



Report on RealWorld4Clinic's ELSI workshops in 2021

Workshop with the EIT Health ELSI Board (MS9.1) – 20 May 2021

On 20 May 2021, the RealWorld4Clinic consortium held a workshop together with the EIT Health ELSI Board bringing together eleven expert participants to discuss key ethical, legal and social issues that could become critical for a wide implementation of the RealWorld4Clinic platform in clinical contract research and outpatient cardiology care. The exchange with EIT Health ELSI Board members allowed participants to identify action points to enhance market and societal acceptance of the RealWorld4Clinic solution for usage in chronic care, and about how RealWorld4Clinic could support EIT Health with respect to proactively addressing ethical, legal and social issues in the development of high value care and harnessing real-world data.

As a concrete outcome of the initial workshop on 20 May 2021, it was agreed to hold a larger, public follow-up workshop, led by Grenoble Ecole de Management, with support and contribution from the EIT Health ELSI Board in autumn 2021. Among the initially envisioned topic areas around which the consortium sought to engage with the wider public, including patients and caregivers, figured both legal and ethical issues, with a particular focus on privacy, trust, and patient involvement.

Public RealWorld4Clinic ELSI workshop "Co-designing for health: Patient involvement and connected medical devices" – 8 December 2021

A public, online follow-up workshop on the initial exchanges with the EIT Health ELSI Board was held on 8 December 2021 with 52 participants including patient representatives, members of the EIT Health ELSI Board, EIT Health, academia, medical start-ups, medical education platforms, and RealWorld4Clinic consortium members. In order to maximize exchanges and learning among participants, the Grenoble Ecole de Management organizing team decided to focus specifically on patient involvement in the co-design of connected medical devices, a core issue identified in the earlier activities of the RealWorld4Clinic ELSI work package (Living Lab, Citizen Panel).

After a brief introduction by RealWorld4Clinic coordinator Prof. Freimut Schliess and ELSI work package leader Prof. Charles-Clemens Rüling, three distinct approaches to patient involvement were introduced and discussed by the invited experts: Prof. Isabelle Huys, University of Leuven, Chair of the EIT Health ELSI Board, introduced ethical, legal, and social issues in the development of drugs and medical devices more broadly before focusing in particular on the challenges of patient involvement in the context of the development of high value care, emphasizing in particular the need to involve patients as partners right from the start of a project.

The second presentation by Dr. Ambre Davat, researcher at Université Grenoble Alpes and collaborator of the RealWorld4Clinic consortium, focused on the contribution of co-design methods to help the shift from technology-centered to user-centered design, building on the insight that the systematic involvement of patients in the design of solutions needs to find its place at the core of patient-centered healthcare approaches. She also emphasized the importance to recognise patient experience and knowledge, especially for patients with chronic conditions who are often highly knowledgeable about their disease.

In the third presentation, Jan-Philipp Reineke, Grenoble Ecole de Management PhD student and RealWorld4Clinic collaborator, highlighted the need to develop new forms of ethical technology assessment that specifically take patient perspectives into account and overcome the largely utilitarian focus of traditional approaches. Ethical technology assessment requires continuous dialogue between developers and users including patients, medical professionals, and caregivers from early stages of development and throughout the entire lifecycle of a medical device. Building on insights from the RealWorld4Clinic Citizen Panel Study, the presentation demonstrated the richness of insights to be gained especially from the qualitative analysis of statements gathered from prospective patients.

All three presentations were followed by lively Q&A and discussion sequences highlighting a wide range of issues and tensions surrounding increased patient involvement, the role of expertise, issues of representativeness of participating patients, the question of how to give voice to patients that lack the ability to actively participate, and also the boundaries and inherent risk of reification of the "patient" category itself. Moreover, the discussion addressed institutional and structural barriers to enhanced patient involvement