945345 – H2O

Health Outcomes Observatory

WP1 – Governance, Sustainability and Capabilities

D1.1 Observatory business architecture

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Document History

Version	Date	Description
V1	01/03/2021	First Draft
V2	18/03/2021	Second Draft
V3	07/04/21	Final Version

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Definitions

- **Participants** of the H2O Consortium are referred to herein according to the following codes:
  1. MUW. Medizinische Universitaet Wien
  2. Charité. Charite – Universitaetmedizin Berlin
  3. EMC. Erasmus Universitair Medisch Centrum Rotterdam
  4. ICS-HUVH. Institut Catala De La Salut – Hospital Universitari Vall d'Hebron
  5. KCL. King's College London
  6. KUL. Katholieke Universiteit Leuven
  7. EPF. Form Europeen des Patients / European Patients' Forum
  8. I-HD. The European Institute for Innovation through Health Data
  9. The Hyve. The Hyve BV
  10. TEAMIT. TEAM IT Research SL
  11. KUH. Karolinska Universitetssjukhuset
  12. UniSR. Universita Vita-Salute San Raffaele
  13. IKNL. De Stichting Integraal Kankercentrum Nederland
  14. TAKEDA. Takeda Pharmaceuticals International AG
  15. NVS. Novartis Pharma AG
  16. ABBVIE. AbbVie INC
  17. Lilly. Ali Lilly and Company Limited
  18. MDT. Medtronic International Trading SARL
  19. Pfizer. Pfizer Limited
  20. ROCHE. F. Hoffman-La Roche Limited
  21. SARD. Sanofi-Aventis Recherche & Development
  22. JDRF. JDRF International
  23. Trial Nation. Trial Nation

- **Grant Agreement**. (Including its annexes and any amendments) The agreement signed between the beneficiaries of the action and the IMI2 JU for the undertaking of the H2O project (Grant Agreement No. 945345).
- **Project**. The sum of all activities carried out in the framework of the Grant Agreement.
- **Consortium**. The H2O Consortium, comprising the above-mentioned legal entities.
- **Consortium Agreement**. Agreement concluded amongst H2O participants for the implementation of the Grant Agreement. The agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.

Abbreviations

Acronym / Abbreviation	Meaning
CPRD	Clinical Practice Research Datalink
DMP	Data Management Plan
EHDEN	European Health Data and Evidence Network
FAIR	Data principles of Findability, Accessibility, Interoperability, and Reusability
HL7 FHIR	Fast Healthcare Interoperability Resources created by the Health Level Seven health care standards organisation
HCP	Health Care Provider
HTA	Health Technology Assessment
H2O	Health Outcomes Observatory
ICHOM	International Consortium for Health Outcomes Measurement
KOL	Key Opinion Leader
OMOP	Observational Medical Outcomes Partnership
PRO	Patient Reported Outcome
PROM	Patient Reported Outcome Measure
RWD	Real World Data
RWE	Real World Evidence

Abstract

The observatory business architecture outlines the initial design of the national and umbrella observatories, together with the principles behind that design. The business architecture covers organizational matters and is complementary to the technical architecture for the observatory network.

The six components of the business architecture include: the mission statement and governance principles (already agreed by the Steering Committee); the legal structure for the formation of the observatories and the network of observatories; a summary of the first version of the data management plan; the organizational characteristics of the observatories; and an outline of the approach for the observatories to be sustained beyond the IMI funding period.

As these aspects of the business architecture are still being developed, this document captures agreement on the approach so far and reflects work in progress to date. Future deliverables will elaborate on this reference document.

1. Introduction

The H2O project will equip patients with tools to measure their outcomes in a standardised way, whilst giving them full control of their data. This is the first-ever attempt at scale to collect and incorporate patient outcomes into health care decision making at an individual and population level.

The H2O project will set up an independent, not-for-profit, entity – an observatory – in each of four European countries, covering three disease areas, initially. These entities will provide information for individual patients and their healthcare providers for use in clinical care. Data for both perspectives - at individual level and at population level - will provide meaningful insights to better inform health care decisions which will ultimately strengthen value based health care systems and will deliver better outcomes for all.

