945345 – H2O

Health Outcomes Observatory

WP6 – WP Observatory management: communication and analysis

D6.12 H2O exploitation and sustainability strategy

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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.
- **Data enabled service providers** (DESPs) In the context of H2O DUs can be Analytics service providers, including the EU-H2O as well as the data holders and patients.
- **Data Governance Act** (DGA)
- **Data Holder** (DH): legal person or data subject who, in accordance with applicable Union or national law, has the right to grant access to or to share certain personal or non-personal data under its control (ref: DGA)
- **Data Sharing (DS):** the provision by a data holder of data to a data user for the purpose of joint or individual use of the shared data, based on voluntary agreements, directly or through an intermediary (ref: DGA)
- **Data Sharing Services** (as defined in Article 9 of the draft DGA)
- **Data Sharing Service Provider (DSSP):** legal persons in the meaning of Article 9 of the DGA proposal, operating under the conditions defined in Articles 10 and 11(H2O)
- **Data Subject:** identified or identifiable natural persons. People from whom or about whom information is collected in connection with an operational objective (ref: GDPR)

- **Data User (DU):** a natural or legal person who has lawful access to certain personal or non-personal data and is authorised to use that data for commercial or non-commercial purposes (ref: DGA)

Abbreviations

AI	Artificial Intelligence
BB	Building Block
CPRD	Clinical Practice Research Datalink
DGA	Data Governance Act
EHDS	European Health Data Space
EHR	Electronic Health Record
EU	European Union
FAIR	Findable, Accessible, Interoperable, and Re-usable
GDPR	General Data Protection Regulation
GP	General Practitioner
H2O	Health Outcomes Observatory
HTA	Health Technology Assessment
ICT	Information and Communications Technology
IMI	Innovative Medicines Initiative
IoT	Internet of Things
KPI	Key Performance Indicator
MS	Milestone
NGO	Non-governmental Organisation
OECD	Organisation for Economic Co-operation and Development
OMOP	Observational Medical Outcomes Partnership
PREMs	Patient-reported experience measures
PROMs	Patient-Reported Outcome Measures
PROs	Patient-Reported Outcomes
RWD	Real World Evidence
RWE	Real World Data
SME	Small Medium Enterprise
S-MS	Sustainability Milestone
WHO	World Health Organisation

Abstract

This document presents the plan and initial concepts for the H2O sustainability roadmap. Sustainability is vital for the H2O Observatory network and needs careful planning because of the innovative nature of the ecosystem it is creating. This innovation focuses on providing the capability for multiple stakeholders to gain insights relating to health outcomes that can inform decision-making across a broad scale ranging from individual patients through to multinational policy-setting organisations like the WHO and OECD, spanning direct care to individuals, care planning and optimisation, public health and health strategy, research and health technology innovation. The mission of H2O is especially challenging because the raw material, the utility, on which it depends barely exists today. Health outcomes are not well collected, and it is critical for sustainability that H2O encourages and fosters the scale up of outcomes data collection and delivers value from outcomes data to the actors close to the patient - who are critical to encouraging that scale up.

As a consequence, this sustainability roadmap distinguishes a “demand side”, which examines the stakeholders who need to, or could be encouraged to, gain value from outcomes insights, and for which they are likely to be willing to pay, from a “supply side” of stakeholders who are critical to providing, or facilitating the provision of, outcomes and complementary clinical data to the H2O network - so that it can deliver its value to the demand side. The supply-side is not envisaged here only as passive data providers, but actors who also gain value from the outcomes data. These supply-side actors would not be expected to pay for outcomes insights but would access such analytics as part of their in-kind (circular) value chain that incentivises good quality and large-scale outcomes data provision. An important goal for H2O is to strengthen the relationships between patients and their clinical teams on the basis of a shared motivation and objective capability to maximise outcomes.

It is important also to emphasise that H2O itself, manifested as national observatories and a co-ordinating European Observatory, will operate as a fully not-for-profit network of entities. They will not seek to “sell data” but to charge for value added services on top of the outcomes data, which would be its revenue base for its operations.

This 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. At the same time, as the delineation of activities across the national and EU level observatories, in compliance to the Data Governance Act (DGA), will become more and solid, this will allow for precision in the business modeling and the respective cost and revenue calculations.

This deliverable is therefore the start of a process which will continue throughout the project duration and be periodically reported in later deliverables.

1. Introduction

1.1. General Considerations

H2O has been conceived as an endeavour, focusing on patient reported outcomes, in a way that it can create a continuum from patient care all the way to research and the creation of new knowledge and innovations. This is achieved through appropriately and concurrently incentivising and serving a rich ecosystem, leveraging on patients' active participation, which powers a virtual network of data providers and data consumers, who all harvest value across the H2O Data Value Chain. What is eventually delivered as value is augmented intelligence injected into the patient - health professional collaboration, the health care systems and the research and innovation sectors. This is generated through the collation and synthesis of evidence and new knowledge from an invaluable supply of individual and population level patient reported outcomes, uniquely linked to their clinical data, that can be aggregated at individual and population levels, both nationally and across Europe.

Recent explorations into the high priority EU policy area of the European Health Data Space (EHDS) as part of the pan-sectoral European Data Space, indicate that the fundamental H2O concepts hold the potential of being exemplary of a sustainable data value chain, through:

- maximising patient and citizen empowerment, by giving a voice to patients to define value in healthcare and giving them control on their health outcomes data;
- optimising subsidiarity between the national and the EU levels, primarily by means of mutualising international high-level expertise, infrastructure and data resources; and
- demonstrating how value is returned to individuals, professionals, the health and innovation sectors and society as a whole in a concrete and transparent way.

