

Request for Expression of Interest (RFEI): Digital Health Solution Providers

Please register your interest by email to: info@imi-h2o.eu

1.0 Introduction

One of the core tenets of value-based healthcare approaches to healthcare delivery is that healthcare systems optimise care based on improving outcomes that matter to patients. In order to be able to do this patient outcomes have to be measured in a standardised way and the outcomes that are achieved need to be made transparent within the system. The Health Outcomes Observatory (H2O) project will set up and operate national entities – “Observatories” – in order to equip patients with digital tools that will allow them to monitor and document their outcomes in a standardised manner. This will empower patients to better manage their healthcare; it will inform the dialogue between the patient and health care provider; it will allow treatments to be better tailored and personalised; and it will develop a resource for healthcare authorities, healthcare providers, innovators and researchers, providing standardised data regarding the health outcomes that are being achieved by patients in the target diseases.

A key factor in the success of H2O will be the use of technology to allow patients to monitor their outcomes in a way that engages and retains patients’ interest. Organisations are invited to respond to this Request for Expressions of Interest (REOI) with their solution for improving patient care by connecting patients with their health information and enlisting them to take control of their care experience.

2.0 Background

H2O is a public-private partnership funded by the Innovative Medicines Initiative (IMI) and European Federation of Pharmaceutical Industries and Associations (EFPIA) members. The project is supported by a grant from the IMI which receives support from the European Union’s Horizon 2020 research and innovation programme and EFPIA. It brings together 23 partners across the public and private sectors, and was launched on 1 October 2020 and will run for 60 months, through September 2025.

A key objective of this project is to set up independent, not-for-profit, national observatories initially in four countries – Austria, Germany, The Netherlands and Spain – each focusing on three disease areas: diabetes, inflammatory bowel disease, and cancer. These four national observatories will operate as a cohesive network during the period of IMI funding, and will be sustained beyond this as self-funding bodies.

The mission of H2O is *“to empower patients with tools to monitor their outcomes independently, to promote the use of their outcomes in decision making with clinicians, to create transparency of outcomes to facilitate value-based healthcare models and to create an ethical governance model for patient-reported health data in the interest of patients, science and society”*.

The H2O project has a number of objectives, including:

- To establish a Health Outcomes Observatory (H2O) as an independent, not-for-profit, legal entity in each participating country, and then to develop and run services in each of the four countries such that these are operational and financially self-sustainable within two years;
- To empower individual patients with the data to better manage their health care; and
- To set up a pan-European observatory that will lead the H2O ecosystem and will extend the H2O concept from its initial focus by adding more disease areas, new data sources, and other settings.

We have attached to this document our Mission and Vision and our Governing Principles in Annexes 1 and 2 respectively. Highlighted here are some key principles:

- a) We consider health data as an 'essential resource' that should be available on a non-for-profit basis to any bona-fide researcher, subject to patients' consent and compliance with appropriate ethical and legal rules. This is why we have opted for a not-for-profit model that imitates that of a 'utility' for the H2O enterprise.
- b) We anticipate revenue from data insights and/or data sharing activities that would allow us to be self-sustainable. We are currently working on our sustainability model to identify the most appropriate method to be self-sufficient and grow the H2O activities to serve our mission.
- c) We are keen to offer patients the possibility to be in full control of their data. Technological and forward-thinking solutions that can facilitate this are of particular interest to us.

To enable patients to manage their own healthcare there is a need for a strong data infrastructure that adheres to applicable laws and ethics, as well as user-friendly tools. H2O is aiming to provide this trusted data infrastructure that will operate according to the principles outlined in Figure 1 below.

3.0 Reason for the Request for Expression of Interest

One of the key objectives for the H2O enterprise is to give patients the ability to measure their outcomes in a standardised manner. We are committed to partnering with parties who have demonstrated success in engaging with patients to collect their health data either through Internet of Things (IoT) devices or from healthcare providers.

The outcomes data collected for patients will be derived from the integration of two core data streams:

1. Data generated directly by patients, either in the form of patient-reported outcome measures (patient responses to standardised questions regarding their general health status, symptoms and functional capabilities), or data generated by patient used devices or patient worn devices (e.g. glucose meters, step counters etc.)
2. Data derived from clinical sources, particularly electronic health records, including clinical data, laboratory testing results etc.