The observatory business architecture covered in this deliverable outlines the initial design of the national and umbrella observatories, together with the principles behind that design. The business architecture covers organizational matters and is complementary to the technical architecture for the observatory network. The scope of this document encompasses six fundamental aspects:

- The mission of the network of observatories;
- The governance principles underpinning the establishment and running of observatories, including the initial observatories and any subsequent observatories included in the network;
- The legal structure for the formation of the network and the observatories;
- A summary of the flows of, and access to, data in the network;
- The organisational characteristics and capabilities of the national and umbrella observatories; and
- The approach to ensuring the network and the observatories are sustained, both financially and non-financially, beyond the IMI funding period.

This document covers work undertaken by WP1 but also references work being undertaken by other WPs, notably WP2 and WP6. While the mission and the governance principles (the text in S3.1 and S3.2 respectively) have been agreed by the Steering Committee, the material in the subsequent sections (S3.3 – S3.6) summarises the outcome of activities conducted to date and is, therefore, still work in progress. Once finalised, this work will be reported in future deliverables.

2. Methods

Drafts of the mission (Section 3.1) and governance principles (Section 3.2) were prepared by WP1 and shared with other WPs in November 2020. A final draft was reviewed by the H2O Steering Committee and endorsed on 28th November 2020.

Text for Section 3.3 summarises work done by a sub-group of WP1 and outlines the principles that have been developed for the legal structures.

Similarly, the text for Section 3.4 summarises the design work for the data management plan and incorporates input received from other WPs, notably WP2.

The material in Section 3.5 outlines the capabilities that will be required in the national and umbrella observatories. This is work in progress and details will be elaborated as the business models for the observatories are developed within WP6.

Section 3.6 summarises the work conducted jointly by WP1 and WP6 to date. More detail on the methods that have been developed to build the sustainability approach, D1.7 due in M18, is given in D6.12, also being delivered at M6.

In summary, while Sections 3.1 and 3.2 represent final work products, the work documented in Section 3.3 to Section 3.6 report work in progress.

3. Results

This section provides detail on the six components that make up the observatory business architecture, namely: the detailed mission statement; the governance principles; the legal structure; the flows of and access to data in the network; the organisational characteristics and capabilities; and the approach to sustainability of the network.

3.1. H2O Mission

As outlined in the Stage II proposal (p28), 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*". In order to provide more detail, and to provide the context for the governance principles, WP1 elaborated on this summary statement and produced an expanded version that, after small revisions, was accepted by the Steering Committee.

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 Healthcare:** Encourage transparency of outcomes [1] in order to promote Value Based Healthcare 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.

3.2. 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. We have 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.

[1] Outcomes will be aggregated at a geographic level that the stakeholders are comfortable with. This level might evolve with the expansion of the project.

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 standardization, 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 Umbrella 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 Umbrella 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 incentivized 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 EHDEN (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: the 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 access to anonymous 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 Umbrella Observatory. The Ethical Council of the Umbrella 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 outcome 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 Umbrella 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

It will be important for the Observatories to set up a robust process for the selection and adoption of these standards in a way that these standards become part of the broader health ecosystem and are respected by HCPs, health authorities, patients etc. The H2O intends to collaborate with existing standardization 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.

3.3. H2O Legal Structure

As outlined in the principles above, the observatories will be established as national, independent bodies. One observatory will cover all disease areas: there will not be separate observatories for different diseases. The constitution of the board of each national institution will follow from Principle a) above. We have proposed the Association as the most appropriate legal form (see rationale below) and this is currently under review at country level.

In addition, 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 organization will be established to allow it to cover all observatories following the H2O mission and governance principle, wherever in the world they are.

The umbrella observatory will also be established as an independent, not-for-profit body, with the scope to conduct revenue raising activities in order to be financially sustainable. The location of the umbrella observatory will be decided by the H2O Steering Committee based on a set of criteria currently being drafted.

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) above;
- The board of the organisation formally adopts the governance principles in 3.2 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 Dx.x.