H2O is well positioned to influence the legal and infrastructural enablers at EU level. It will subsequently enjoy the benefits of increased legal certainty and harmonisation across its different countries. It will also benefit at the EU level from secure, trusted and as appropriate regulated infrastructures (including cloud and AI) that it can leverage to deliver to maximum value in a sustainable and cost-effective way.

It is important to mention that, at this stage, the business model and operational design of the national and EU level observatories have not yet been finalized. The Digital Governance Act (DGA), although still under consultation, provides for the essential legal foundations for building the data sharing infrastructures of the observatories, and the data value chains presented in section 3.4 envisage a separation of roles between the national and EU observatories, as well as potential external partners that can be mapped to the current DGA proposal. Further analysis, over the next period and in several WPs is expected to allow for the elaboration of the business, operational and cost models for the observatories by the end of the first project year, as shown in chapter 5.

Given this uncertainty, in this document we often refer to the "H2O ecosystem" to reflect the totality of operational structures and (national and EU) legal entities on the supply and on the demand side, that will bring to fruition the H2O vision, in compliance with the applicable legal and EU governance framework.

The primary audience of this document is the project consortium and its main aim is to reflect the current vision for sustainability and to support its continuous development and evolution. This vison is expected to be progressively informed by additional information from the supply and demand side

partners and eventually from the national observatories and the prospective audience towards which scalability will be pursued progressively during the project.

The main goals of this document are to consolidate the overarching sustainability concepts that have been discussed within the consortium and developed over the past few months in several work areas of H2O; to build on these explorations and intelligence collected from partners and partners' networks and to substantiate realistic yet ambitious sustainability strategies to be further validated over the next 2-3 months. This will therefore be a living document, which will be regularly updated and maintained as an internal project resource.

The following two chapters, 2 and 3, each focus on the characteristics of the data demand and the data supply side, respectively. The "Demand Supply side" has been treated here with a view to income generation that will be used to power the critical operations of the national and EU Observatories. It is important to note that what is described here as a "Data Supply side" is not a passive supplier of data but an active community of patients and clinicians that both generate and consume data, that is returned to them in the form of data derivatives of added value (e.g. linked and harmonised) and with information derived from population level analyses to support clinical decisions and patient choices. Data supply side also includes public healthcare providers and public health authorities as a whole.

It should be however noted, that while the private sector demand side is rather homogeneous across Europe in terms of its needs and data acquisition practices, the organisation of health care systems is highly diversified across Europe; hence, the assumption made in this document, concerning the payer role of the public health policy sector in the demand side will not apply to all situations and it will need to be investigated on a country-by-country basis, initially for the countries of the consortium and subsequently the rest of Member States.

This analysis, which is initially being undertaken qualitatively, will be formalised within the relevant workstreams of the project with a view to capturing the needed information for structuring quantitative demand and supply models, around the envisaged H2O products and services (and their disease-oriented specifications) that will be offered nationally and at EU level. These quantitative assessments should be capable of predicting the capacity of the data supply at any time, to respond to demand as well as its capacity to scale, also to confirm which are the most critical parameters for achieving such levels.

Chapter 4 establishes the integrated picture of sustainability challenges and strategies, based on our best current knowledge of the H2O internal and external environment; it offers an accompanying list of guiding questions that need to be addressed across the work packages, to their appropriate scope and relevance over the different stages of the project life-cycle. Finally, chapter 5 draws a Sustainability Roadmap from the present stage to actually delivering actionable and specific 3-year business plans by M36 of the project, which considers the main sustainability milestones within those of the project workplan including a fine level analysis of the relevant work up to the end of 2021.

1.2. Sustainability Objectives

From the outset, this project has been designed as an effort to create an ecosystem that will create true patient empowerment and will have a catalytic influence on healthcare systems. An equally important goal is that value of data, collected during the care process is maximised through its re-use in creating new knowledge and supporting innovation. Eventually, monetary value from the further use

of this data should be used to ensure the financial sustainability of the Observatory ecosystem outside of any IMI support, hence powering a virtuous cycle that can continuously deliver value to healthcare systems and to society as a whole.

As a consequence, and though this will be a not-for-profit multi-entity network, it will need to sell products and services (data derivatives), provisionally defined in section 2.2.1 to a diversity of public and private customer organisations to generate its necessary income for operations and growth.

It is presently envisaged that the vast majority (estimated to be around 70%, but to be validated in practice) of these sales will be on the basis of multi-country, initially European level, outcomes data and analytics services, provided by the European Observatory, although some customers will be attracted to information within a single country, probably marketed and sold by the relevant national Observatory, depending on the business model of the observatory adopted by each country. The governance and business relationships between the European and the national observatories is the subject of other deliverables being developed in parallel to this one, which formalise how these entities will collaborate, share opportunities, share data, share responsibilities and share revenue streams.

This long-term vision is critically dependent upon securing a constant and high-quality trusted flow of PRO data provided primarily by patients; concurrent patient enabled access to clinical data would enrich the data sets and increase their potential subsequent exploitation in the digital value chain. It is however important, for this critical resource to be exploitable, that the data is of sufficient quality and readily re-usable for current and future use-cases. The challenge is therefore not only to secure an adequate data supply but also data of the required quality, re-usability, variety, granularity and generally fit for the purpose of addressing a broad spectrum of multi-stakeholder needs of the current and emerging demand within the knowledge areas served by the EU and the national observatories.

