. The subtask will inform ROADMAP phase 2 by the provision of recommendations based on the current state of the art.

Read further about the industry perspective on WP3 in the interview with Antje Hottgenroth here.

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