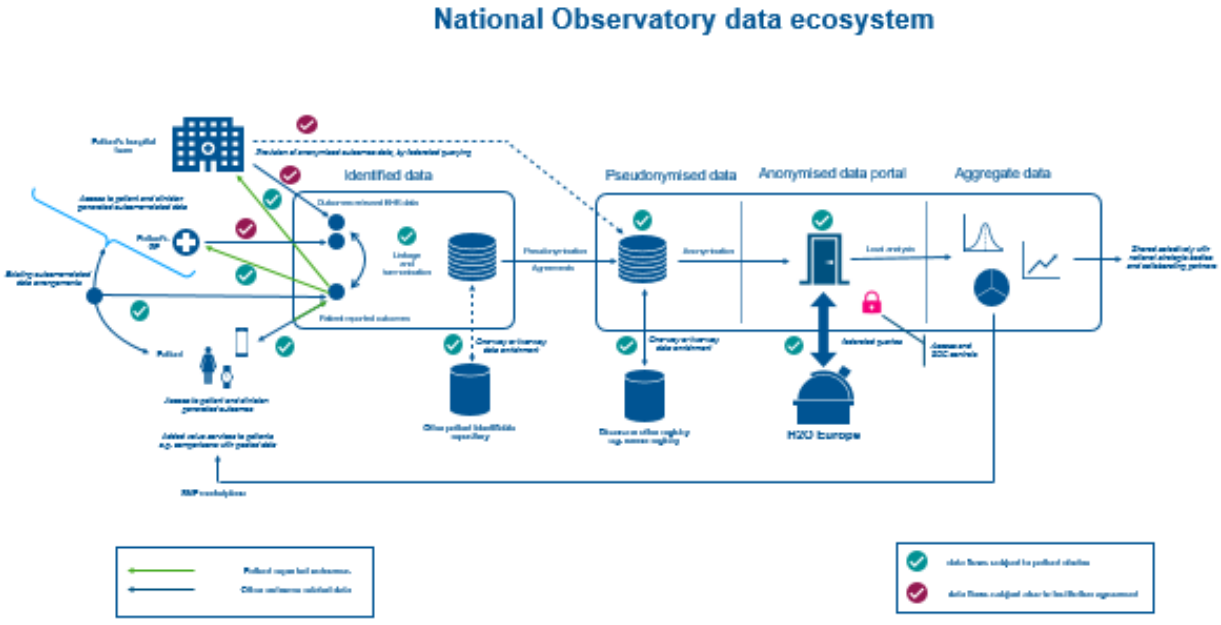
3.4. Outline of data flows and access in H2O

The following diagrams, based on work on the data management plan (Deliverable D1.2) conducted by WP1 and WP2, depict the main data flows expected in the observatory network. This initial design reflects the intended collection, storage, linkage and release of data (a corresponding diagram with consents is also being drawn up).

At the core of this is the prospective collection of data from patients using an app commissioned or developed by WP2 (note that it is intended that **PROMs recorded by institutions (or other parties) and supporting EHR data will be linked to make the PROM data meaningful**). This patient generated data will be held in an independent repository managed by the relevant national observatory. With the app, patients will be able to see a dashboard with their own data and comparisons to corresponding measures for patients with their condition as a whole (averages or medians, for example). In the early days, these averages are likely to be published figures or numbers agreed with key opinion leaders (KOLs); as the population covered by the H2O network builds, these comparator results will also include overall results from other patients in the H2O network.

Other organisations will be able to participate by providing information and accessing data. Initially, agreements will be made with participating hospitals to share an extract of each patient's clinical record, thereby enriching the data available per patient. With patient identifiers, and linkage skills based in the observatories, these data sources will be brought together in order that: an individual patient has a more complete picture of their treatment and health status; the patient's clinician will have a broader view of the outcomes of care; and hospitals participating in this 'eco-system' will be able to query the data themselves both for clinical and research purposes and, for example, enhance their ability to conduct RWD studies.

For the data flows in situation such as the last, agreements will need to be set up with participating hospitals for the creation of a system of linkages to match the patient generated data with the routine clinical data. Correspondingly, an individual clinician will always be able to access the data generated by their patient, provided the patient has given consent. More generally, based on the system of consents that will be proposed, access to data – identifiable, pseudonymous or anonymous – will be defined and created for appropriate users.