2. Market analysis plan for the demand side of H2O

2.1. Objective

An important part of the sustainability strategy is to better understand the products and services that each customer segment would be most interested in (willing to pay for), to understand their motivational factors (including any role that H2O can play to help ensure that they get the best possible value out of our products and services) and what alternatives exist or might exist to our solutions that we need to be mindful of (potential competitors). This section outlines the proposed methodology for undertaking the qualitative market analysis, which is the demand side, and which will be the predominant income stream to sustain the H2O Observatory network.
It will be important to map out, or at best estimate, the capacity available from each of the stakeholders of the demand side for accessing the services and products offered by H2O. A system wide analysis will preclude any counterproductive, perverse or destabilizing effect on the national health systems and mitigate any risk to guarantee a benefit to the country health ecosystem and society at large.

The currently funded IMI project is regarded as a pump priming resource, as this project will cease to receive funds from the European Comission after 5 years and will need to find sustainable alternative sources of funding. Furthermore, ideally the network will largely become self-sustaining during the period of the five-year project, so that later project resources can be redirected from instantiation towards its growth and the generation of evidence of its value.

This market analysis will initially be undertaken qualitatively, but with a view to formalising a quantitative business model once we have assimilated this initial market understanding. The rest of this section summarises the methodology (work plan) that will be pursued in the coming months to develop this market evidence.

2.2. Market analysis plan

2.2.1. Developing sample products and services

In order to obtain realistic feedback from potential example H2O clients, it is necessary to provide illustrations of the kinds of products and services that they might be able to purchase or license through subscription. The first step is therefore to develop examples, using fictitious data or anonymised data from partner sites, of the main intended products and services that the Observatory network intends to offer. The priority will be to exemplify the services that would be provided for a fee, rather than other more general contributions that the observatories would make to the health and research ecosystems. These will only be examples, and when interacting with exemplary clients we will seek to elicit other possible products and services they would be willing to subscribe to or to pay for.

Notwithstanding differences across the different countries, the initial expectation is that income streams will be generated by products and services along the lines of the following: non exhaustive list examples:

1. Regularly performed analyses across countries of current outcomes, and trends in outcomes, linked to outcomes relevant clinical data items for each of the disease areas, potentially with drill down to smaller geographical levels yet excluding the level of named healthcare providers. These might be offered on a pay to access or a subscription model to regularly published updates and novel analyses.

2. Access to aggregated anonymized data sets, which would be curated by the European 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 (i.e.to query but not to take a copy of the data – see next item).

3. The ability for clients to request the conduct of queries that help to profile patient populations, potentially to specify a (virtual) cohort for which H2O could facilitate recruitment of patients for a prospective observational or interventional study, with recruitment and data collection run through one or more of the observatories.

4. Copies of anonymised data sets that have been robustly checked, mirroring the model of CPRD, for example. These might be used as RWE data sets by a client e.g. as a control arm for a clinical trial.

5. Bespoke analyses and reports undertaken by H2O on behalf of clients (with the results to be privately owned by each client). H2O might serve as a trusted party to generate evidence for value-based contracts.

6. 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.

The example material we prepare for the interviews should also include some examples of client needs (evidence gaps, decisions benefiting from outcomes knowledge, research queries, clinical trials eligibility criteria with outcomes data points etc.). These example needs should be mapped to our proposed products and services that would help to address them.

2.2.2. Defining the customer segments

H2O offerings may appeal to a wide range of public and private organisations and sectors, and this market analysis needs to canvass the attitudes and opportunities across as many of these as possible. (In business modelling terms these categories are called "customer segments".) A full inventory of the intended customer segments to survey will be developed in the coming weeks. An initial list of high-level categories is presented here.

Industry

- Pharma
- Biotech
- MedTech, health ICT
- Algorithm developers
- Data analytics companies
- Data brokers
- SMEs, especially app developers
- Consulting companies in the health and life sciences sectors

Public bodies

- Health ministries
- Health insurance
- Regulators, HTA
- Regional health authorities, healthcare provider networks
- National and multinational policy-making bodies (e.g. WHO, OECD)
- Healthcare professional associations
- Patient organisations other charities
- Academic research organisations and NGOs

Because of possible important national differences, it may be advisable for interviews to be conducted with health ministries in all four of the consortium countries, for some public stakeholders like patient organisations and academic research organisations it may not be necessary for these initial interviews to span all four countries. The precise decisions about whom to interview, and where, will be determined as an early step in the methodology.

2.3. Methodology

The organisations sampled through this analysis will deliberately be a mixture of multinational organisations, and national organisations within some or of the four countries in which national observatories will first be established. An inventory of candidate organisations and individuals will be compiled through pooled consortium network knowledge, and a target group of between 20 and 30 interviewees representative for each country will be prioritised from this inventory.

The initial customer stakeholder engagement will be through structured interviews, undertaken by members of the H2O sustainability team with an understanding of the stakeholder perspectives they will be interviewing. Once an initial body of insights has been gathered and synthesised, a wider online survey will be considered to validate the interview findings.

Contact names will be retained for follow-up:

- to periodically provide updates on the progress of establishing the Observatory network and its emergent product and service portfolio
- to re-consult with these interviewees, and with others on the inventory, to re-consult them with more concrete examples of Observatory products that have been developed from data at the consortium sites, and to more formally quantify their potential interest in terms of willingness to pay for why, and at what order of price magnitude.

2.3.1. Value propositions

In order to appropriately frame the interview with each customer segment, and initial value propositions for each segment should be defined these could be validated with each interviewee, in terms of their relative weight in influencing their interest in becoming H2O customers. Some example drivers that might be formulated as value propositions are illustrated below in Table I.