The H2O project will be establishing the infrastructure for data hosting and collection of the clinically generated data and plans to develop a patient facing application (app) for the collection of the patient generated data and device data, and a healthcare professional dashboard to visualise the data in clinical care settings. However, it is clear to the project that patients are selective in the way they choose apps to support them in the management of their health and value a range of functionalities, including disease information, coaching and disease management support. It is beyond the scope of the H2O project to develop these additional functionalities.

Therefore we believe there is an opportunity for immense synergies and value to patients if we establish strong partnerships with parties who have developed such functionalities and have demonstrated success in engaging with patients through digital tools and devices.

We will prioritise partners who have developed such functionalities with an established and growing user base that can create additional value by integrating the collection of outcomes data in the way the H2O project envisages as part of their offering to their patient user base. A pre-requisite for any partnership will be partners' willingness to adhere to our ethical and governance principles.

Partners who engage with H2O can gain access to broader markets, have opportunities to establish relationships with all contributing parties (e.g. pharmaceutical companies, hospitals, non-profits), and can become an important contributor to improved health outcomes across countries in Europe.

Organisations are invited to respond to this Request for Expressions of Interest (REOI) with their solution for improving patient care by connecting the patient with their health information and enlisting them to take control of their care experience.

4.0 Key assumptions

At the Observatory level, the following can be assumed:

- Patient data collected for the use by the Observatories will be at the individual level where possible, and aggregated if needed
- Data may flow bi-directionally between Observatories and anonymised data will not be re-identified

