Embedding Patient Voice within European Healthcare: Achievements and Future Directions of the Health Outcomes Observatory (H2O)

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FACTS & FIGURES

Start date:	01 October 2020
End date:	31 March 2026
IMI funding:	10 476 687 €
EFPIA in kind:	11 940 094 €
Associated Partners:	168 000 €
Other:	156 250 €
Total Cost:	22 741 031 €
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CHALLENGE

Real-world evidence (RWE) is a crucial data source for achieving sustainable person-centred and value-based healthcare, yet fragmentation, standardisation, and access and ownership questions remain problematic. Few efforts incorporate patient-reported outcomes (PROs) and thus standardised measures of the patient voice are a major gap despite evidence supporting multi-faceted benefits including patient empowerment, improved patient-provider communication, better longitudinal disease monitoring, quality and health technology assessment, and policy evaluation.

APPROACH & METHODOLOGY

Aiming to improve patient outcomes and encourage value-based healthcare systems, H2O amplified the patient voice by creating and internationally implementing standardised PROs.

As a first step, H2O developed a governance model for cross-border ethical and compliant data use and sharing based on representative stakeholder collaboration and patient consent. The H2O Patient Agreement empowers patients with data control while supporting both primary and secondary research use.

Core outcome sets merging patient-reported and clinical outcomes for initial areas Diabetes, Inflammatory Bowel Disease (IBD) and Cancer (breast and lung) were developed according to H2O's multi-stakeholder Delphi-based methodology.

National Observatories were established in Austria, Germany, Netherlands and Spain following the governance model, with a Pan-European Observatory to provide coordination and guidance. A federated structure with technical standardisation and interoperability allow for country-specific adaptations and flexibility in technical solutions while enabling cross-country research.

RESULTS

H2O is the first multi-country effort to standardise, adopt and analyse patient-reported and clinical outcomes in routine care settings. H2O provides data infrastructures that allow cross-sector and pan-European aggregation of data, delivering insights for policymaking and research.

Clinical and/or PRO data has been included from more than 6000 patients in the 4 countries since launch in 2023. In initial stratified analyses, 78% of patients were repeat responders (2905 of 3701).

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Results support feasibility, uptake and stakeholder acceptance, yet local variance remains a complex influence on implementation. Scaling to further settings and countries must adequately consider adaptations.

Scaling to additional sites will require continued adaptation, and collected data must be made actionable in the clinic in a timely manner to maintain patient enthusiasm.

Safeguarding patient trust and engagement in data-sharing and standardisation will drive sustainable adoption and impact.

VALUE OF IMI COLLABORATION

H2O's multi-stakeholder consortium included 26 academic, public and private partners who worked together to achieve the H2O vision over more than five and a half years. The project's co-leaders the Medical University of Vienna and Takeda formed a strategic alliance to promote the European dialogue on and implementation of PROs in order to improve care and outcomes while advancing innovative science.

The basis of H2O's success, governance structure and future sustainability is its robust public-private partnership enabled by IMI funding. The consortium ensured that from the start all work was conducted with involvement and cooperation of all relevant stakeholders, including patients, health care providers, researchers, life-sciences industry, health authorities and regulatory bodies. This is one of the founding principles of H2O, that only through collaboration can we safeguard the resource of patient health data.

CAREER IMPACT

My research focuses on how enabling stakeholder involvement and cooperation contributes to realising inclusive, value(s)-based learning health systems. A subtopic is how Europe accelerates digital health innovation. H2O was a fantastic opportunity to work with many experts throughout Europe and to not only study stakeholder relationships and health systems implementation but to be personally directly involved in the project coordination. It was therefore meaningful both for the research output, but also for the career experience of working with leading senior-level decision-makers in my field.

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