Table I: Value Created through the H2O umbrella observatory		
	Why would I pay for H2O data and analytics?	What might I specifically pay for?
Life sciences industry e.g. pharma, MedTech	• Calibrate value-based models, negotiate pricing • Evidence medicines (comparative) effectiveness • Design new clinical trial protocols • Obtain control arm data • Understand new treatment needs • Develop or refine tools to capture and analyse outcomes	• Subscribe to EU + national outcomes knowledge and updates • Commission customised outcomes research insights and queries • Pay for anonymised data sets • Co-fund H2O EU to establish new disease areas • ICT: pay for app accreditation
Researchers	• Discover research needs and opportunities • Leverage the H2O infrastructure for hypothesis testing, and to conduct research studies into needs assessments, comparative effectiveness, longitudinal studies, personalised medicine	• Subscribe to EU + national outcomes knowledge and updates • Commission customised outcomes research insights and queries • Pay for anonymised data sets
Healthcare payers, public health agencies	• Compare health system performance • Determine the evidence of value from care pathway innovations, compare pathways • Improve the quality, sustainability and resilience of health services • Better understand health needs and risks, burden of disease • Better target public health interventions and strategies • Outcomes-evidenced policy making	• Subscribe to EU + national outcomes knowledge and updates • Commission customised outcomes research and insights • Sponsor H2O EU to establish new disease areas
Regulators, HTAs	• Calibrate and set payments (reimbursements) using value-based models and outcomes evidence • Use PROs and PROMs to better evaluate treatment effectiveness	• Subscribe to EU + national outcomes knowledge and updates • Commission customised outcomes research and insights • Sponsor H2O EU to establish new disease areas
Policy bodies, EC, eHealth Network, WHO, OECD…	• Compare health system performance and inequalities • Evidence for policymaking • Identify topics for future research calls	• Subscribe to EU + national outcomes knowledge and updates • Provide grant funding through calls and instruments

2.3.2. Gaining understanding of the motivational factors

It will be important to understand from each of these customer segments why they would pay, what kinds of product and service they would most value, and how much they might be willing to pay and through what payment model. Examples of business value topics that will be developed as questions for the structured interview will include:

- What is their biggest need in terms of health outcomes data? How they would like to be able to access them, how often and under which terms;
- How important is it for them to access structured data (standardised outcomes) and what could be in their view the potential value of this offering;
- What analytics products and services the different customer segments would pay for (do they like our examples, would they buy them?)
- Why would the customer pay for our analytics services: what is the business value to them from our services (how will they use these insights? This will influence how much they may pay.)
- What is their present-day alternative to having our analytics (= competitors or barriers to our uptake) or access to data sets;
- What else do they need alongside our analytics to maximise their value (= possible dependence, possible strategic partnerships)
- What else apart from access to analytics currently inhibits them from getting maximum benefit from outcomes-oriented decision making (= potential lobbying)

2.3.3. Acceptance and success factors

It is important to recognise that the initial product and service offerings from H2O will be based on the available data obtained through the patient and clinician networks of the initial sites in the four project countries, in the first three disease areas. It will be important to understand the acceptance and success factors, and what are the quality characteristics, that would favour each customer segment agreeing to purchase or license our products and services on that basis.

Given that the existing project scope is only the starting point, it will also be important to know what our growth should prioritise, in terms of diseases, geographical spread, cross referencing with other sources of data, more sophisticated analytics, or other offerings. Although the survey respondents will be reacting only to fictitious examples in this initial market analysis, it will be helpful for us to have a sense of what they would prioritise in order for us to in future retain and expand their custom.

The examples below will be expanded and converted into a format suitable for an interview. A Likert scale may also prove suitable.

What would influence their willingness to pay and the amount they would pay? (which influences our implementation priorities, growth strategy)

- Number of countries
- Geographical coverage within each country
- Number of diseases
- Diversity of patients with each condition

- Frequency of patient outcomes collection
- Data quality (if formally assessed)
- Longitudinal linkage
- Complementary outcomes data items from EHRs
- Complementary care pathway data from EHRs
- Supplementary data from registries
- Granularity of the analysis
- Longitudinal trends of consistently captured data
- Additional options, such as identification of the healthcare provider sites within performance data.

2.3.4. Implementation of this analysis

This market analysis plan will be formalised during March 2021and implemented from April for a period of 4 to 6 months. The results of this market analysis, together with a second more quantitative exercise, will be reported in month 18 within deliverable 1.7. Early findings will be used by the project to impact on the instantiation of the national observatories and will be taken on board by the technical work plan.

3. Stimulation of the supply side of H2O

3.1. The importance of the supply side for H2O

This section concentrates on the data supply side that will support the sustainability of the H2O Observatories (national and EU Umbrella Observatory) and their network. As indicated in the demand-side section above, the principal revenue streams that will financially sustain the European and national Observatory network will come from products and services that are mainly marketed at a European level and to some extent at a national level. These products and services comprise anonymised or pseudonymised or aggregated - in a legally and ethically appropriate manner - outcomes data; supported by an App; aggregate analytics derived from the outcomes data; and some services such as technology platform and app certification, because there is multi-stakeholder value in having and using high-quality outcomes data. These products and services are therefore critically reliant upon a thriving outcomes-utilising ecosystem underpinned by a steady supply of reliable outcomes data on a sufficient scale and of a sufficient quality.

The main provider of H2O data is the patient and the key data resource is the patient reported outcomes. Encouraging and equipping patients to collect and share their outcomes data with their national Observatory is therefore the first objective of the supply-side work plan.

