



H2O: Strengthening the patient voice in health care

Facts & figures

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IMI2 – Call 18

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and Innovation Action)

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20.6 million €

What is H2O?

The Health Outcomes Observatory (H2O) is a strategic alliance between the public and private sectors to create an **unprecedented, standardised data governance and infrastructure system** across Europe that **incorporates patients' experiences and preferences** in decisions affecting their individual health care and those of the entire patient community.

This will materialise in a network of Observatories that will allow an ethical and legal use of data to:

- Measure outcomes more effectively.
- Facilitate personalised treatments.
- Enhance health research prospects.
- Promote value-based approaches in health care systems.

Our mission

H2O is set to **transform the use of patient-reported information in health care**, enrich the interaction between patients and health care providers and, as a result, drive better outcomes for patients. The project will **fill an important gap** as outcomes reported by patients are not usually incorporated in a comprehensive and systematic way into the decision-making process affecting their individual clinical care.

H2O plans to:

- Set up national Observatories, initially in 4 countries and focusing on 3 disease areas, before extending the concept across Europe and to other diseases.
- Adopt user friendly digital tools and processes for patients and providers to share relevant information.
- Empower patients with digital tools to better manage their health care.

Who participates in H2O?

The Consortium brings together 13 leading Academic institutions, SMEs and patients' organisations and 10 EFPIA companies. The project is led by Takeda Pharmaceutical and the Medical University of Vienna (MUW).



Why is H2O important?

H2O is creating an innovative governance and infrastructure model to unleash the potential of health data in Europe, whilst making sure that patient's privacy rights are protected and data, as an essential resource, is better safeguarded and used in the interest of society.

How will Regulators and HTAs benefit?

Outcomes are amongst the most powerful indicators of effectiveness, but often the least available to decision-makers. They have instead to rely upon a series of process measures, and some limited clinician collected outcomes, instead of making decisions based more often on the basis of real-world evidence, especially in relation to indication extensions and post marketing surveillance.

H2O will ensure that Regulators and HTAs:

- Have **access to quality, trustworthy outcomes data**, especially on newly approved medicines and high-cost treatments. The data collected by the Observatories will **represent diverse patient populations** and will also specify clinical populations in terms of disease severity, comorbidities, etc to provide the sound evidence needed to **incorporate patient perspectives into their decisions**.
- Incorporate patients' PROs and PROMs in their analyses to **inform of potential improvements in health care**, thus contributing to **value based health care**.

What are the Observatories?

The national Observatories are **independent, not-for-profit, legal entities** created for **data collection, analysis and evidence sharing** to inform clinical practice and healthcare decisions.

These ethically and legally sound national Observatories are initially being created in **four countries** –the Netherlands, Austria, Germany and Spain– covering **three diseases** –cancer, diabetes and IBD (Inflammatory Bowel Disease)–.

They operate under a **governance model** that guarantees **data protection** under national and European jurisdictions. These independent entities (Observatories) guard data on behalf of patients, who keep control of their own data being used for individual and collective care, research or the evaluation of new technologies.

These entities connect to a **pan-European Observatory** to facilitate interoperability, guide reproducibility in other countries, and promote the benefit of measuring and using patient-centred outcomes at regional, national, European, and global levels.

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