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

Introduction

The ROADMAP communications team carried out an interview with the leaders of Work Package 8 (WP8), Andrew Turner from the University of Oxford and Zuzanna Angehrn from Novartis. This interview features the work they are currently doing and gives you a deeper understanding of the Ethical, Legal and Social considerations with regard to the project and its potential future implications.

Meet ROADMAP's Ethical, Legal and Social Implication (ELSI) team co-leaders

Andrew Turner is researcher in the Digital Ethics Lab at the Oxford Internet Institute. He is a philosopher with training in social science research methods. His research focuses on bringing philosophical perspectives to understanding the socio-technical challenges of sharing and protecting biomedical data.

Zuzanna Angehrn (Novartis/Analytica Laser) is a social scientist and consultant specialised in data analytics and modelling. She has been involved in multiple projects where real-world data (RWD) are used to better understand how a disease progresses in real life and how to optimize patient's care.

What is your team doing within ROADMAP?

Andrew: Our Work Package (WP8) focuses on the ethical, social, and legal aspects of the project (and of pooling different data from various studies generally). We are interested in the ethical principles that guide the direction we think research like ROADMAP should be going in. The governance measures that need to be in place to make this type of project as efficient as possible, but also acceptable to all stakeholders. And the changing regulatory environment in Europe, most notably the introduction of the EU General Data Protection Regulation, which many people have argued still has uncertain implications for scientific research.

One of the challenges is fitting all those aspects together in an efficient way and not hindering progress at the same time.

Zuzanna: In ROADMAP, we want to support the development of an "integrated data platform" gathering data of multiple patients from throughout Europe. Scientists could then analyse this data and expand their knowledge about the processes that lead to the development and progression of Alzheimer's disease (AD). Further, this platform will help scientists to better understand who is most at risk of developing AD and eventually how to best help these patients when a new drug is available so that AD is delayed or perhaps even prevented.

We will not have this fully developed integrated data environment or platform during ROADMAP phase 1 yet.

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However, we need to start early and make every effort to understand the legal requirements and other safeguards which need to be put in place to protect patients and data which they contributed in good faith for research. This is why we must make sure that we use these data in an ethical, socially responsible way, consistently with good practices. That is the first goal of WP8.

The second goal is more scientific. Our aim is to understand the ethical and legal "trade-offs", to weigh the benefit versus risks that are associated with pooling this sort of very sensitive, medical data together and analysing them.

This is not trivial since we need to consider the tensions that arise between the benefit of an individual and a society, between what we can do with the AD data at present versus how collecting data now could serve future generations.

What are your expectations regarding the impact of your work on ROADMAP?

Andrew: The key output is going to be a set of requirements for a framework for thinking about these types of ethical, legal, and social issues. Going forward, the plan is to implement that in a potential phase 2 of ROADMAP. Part of the work we are doing is proposing ways to address challenges that are known in the literature and have been identified by similar projects. In addition, we need to address the specific challenges that arise during this first phase of ROADMAP and develop strategies to solve them going forward in phase 2.

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Zuzanna: By doing this, we are trying to make sure that sensitive personal information that patients contributed for scientific research are used for overall benefit, without affecting patients' privacy or dignity.

How do you ensure that the perspective of people with dementia is considered in your work?

Andrew: As well as the conceptual and documentary work that includes reviewing existing data sharing policies, for example, we also have tasks that involve speaking to people affected by the disease.

We want to have a conversation about the way health data are used for research. For example, exploring patient's concerns and expectations about having data about them from multiple sources collected altogether, as well as asking what they would like to know about the research going on with their data and how they can engage with it further. In December we ran a consultation and talked about precisely these issues with the European Working Group of People With Dementia (EWGPWD).

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What potential value do you see in the use of RWE for AD research?

Zuzanna: Using RWE in AD has a massive potential value for patients themselves! By combining and analysing their data, scientists will be able to come up with a better statistical model of AD progression and make a better prediction of if and how a patient will advance. This might be particularly relevant for people who fear that they might be at risk of developing AD. Understanding where they are on the disease journey offers a patient some empowerment so that they are more in control.

The other value is building a data environment in which we can test potential future AD drugs which are currently in development, as well as a consensus about how this should be done. This way we can find out quicker how these new drugs work in different types of patients.

The clinical trial answers the question ‘does the drug work?’ using specific end points measured in patients that were qualified for this trial and who typically received a very good care and close, regular monitoring from their doctors while being in the trial. But what patients would really like to know is ‘will this drug work for me?’ given my circumstances, my disease history and the care options which are available to me. We need real-world data to understand how the drugs work in real life and how to best use them. Eventually in the future we would like physicians to be able to make a better assessment of whether an individual drug would work for an individual patient.

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Andrew: Before starting this project, I was familiar with evidence from observational studies, epidemiology, and evidence from clinical trials; however, I hadn't encountered the concept of RWE before. It's a powerful idea that makes a lot of sense. We need to combine evidence from different areas to address complex questions about how well tests or treatments work in the real world and impact us. Equally it can provide the evidence to enable controlled clinical trials to become more efficient and answer the questions patients want answers to.

The concept of an outcome can be challenging. What's important to consider from your perspective?

Andrew: Outcomes should reflect what's important, what matters to people with the condition. They are the things you want to be able to change, to improve people's lives.

Outcomes can take many different forms; it might be something biological, it might be differences on scans or blood tests, or equally it can be something harder to quantify. It might be how long or easily someone can stay at home for before they have to move to an institution, or whether they can continue to do the day to day tasks that they could previously.

What this highlights is that the question about outcomes is not just a technical or scientific question. It's also a social and ethical question, there are important questions to ask about which outcomes are the ones that matter. Which are the ones that should be prioritised by a project like ROADMAP that can really make a difference to people's lives?

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