However, decision-making on the basis of outcomes needs to be complemented by information about the health care interventions, treatment plans and other care plan elements that are influencing the outcomes that the patient reports. This is critical to enable comparisons between different care interventions that may have given rise to different outcomes. It is therefore essential that patient data stored under the custody of treating clinician and healthcare provider institutions is also shared with the national observatory in a way that is already linked, or can be linked, to the corresponding patient reported outcomes information. It should be also possible that both clinical data and patient reported outcome data comes from the health care provider institution and not directly from the patient. This will enable rich data collections that will increase the potential of exploitation:

(i) to return high value information to patients and their treating clinicians to enhance their collaboration experience, putting them in the best possible position to improve health outcomes
(ii) increase the value of the data and analytics products and services that can be marketed to a diversity of customer segments.

It is of critical importance therefore to establish and maintain trust with the clinical community through design features, such as securing the treating clinicians' role in interpreting comparison results, and hence further supporting their patient – healthcare provider relationships. In this way, we will create convincing supportive conditions of strengthening the bond between the patient and the doctor/healthcare provider, rather than what may be feared as empowering the patient to the detriment of this trusted relationship.

The supply side is therefore regarded not simply as a collection of sources of patient health and outcome data, but as a complete circular data value chain, returning direct value and benefits to the data contributors, namely patients, clinicians, the institutions that deliver and fund healthcare and their patient communities; these are directly proportional to the capacity to create flows of data that is itself of high value, trusted and readily processable into derivatives that will fuel added value services to all stakeholders.

An important part of the sustainability strategy is therefore to better understand the motivation and interests of the supply side actors to participate in H2O programmes, their expectations and their fears

when it comes to sharing health data and the role that H2O can play in serving these interests and providing the necessary safeguards and transparency to create a trusted data sharing environment.

This analysis, which is initially being undertaken qualitatively, will be formalised within the relevant workstreams of the project with a view to capturing the needed information for structuring quantitative supply chain models. From a business model canvas perspective, the supply side is likely to be most visible in terms of its costs. There will be the data-related costs for provision in the data flows: equipping patients with apps and other tools to collect their outcomes, potentially some costs to enable hospitals to map and connect their data for H2O use, the core infrastructure required by the national Observatory itself, and costs required to harmonise, link and clean data to make it suitable for demand side purposes. There may also be incentivisation costs, which are investments made to promote and maximise the value of outcomes data to patients and clinicians so that they are motivated to participate, provide high-quality data and be retained in the long term. These may be in the form of educational resources, improvements to patient applications, the provision of clinician dashboards, and analytics provided without charge to them to maximise their benefit from continuing to contribute to H2O.

These quantitative assessments should be capable of predicting the capacity of the data supply at any time, to respond to demand as well as its capacity to scale and confirm which are the most critical parameters for achieving such levels.

This section summarises our current qualitative sustainability analysis as well as the methodology that will be pursued in the coming months to develop an evidence based in depth understanding of the motivational factors and success strategies for each of the segments of the data generating communities.

3.2. Characterising the data supplier segments

3.2.1. Patients

There is a growing volume of evidence emerging from consultations with patient groups, studies and surveys (including Eurobarometer studies[1]) showing that patients and citizens:

- want to combine their EHR with their self-management and lifestyle data
- wish to make better informed decisions themselves and with their healthcare professionals
- want to be able to compare with anonymised data of similar patients
- support the use of their health data to improve the quality of health services, for public health and for research, whether publicly or industry funded
- are concerned about privacy and that the use purposes must target benefits for healthcare, by approved trustworthy bodies with transparent rules and decisions.

A recent survey run by DigitalHealthEurope[2] showed that 57% out of 936 Europe & US respondents did not know who could access their health data, but 80% felt their health data might be of use in disease and medicine research. The majority would consent to sharing their data with a research organisation (76%) or a health and care provider (72%). Few would share with commercial

1 Eurobarometer 460: 'Citizens' attitudes towards the impact of digitisation and automation on daily life'

2 Source DHE survey, 2020

organisations (<1%; but 11,4% if company develops value-added health services and products). 93% would share their data for common good, either freely (30%) or case-by-case (58%). Rather than monetary rewards (10%), most participants want to be notified if their data contributed to helpful research for society (63%) or their own condition (60%).

This is a positive signal of likely patient support for the mission of H2O, which is intending that its products and services to support different stakeholders to shape healthcare delivery and to develop products for societal health benefit. However, the mixed findings from different surveys about public acceptance of sharing data with commercial organisations will need to be addressed, through measures such as cocreation of the data sharing framework and securing the needed degree of transparency of how data is being used and how.

The right to portability as part of the implementation of the GDPR is an important legal enabler, as it allows patients to obtain and reuse their personal data for their own purposes across different services. The actual implementation of the portability right in the health sector encounters several challenges, especially in terms of preserving the re-usability of data and its implementation and progress varies across the different Member States. Although this is a general negative, it is also a positive opportunity for H2O to provide patients with a portability feature that they presently lack.

Important incentives for patients to collect outcomes and provide their data to H2O will be the value they directly gain themselves from having an application to collect and present them their own data, the potential added value of allowing their anonymous data to be used for comparisons with similar patients in an aggregated form, the possibility to opt-out from sharing data with specific organisations, the potential ability for them to view their outcomes alongside their treatment plan, and for them to be able to share their personally collected outcomes with their treating clinicians.