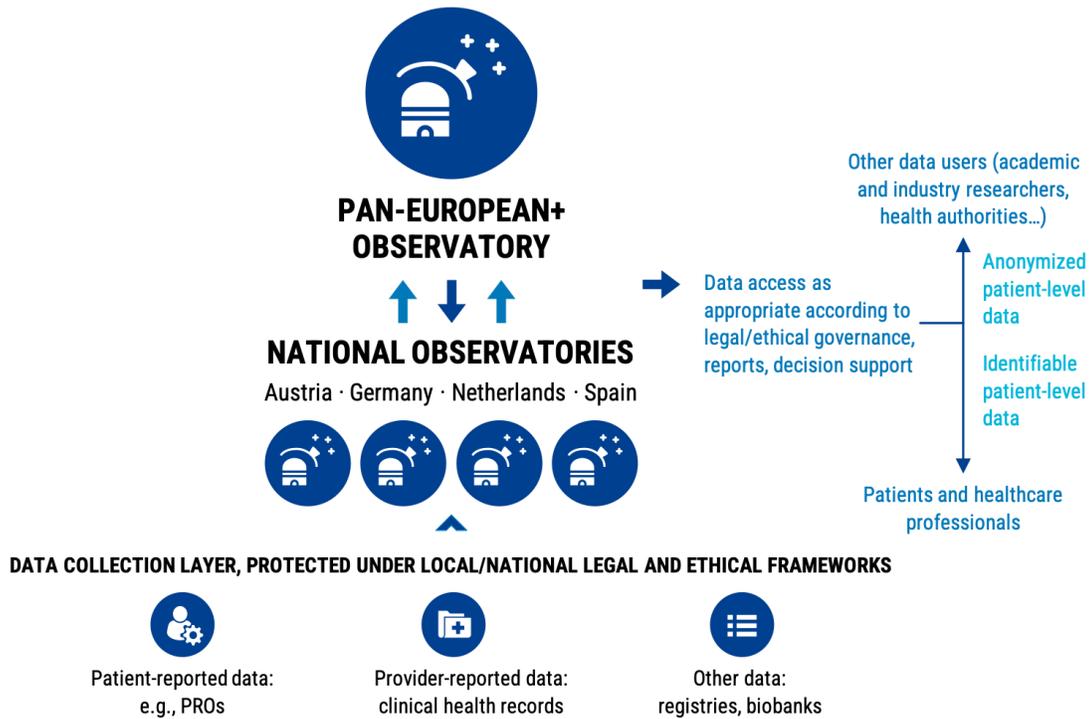


Figure 1 | High-level overview of the Observatory concept and data flows

A key principle of the H2O philosophy is that patients control their own personally identifiable data and entrust this to the H2O network to safeguard their data on their behalf. Within the H2O construct the use of patient identifiable data will be confined to individual clinical care settings, and leveraged as the foundation for patient-centered care delivery and shared decision making between patients and care teams – reflecting patients’ individual preferences, and the outcomes that matter most to them. Secondary use of data within the H2O ecosystem will not compromise this primary use, and any partnership with technology providers must safeguard these requirements. The H2O enterprise is developing a utility model that will allow non-exclusive access to aggregated and anonymised data, insights, or analytical outputs, to legitimate stakeholders in the healthcare ecosystem if and when the patients consent. We believe that the sharing of health data within this ethical framework will foster innovation in the interest of patients, science, and society. Patient consent to share any or all of their data with the H2O enterprise does not transfer to any individual partner – and the right to dynamically consent to sharing their data with different healthcare system actors will be retained by patients.

5.0 Expected features of the solution

The candidate digital solution(s)/app should include a broad range of functionalities that create value for patients along their care journey, and an intuitive, user-friendly and customisable interface essential to attracting and retaining patients as users, and support data-enabled healthcare system interactions. The

solution should be customisable to the requirements of patients living with one or more disease in scope for H2O: IBD, diabetes, cancer. It should also support generic measures administered to all patients independent of a specific disease. Filtering options according to certain decision rules, as well as different formats of questions are essential.

The candidate digital solution may also have an interface for healthcare professionals to visualise patient data.

The ability of solutions to support patient-reported outcome questionnaires is essential.

Platform / application design

- Compatible with Chrome, Safari and Edge web
- Compatible with Android and iOS mobile devices and tablets (where applicable)
- Able to manage dynamic consent and onboarding of users
- Ability to exchange data with other platforms
- Customisable features that encourage user adoption (e.g. turn on/off notifications)

Patient functionality

We are seeking partners who provide one or more (preferably several) of the following functionalities:

- Education – provide relevant, pertinent, and disease-specific information to support patient empowerment, engagement and health literacy (e.g. updates on new research or innovative treatments)
- Communication – ability to message care teams, engage in peer-to-peer social networking, link to experience sharing platforms
- Medication – self track medication usage
- Information and reminders – provide a clear overview of care journey (e.g. medical appointments), support to prepare, and questionnaire time points, ability to set alerts for medical appointments and data entry
- Feedback – provide summaries of patient health data that can be visualised against aggregated data from a reference population in a customisable and easy-to-consume view (e.g. charts, graphs).

Functionality for clinicians

- Reminders – ability to send prompts to patients to encourage completion of patient-reported outcome questionnaires
- Communication – ability to personalise messages to patients and provide additional resources for the patient to review
- Reports – ability to view integrated data on patient health status in the Observatory, and if desired to track evolution of health outcomes.

6.0 Assessment process

Through your response to this RFEI, we would like to be able to assess why and how you could be a preferred partner to work with H2O.

On a whole, throughout the process, we are interested in learning the following from you:

- Company value proposition
 - Description of your company's vision, mission and purpose
 - Current global footprint
 - Roadmap for future expansion
 - Your company's fit with H2O's vision, activities and governance principles.
- Number of current users and application areas
 - Number of downloads or registered and active users
 - Retention rates and statistics on persistent/active use
 - Disease areas and patient populations covered
 - How you envisage your approach could enhance H2O's stakeholder engagement.
- Architecture & security
 - Data protection criteria and methods
 - Data storage methods
 - Common enterprise systems your company uses
 - How your architecture and security would be compatible with, and enhance, the H2O architecture and security
- Expected partnership model for working with H2O.

Please indicate as soon as possible intent to respond to this RFEI. In order to respond to specific questions about this RFEI, a webinar will be held for all interested applicants on:

- 2.00-3.30 PM CET Friday 1 October 2021

Register for the informational webinar and Q&A [here](#). Where possible, questions should be submitted in advance.

Please declare your interest by 6 October 2021 through email to: info@imi-h2o.eu. We are still open to discussions with solution providers beyond this date.