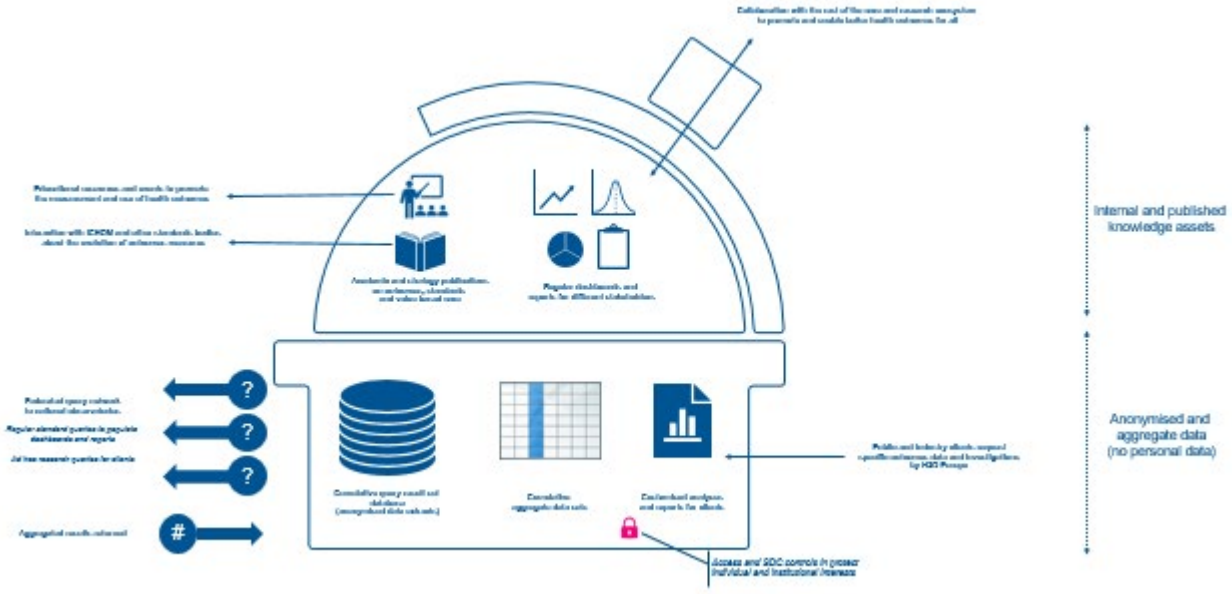


The umbrella observatory will play a complementary role to that of the national observatories. Broadly speaking, while the latter will be responsible for collecting, storing and linking data, and managing the individual consents, the former will play a larger role in access to the data for secondary use.

The umbrella observatory will primarily hold data that has been derived from its network of national observatories, through secure federated querying, which will give rise to aggregate data sets that the umbrella observatory will cumulatively store in order to provide the latest outcomes and outcomes-relevant insights and to be able to track trends over time.

It is expected that much of the demand for data and analytics of population-level, rather than individual-level, data will come through the umbrella observatory (the work described in D6.12 outlines how this demand for data and analytics will be evaluated over the next twelve months, for the sustainability plan). With the federated data model that has been put forward for H2O, flows of data and analytic queries will largely be managed by the umbrella observatory (though there will be the option for analyses by national observatories).

The umbrella observatory, therefore will play an important role in generating insights at a European level and with potential country specific or region-specific detail for more restricted audiences. Apart from providing specific insights, the umbrella observatory will also play an important role in promoting the value of outcomes measurement in general, and of the collection and use of outcomes information at different levels of granularity across different stakeholders.



3.5. H2O organisational characteristics and capabilities

Each national observatory will be an independent, not-for-profit organisation, led by a board constituted according to governance principle a) above. The board will be responsible for overseeing the activities of the observatory and will appoint a team of staff to manage the operations of the observatory. While the make-up of teams may differ across national observatories depending upon national focus, workload, budget etc, it is expected that the following functions would be included:

- A managing director reporting to the Board and responsible for the finance and operations of the observatory;
- An Ethics Officer reporting directly to the Board
- Health professional staff to respond to patient requests and queries;

- Data engineers and scientists responsible for curating the data; managing the anonymisation and pseudonymisation processes; data linkage; and conducting analyses on the national data;
- Support staff, including legal, IT, finance and administrative staff

Some capabilities will be able to be shared or centralised at the umbrella observatory level. Some activities may be outsourced depending on demand.

At the umbrella observatory level, it is expected that the following functions would be included:

- A managing director responsible for the finance and operations of the umbrella observatory, reporting directly to the board of the umbrella observatory;
- Chief Ethics Officer reporting directly to the Board and also chairing the Ethics Advisory Board;
- Chief Scientist (who would also chair the Scientific Advisory Board);
- Chief Patient Officer (who would also chair the Patient Advisory Board);
- Chief Technology Officer;
- Chief Methodologist who will also coordinate the team of data scientists and engineers for data management, analytics, standard reporting, scientific advice etc.
- Chief Communications Officer;
- Support staff including legal, IT, finance, administration, marketing etc.