These global trends, opportunities and challenges will be investigated and over the next few months in each of the 4 countries, through a mixed method approach of interviews, surveys and focus groups. The investigation will be then extended outside this core community with a view to understanding behaviours more widely across Europe and their effect on the geographic scalability of H2O.

3.2.2. Health Data Providers

Under this data provider segment, we position a variety of health care providers (hospitals, primary care units, outpatient facilities, biomedical laboratories, rehabilitation centres, research facilities which collect health data etc) as entities that are entrusted with the collection, storage and protection of personal health data, generated during care encounters over the lifetime of citizens and patients. Data providers may be also individual practices of health professionals that similarly store data of their patients for similar purposes (such as GPs, mental health specialists and midwives).

The degree of re-usability of data stored in these provider EHR systems in terms of its quality and adherence to interoperability standards differs between countries as well as between organisations. This limits the capacity of these organisations today to share data with other health care providers and other members of their data sharing ecosystem, in pursuit of improving also their own insights and optimising the level of clinical care they deliver. Data quality is a recognised challenge with routinely collected clinical data. A supply-side issue will be the potential costs of extracting an outcomes-relevant EHR dataset and mapping this to a standardised information model and standardised semantics (such as to the OMOP Common Data Model), and including the necessary metadata to allow safe interpretation by H2O and its downstream customers.

The patient's right to portability is recognised to be a considerable potential cost to health care organisations. However, the involvement of the provider with H2O, possibly helping to champion some investment in their capability for interoperability, will assist the provider with building their implementation capacity to live up to patient's expectations, give them more transparency, insight and control over their own data, providing strategic opportunities to strengthen their own capacity and potential to excel.

The advancement of value-based reimbursement is still fairly slow across Europe, but there is a growing recognition among European hospitals that they need to be able to demonstrate that they achieve good health outcomes, and that targeted reimbursements or KPIs will be associated with outcomes in the future. There will therefore be a slightly forward-looking incentive for hospitals to provide their data to H2O, so that they can perform comparisons (in a private and confidential way, by comparing their own performance with anonymised equivalent sites) and be in a better position to improve their outcomes. A complementary incentive will be for them to engage with H2O through their patients, since patient reported outcomes will be a critical part of their evidence base on their performance.

Additionally, and depending on the dynamics in each country, participating in a broader ecosystem that collects routinely health outcomes and leverages state of the art technology to improve patient care and advance science, can be an important incentive for attracting and engaging forward looking healthcare providers and providing them with an environment to advance their research efforts, their careers and their ability to advance science. This can create important attraction poles for medical researchers and place the healthcare organisations involved at the forefront of medical science.

There will also counter-incentives that we need to be aware of. An additional and very important task will be to identify what health care providers and other data holders do not want or which they fear. Understanding these parameters will be extremely important for sustainability. It should be however recognised that they will vary from country to country and they need to be captured at country level. The specification of what data may be used for, and what not, will manifest itself in data sharing agreements that will be national flavours of standard H2O templates. The implications of such restrictions on the ability to contribute towards the demand side will need to be assessed and properly anticipated. These elements are health care system specific and hence vary across countries.

These identified incentivisation areas will be investigated and quantified in the health care providers participating in the consortium; this will set the basis for a broader EU survey for understanding behaviours and incentivisation strategies of this group of this supply segment on the scalability of H2O.

3.2.3. Registry Holders

Patient registries can provide a real-world view of clinical practice, patient outcomes, safety, and comparative effectiveness. They are used for a broad range of purposes in public health and medicine serving different public health purposes and research communities. They can be potential data sources for H2O as they cater to the collection, storage, retrieval, analysis, and dissemination of information on individual persons or populations. Their objectives vary considerably, so does their ownership, operational model and access policies. In their majority, existing registries take an approach of examining requests for access or exchange of data on a case-by-case basis.

It is difficult at this stage to derive common incentivisation principles for this category of potential data suppliers. The most realistic approach is a bottom-up identification of registry holders of relevance to each of the disease areas of H2O and bilateral explorations in search of the common goals that could be supported through data sharing and data sharing agreements. An interview survey of registries is currently being developed, as the first step in this area of investigation.

3.2.4. Other data suppliers

While these are the most prevalent anticipated sources of data for the current H2O use cases, additional data sources such as medical device and sensor data (IoT data) may need to be collected from platform holders collecting, processing and storing such data.

Weather and environmental data associated to factors known to trigger particular disease systems and outcomes would come into focus. These and other types of data, of open public nature, are not foreseen to impose significant challenge to H2O.

3.3. Success factors

3.3.1. Patient Choice

It is a patient's direct choice to participate in one of the H2O's programmes. The value of the feedback received upon submission of PROs will be proportionate to the ability to correlate these to clinical data on one hand but also to population level data through comparisons with anonymised sets of similar patient populations.

The richness of the information returned to the patient is therefore directly dependant on the richness of data and the degree to which this can be exploited in population level comparisons. The initial expectation is that the following incentives and respective patient choices may fuel patient PRO supply, in several ways:

- Patient choice to enrol in an H2O PRO programme will enable monitoring of their outcomes through the use of a free App.
- Patient choice to allow further sharing of anonymised data towards increasing capacity of population level comparisons, will return additional value in terms of comparative health outcome assessment.
- Patient choice to allow or exclude data sharing with specific providers.
- If the patient's care providers also agree to participate in the programme, then additional patient value involving linked outcomes to clinical data and patient-doctor communication may be enabled at the request of the patient. A patient role as a consumer of health care services can have an impact on the decisions of health care providers, e.g. in the course of exercising the right to data portability.
- Every time the patient permits that anonymised data is made available for the creation of new scientific knowledge and public health learning, new drugs and innovative services benefits return to society - not only as dashboards in terms of increased intelligence of health systems but also in terms of making healthcare more sustainable, through the data value chains portayed in figures 2 and 3.