The H2O team will review all submitted information, and engage in a dialogue with interested parties who met our described criteria. We envisage the potential for multiple partnerships between H2O and different solution providers.

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More detailed information on the Health Outcomes Observatory project, its goals and approach can be found here: <https://health-outcomes-observatory.eu/>

Annex 1 – H2O Mission

The mission of H2O is *“to empower patients with tools to monitor their outcomes independently, to promote the use of their outcomes in decision making with clinicians, to create transparency of outcomes to facilitate value-based healthcare models and to create an ethical governance model for patient-reported health data in the interest of patients, science and society”*. The expanded mission statement includes seven imperatives:

- a) **Empower patients:** engage patients and equip them with digital tools that allow them to monitor their outcomes and to improve their communications with the health care providers (HCPs) and in the long run feel more empowered in the management of their conditions. At the same time, this same data will help to advance science and to create supporting evidence for the development of better health policy.
- b) **Provide full control and ultimately full portability to patients of their outcome data:** patients’ full control of their data is a fundamental principle of this project. To be practical we envision a staged approach whereby patients will have full access to the PROs from the start even if they move hospitals etc. and proceed towards full portability of all their health data ultimately.
- c) **Promote trust through an ethical governance of health data:** Develop an ethical governance model, with input from patients, for the collection and management of health outcome data in order to secure trust with the society and patients while allowing ethical access to this data for the benefit of science, health policy and patients.
- d) **Ensure an ethical framework around access to health outcome data to advance science and health policy while respecting patients’ rights to control their data:** allow bona fide stakeholders with a legitimate interest to have access to the data, subject to an appropriate process and in a sustainable manner, and in compliance with the ethical and legal requirements agreed in the H2O governance model, in order to advance science and improve healthcare management and delivery.
- e) **Create an ecosystem open to all healthcare providers and patients** that creates the right incentives for all stakeholders to ensure interoperability among health data sets and allows the use of technology to analyse outcomes sets by all bona fide researchers;
- f) **Create transparency of outcomes to advance Value Based Health Care:** Encourage transparency of outcomes¹ in order to promote Value Based Health Care and encourage society, HCPs, and all stakeholders to make evidence- based decisions on how to manage healthcare.
- g) **Support evidence-based decisions on health policy:** Publish regularly comparative reports on outcomes to promote best practices and advance science and health policy in the interest of society and patients.

Annex 2 – H2O Governance principles

While the mission statement states what we are going to do, the principles behind how we do this are outlined in the H2O governance principles. The H2O Consortium has agreed nine governance principles:

Principle a: we will set up one Health Outcome Observatory per country.

Each observatory can support several disease areas. They will be local, not for profit entities with a supervisory multi-stakeholder Board comprising representatives from all key stakeholder constituencies enumerated below. Each constituency will appoint one Board member and all Board members will have equal voting rights. The constituencies represented within the Board are:

- a) Society overall (key representative could be appointed by the government)
- b) Patient Organisations
- c) Medical Professionals
- d) Regulatory Agency and/or HTA authority
- e) Private sector (Life science industry, healthcare consultancies etc.)

The Board will appoint the management structure.

Principle b: The Health Outcome Observatories will only be truly impactful if there is consistency in the measurements, the possibility to make comparisons, the ability to conduct analysis on large data sets, but also and most importantly, strong trust in the Observatory by society overall and by stakeholders, including patients, citizens, regulators, HCPs, researchers, and industry.

To ensure this consistency, standardization and harmonization, there needs to be a forum and a process where all national Health Outcome Observatories agree on a level of standardisation, on methodologies for measurement of outcomes, on the technologies to ensure data security and integrity but also on the code of conduct for the Observatories towards various stakeholders. Interoperability among the Observatories, consistency in measurement and strong trust in the code of conduct of the Observatories are important prerequisites in order to allow for research and analysis across countries. This will be the role of the pan-European Observatory that will be set up as a separate entity to be the guardian of the Health Outcome Observatory Vision and Mission.

The relationship between the pan-European Observatory and the National Observatories will be governed by a Constitution (Incorporation) Agreement.

Principle c: the emphasis of H2O is to enable patients to measure patient reported outcomes (PROs). However, the value of the data not only for individual patients and their clinicians but also for health policy and scientific analysis will be significantly enhanced if the H2O tools also incorporate an extract of important clinically captured outcomes.