3.6. Approach to H2O sustainability

Our aim over the period of the project is to create the conditions for, and then promote, the sustainability, adoption and expansion of the network of H2O observatories. Broadly, we will do this by designing and implementing a strategy addressed to promote a) the broad use and take-up of services including, for example, analyses, access to data for research, capabilities for research studies) and outputs generated by the Observatories (tools, reports, etc.) and b) to expand the Observatories at the internal level (increasing the number of centres providing data) and at the external level (promoting and supporting the creation of new observatories in additional countries and additional disease areas.

WP1 is working with WP6 to develop a plan and initial concepts for an “H2O sustainability roadmap”. This sustainability roadmap distinguishes a “demand side”, which examines the stakeholders who need to, or could be encouraged to, gain value from outcomes from the H2O observatories, and for which they are likely to be willing to pay, from a “supply side” of stakeholders that is critical to providing, or facilitating the provision of, patient data and complementary clinical data to the H2O network. Note that the supply-side is not envisaged here only as passive data providers, but actors who also gain value from the outcomes data.

More detail on developing the sustainability roadmap is given in D6.12. That document presents an initial qualitative analysis of the demand side and supply side perspectives and explains how each of these will be investigated in more detail in the coming months. The sustainability plan will progressively shift from qualitative interview and survey style intelligence gathering to quantitative business modelling in which projected costs and projected revenues will be quantified. The deliverable is therefore the start of a process which will continue throughout the project duration and be periodically reported in later deliverables.

Income for the network is anticipated from a number of sources, including commercial organisations, governments, researchers and patient organisations. It is anticipated that income will be generated by H2O products and services that could include the following, as examples:

- Standard analyses, regularly performed across countries, of current outcomes, and trends in outcomes, linked to relevant clinical data items for each of the disease areas. Eventually these could be disaggregated to smaller geographical levels though not to the level of individual healthcare providers. These could be offered on a pay to access individual analyses, or based on a subscription for regularly published updates and novel analyses;

- Access to anonymous data sets, which would be curated by the umbrella observatory and made available for query analysis by customers, for example to profile patient outcomes when designing a research study such as a trial protocol, platform trials, rare disease studies;
- Access to anonymised data sets that have been robustly checked, mirroring the model of current providers such as CPRD in the UK, for example. These might be used as RWE data sets by a client e.g. to set up a control arm for a single arm clinical trial;

- Bespoke analyses and reports undertaken by H2O on behalf of clients (with the results to be privately owned by each client);

- The use of H2O as a platform, rather than as a source of existing data, eg to invite patients to participate in other studies, or to recruit subjects for a prospective observational or interventional studies, and collect data for such a study;

- The use of H2O as a platform for tracking and assessing value-based contracts (ie with the observatory acting as a trusted party to generate evidence for value-based contracts);

- Certification programmes for products and services that collect or process outcomes data, in order to ensure a high-quality and interoperable end to end outcomes data ecosystem, starting from the patient and healthcare provider.

Depending on the nature and extent of these income-generating services offered, the investment required would differ. Funds for these investments at the level of the national observatory, following the end of the IMI funding period, could come from the above sources – either directly or indirectly via the umbrella observatory – or from other sources, eg public grants.

…

4. Conclusion and next steps

This document encompasses key aspects of the business architecture of the observatories. As these aspects of the architecture are still being developed, the document reflects agreement on the approach so far and work in progress to date.

Future deliverables will elaborate on this reference document. The first version of the Data Management Plan (D1.2) provides more detail on Section 3.3 above and will be followed by a second version in M30 (D1.9) and a final version in M54 (D1.11).

A “blueprint” or manual for observatories based on the business architecture and on other outputs from the WPs will be developed: this will subsequently be submitted as a manuscript by M24 (D7.4).

Work on sustainability will continue throughout the life of the project. Section 3.6 summarises the work conducted jointly by WP1 and WP6 to date. More detail on the methods that have been developed to build the sustainability approach, D1.7 due in M18, is given in D6.12, also being delivered at M6.