These scenarios are illustrated in Figure 1 below.

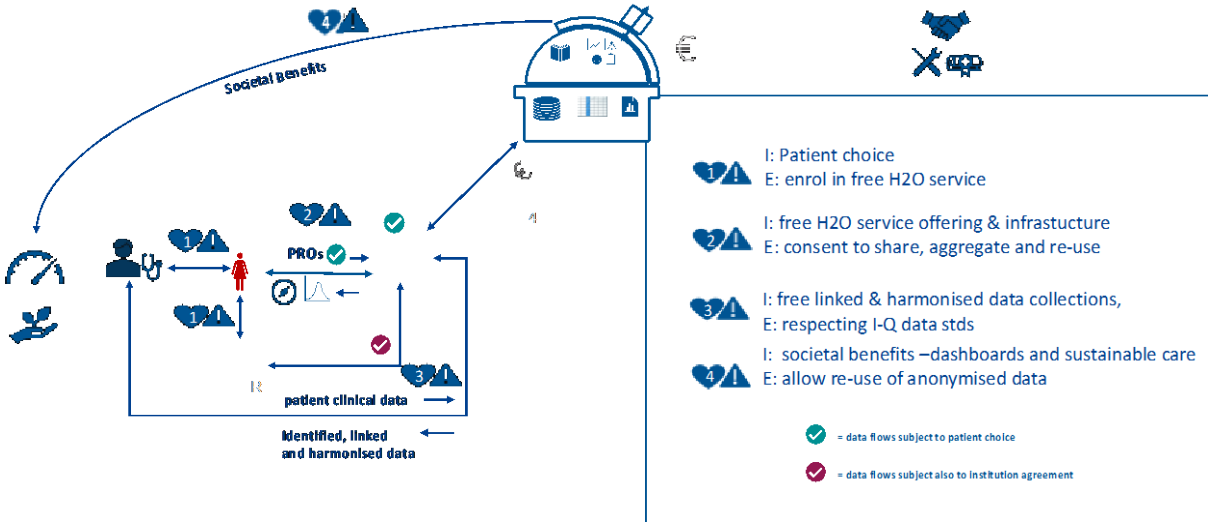

Figure 1. Supply Side: Offerings and necessary pre-conditions

3.3.2. Incentivisation of data providers

Collected PRO data will be made available by the H2O to the care providers at the request of the patient, in the standardised format in which it has been collected.

- Data-contributing clinicians and other data providers will benefit from value added patient reported outcome data directly harmonised and linked to patient's clinical data and from services allowing richer patient – clinician communication.
- Data holders can increase the value of the patient data they hold through addition of PRO data.
- For this mutual data added value to be accrued, the mutual goal for data minimum standards for data quality and interoperability can be supported through incentivising the use of interoperability standards and certification and be supplemented by relevant H2O data curation services; patient enabled access to and use of data, and data sharing agreements will be effectively supported by H2O's data sharing services and supporting infrastructure.

3.4. Data Value Chains and Value Propositions

3.4.1. Value created through collection, harmonisation, curation, access

Data suppliers are also data consumers. Data will be submitted by patients in standardised formats from the start, it will be processed and converted to information on the status of their conditions and will return to them as added value information. To the extent that this data can be linked to their clinical data, additional services supporting their collaboration with their clinicians will become feasible. The H2O has a critical role both at its national and EU level expressions, in multiplying the data value across the data value chain.

At the local level where care is provided, data sharing will be enabled through a wide range of activities that are necessary for the observatory to perform:

- defining and managing patient preferences,
- engaging data providers,
- matching supply to demand,
- establishing the requirements for data quality and interoperability
- supporting data quality and interoperability certification programs,
- establishing and managing data sharing agreements,
- a range of data related services such as cleaning, curating, linking, pseudo and anonymisation
- providing these data derivatives to an appropriate re-usability level to the various data consumers of its ecosystem.

Table II. Value created through collection, harmonisation, curation, access		
In-kind or freely offered	Value to me when I provide my data to H2O	Value to me when I access H2O hosted outcomes data
Patient	• Tools to capture my own outcomes • Trusted and secure cloud storage of my outcomes • Transparency in protection of my privacy	• Access to my own + clinician outcomes relevant data in a structured form • Track my own progress through smart tools, see the impact of care planning decisions • Express my care preferences and priorities via an app • Able to have informed empowered discussions with my clinicians • View my integrated health information at my convenience • Portability of my outcomes data to another healthcare provider
Patient's clinical team	• Share my patient's clinical data to support my patients • Encourages me to collect patient outcomes myself	• Access the patient reported outcomes of my patients, in a structured and standardised form, during and between patient contacts • View my patients' care preferences and priorities • Make shared, better, outcomes-based decisions with them • Observe my own quality of care • Monitor the success of the care pathway we have chosen
Registry Holder	• Enrich the data available to the patient, from my registry	• Provide possibilities for • tracking quality of care, and value • comparing provider performance • Using the data for reports to our healthcare payer/ministry