To achieve this, the Health Outcome Observatories will focus on creating an ecosystem whereby healthcare providers beyond the founding members are encouraged and incentivised to

participate in order to allow their patients to access clinical outcomes through the same tool. An important focus area for the Observatories will be to work with other partners such as the EH DEN (European Health Data and Evidence Network) consortium, the Data Saves Lives initiative led by the European Patient Forum, public sector entities or additional stakeholders to promote the adoption of a federated approach to data analysis in order to create an interoperable environment and remove technological barriers.

Principle d: Health Outcome Observatories will only succeed if there is sustainability in the model while at the same time a robust and ethical governance model for access to data that will build trust with patients and society.

To ensure sustainability, observatories will need stable income streams. To this end, the Observatories will consider various possible innovative funding models including a subscription and/or sponsorship model to entities interested in the anonymised health data for scientific or health policy research as well as appropriate fee structure for supporting researchers in full research studies. Other novel funding models will also be explored by inviting all stakeholders to look for solutions to the debate about access of health data. There will be different fee structures for different types of stakeholders and consistency in the approach among all Observatories including the pan-European Observatory. The Ethical Council of the pan-European Observatory will assume the overall oversight of the model and will publish appropriate instructions regularly.

The Observatories will also introduce terms and conditions to make it interesting for additional partners including registries, additional healthcare providers, patient organisations etc. to join the H2O ecosystem in order to allow ethical health outcomes analysis on a larger scale.

Principle e: Health Outcome Observatories need to ensure that patients receive clear value from the Observatory, consent to the data collection and are fully appreciative of the scope and objectives of the Observatories.

An important priority for the H2O project will be to provide to individual patients the possibility of a dashboard with personalised information on their disease progression, treatment and outcomes in order to allow them to have better discussions with their HCPs. Each individual patient will be able to compare his/her well-being with aggregated data from similar patients with the goal of empowering the patient on his/her journey to better outcomes and better care. With the patient's consent, the relevant healthcare provider will also receive the patient reported information, allowing for a 2-way engagement between patient and healthcare provider on continual improvement of individual care.

To achieve this, the H2O Observatories will have to develop patient consents in line with national laws and regulations and to sustain continuous communication with patients in order to ensure strong patient engagement in the project.

This project will only succeed if patients, as well as other stakeholders, embrace it as a useful approach to improve their communications with the healthcare ecosystem. Patient support is also needed to strengthen the ability of patient advocacy groups to engage in evidence-based advocacy and also contribute to further scientific research in their disease or related health issues.

Thus, it is critical for the Observatories to work closely with the patient community and build a strong relationship of interdependence and trust.

Principle f: Health Outcomes Observatories will publish regular reports on the status of outcomes in the various diseases in order to promote transparency of outcomes, to support the health authorities in managing healthcare, and to advance science in the disease areas of focus

One of the key objectives of the Observatory is to encourage transparency of health outcomes in order to allow for better health policy. It is thus important that this becomes an integral part of the project and appropriate resources are being allocated to make sure that reports are being regularly published both with scientific rigour and also in a language understood by the broader public.

Principle g: Health Outcome Observatories will leverage technologies in order to collect patient reported outcomes and will create an ecosystem that encourages state of the art solutions for patients

Technology innovation moves fast and it is important to ensure that the best possible solutions reach the patients. To this end, the H2O aims at creating an ecosystem that stimulates innovation and fair competition in possible technological solutions for patients while at the same time ensuring standardization in outcomes measurement and ethical governance of any health outcome data.

Principle h: The ultimate objective of the H2O is to measure outcomes in all disease areas, including co-morbidities. However, there is a need for prioritization in order to decide on the roll-out. Decisions on prioritization will be made within the pan-European Observatory in collaboration with experts and the national Observatories in order to ensure consistency of measurements going forward

In the short term, the project team will identify the next disease areas for H2O in a pragmatic manner. Moving forward, these decisions will be made through the governing bodies set up by the Umbrella Observatory with the participation of all National Observatories. Ensuring the consistency in measurements is a critical prerequisite for success and as a result, these decisions would need to be taken through a rigorous and robust process.

Principle i: The Observatories will focus on measuring outcomes according to internationally accepted standards of health outcomes (both what to measure and how). Where no standards exist, the Observatories will introduce and commission an objective process for creating such standards

The H2O intends to collaborate with existing standardisation organisations such as the International Consortium for Outcome Measurement (ICHOM) or other initiatives in order to build on prior work and expertise. Furthermore, the H2O will introduce a methodology and a process to ensure co-creation with multiple stakeholders, including health authorities, HCPs, patients and patient groups, to ensure broad acceptance of outcome measurements.

Annex 3 – Characteristics of the Constitution Agreement

An umbrella observatory will be established to ensure consistency and comparability in outcome measurements but also in the overall policies, code of conduct and operations of the network of national observatories. This will be a pan-European body initially, but its structure and organisation will be established to allow it to cover all observatories following the H2O mission and governance principle, wherever in the world they are.

Like the national observatories, the umbrella observatory will also be established as an independent, not-for-profit body, and with the scope to conduct revenue raising activities in order to be financially sustainable. The aims of the umbrella organisation are to:

- build a community of patient-centric and outcomes-driven organisations based on transparency and trust to function as a common repository for reports, analytic tools and educational material in connection with national health outcome observatories;
- manage consistency and interoperability across national health outcome observatories and to support the creation of health outcome observatories in other countries in Europe (initially);
- act as a catalyst for future growth of the network of national health outcome observatories; and
- facilitate interoperability, guide reproducibility in other countries, avoid fragmentation using a federated data management approach and promote the benefit of measuring and using outcomes at regional, national, European and global levels.

The organisation of the board of the umbrella observatory will adopt the following representation structure:

- Equal representation of national observatories (60%);
- Representative of patient organisations (20%); and
- Representation of HTA agencies/regulators (20%).

A detailed Constitution Agreement for the umbrella observatory is currently being drafted. This Agreement will not only define the relationship between the national and umbrella observatories, but will also outline a code of conduct covering, amongst other things, the use of and access to data in the network.

Based on a preliminary analysis of the potential legal organisation of the umbrella observatory and the national observatories, we have identified the Association as the most appropriate legal form with the following advantages:

- An Association is a not-for-profit organisation that can use various financial flows, including grants, to be sustainable;
- An Association is an organisation with limited liability, that offers its members protection from personal liability for the activities of the Association;

- The articles of association will reflect the governance model and be compatible with the project principles
- New members can be included easily and the Association can expand as needed;
- In general, formalities are straightforward and registration is simple
- The articles of an association can reflect our agreed Governance Principles. They can include different 'blocs' of stakeholders with separate voting rights (as in Principle a), for example) and allow the multi-stakeholder participation that we would like to achieve in the observatories.

New organisations will be eligible to join the H2O network of national observatories. The umbrella observatory will be responsible for any decision on whether to accept a new member based on the following criteria:

- The organisation is, or will be, an independent, not-for-profit entity;
- The board of the organisation is constituted in line with Principle a) in Annex 2 above;
- The board of the organisation formally adopts the governance principles in Annex 2 above;
- The organisation adheres to the Constitution Agreement agreeing to:
 - safeguard the comparability and consistency of outcome measurements in the interest of patients, society and science.
 - adopt the Code of Conduct that is part of the Constitution Agreement and safeguards how the Observatories handle health data in the interest of patients, society and science.
 - become a valuable contributor to the governing bodies of the Umbrella Observatory and contribute scientific and health policy expertise in order to advance the mission of the Observatory.
- A plan, agreed between the new organisation and the umbrella observatory, is in place. This plan will cover the establishment and growth of the new observatory, including the commitment of at least one major academic hospital to be an active partner in the new observatory;
- The organisation agrees to adopt the technology standards of the H2O network, including for example a common data model (such as the OMOP Common Data Model), the FAIR data principles and interoperability standards such as HL7 FHIR.

Existing members of the H2O network will be required to continue to adhere to the criteria above. Where an existing observatory fails to meet the criteria, the umbrella observatory will be responsible for deciding on remedial measures including, if necessary, expulsion from the network. The process and criteria for sanctions and ultimately, termination, will be outlined in a subsequent H2O Deliverable.

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