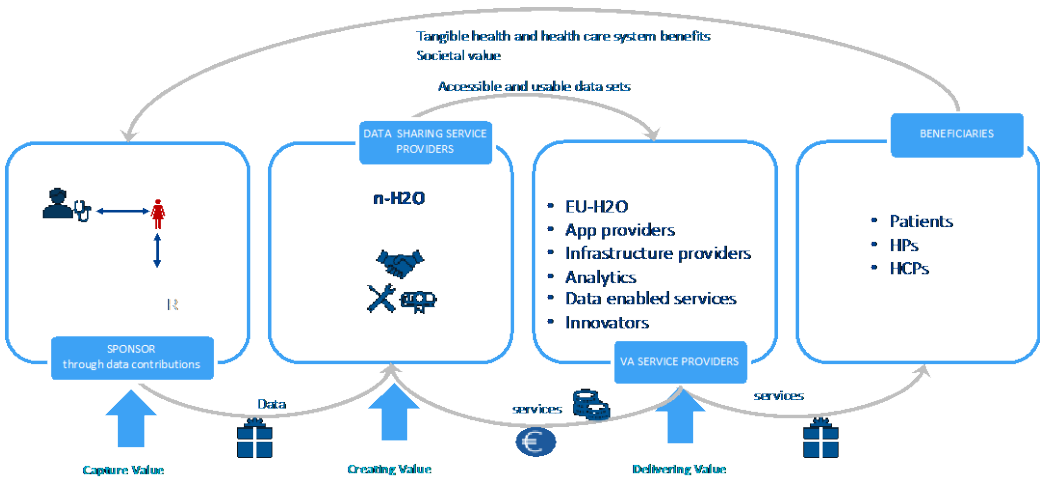

Figure 2. Patient and Data Provider services Data Value Chain

Value will return to the data suppliers through value added services, such as App and infrastructure providers, analytics services which may be internal or external to the H2Os, and also through innovators and data enabled service providers that fall within the remit of the H2O ecosystem. The EU H2O observatory will create the volume of new knowledge to support all levels of learning health systems and dissipate value back to society in a variety of immediate and intermediate benefits.

3.4.2. Value created through supporting additional data uses

Whenever patients choose to allow the re-use of their anonymised data in population level studies, and for pre-agreed data uses, their data will be used to enrich a pool of knowledge and this will create additional possibilities for value to them in ways described in Table III.

Table III. Value created through supporting additional data uses

In-kind or freely offered	Value to me when I permit wider uses of the data	Value to me when I access H2O data (added value) services
Patients	• My anonymised data can: - help other patients like me - help improve healthcare services - help research and innovations (including apps for me) - Help patient groups advocate for treatments/therapies that report better outcomes than others	• Access aggregate outcomes on patients like me • Learn about what outcomes others achieve, that I could achieve • Compare my care pathway with other care options
Patient's clinical team	• Contribute to shared learning about outcomes • Help identify the most effective care pathways	• Access national outcomes profiles • Benchmark my performance, anonymously • Learn how to improve the care pathways I provide • Identify the most effective care pathways
Health care organisation	• Contribute our outcomes for national benchmarking • Contribute to value model calibration	• Track our quality of care, and value • Compare provider performance • Use the data for reports to our healthcare payer/ministry

To the extent that this data can be linked to their clinical data, additional services supporting their collaboration with their clinicians will become feasible. This will also fuel clinical and management dash bords for health care professionals and health care organisations.

The EU H2O injects value to the operations of the national H2Os though mutualising effort, knowledge and costs for the development of critical assets including:

- securing access to the Infrastructure

- developing data interoperability and data quality assets
- providing consolidated EU level data collections
- working out operational and business models
- providing support and expertise
- designing and supporting the implementation of certification schemes

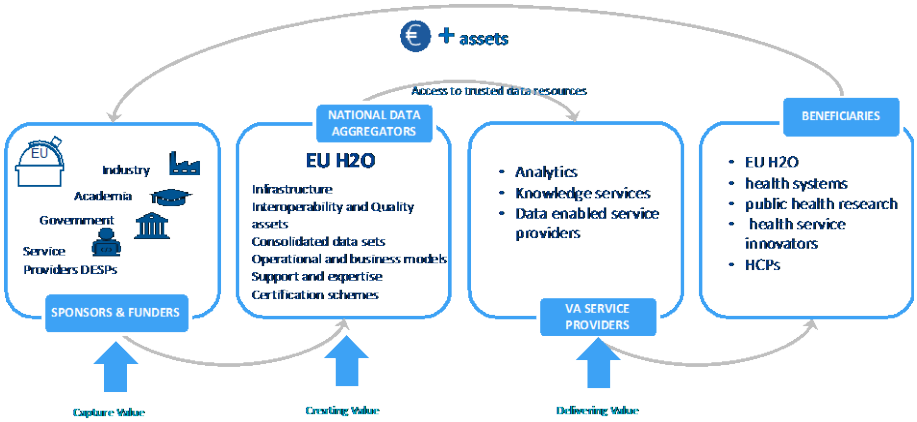

Figure 3. National H2O observatories Data Value Chain

Through providing Value Added Service Providers -whether internal H2O services or external customers - regulated access of to EU data resources, through a single point, the H2Os will create a variety of value potential for an array of public and private stakeholders.

3.4.3. Value created through the European Observatory services

This section focuses on the in-kind value which is complementary to the commercial value of the previous section. The EU added value of data collection and consolidation is freely offered to organisations that create and/or contribute to the improvement of public health and scientific knowledge, in ways described in Table IV.

Table IV. Value created through the European Observatory services

In-kind or freely offered	Why would H2O value my collaboration?	What would I gain from H2O knowledge and services
Patient and professional organisations	• Provide input on outcomes priorities and needs • Promote the value of outcomes to my community • Ensure the inclusion of the patient voice	• Insights into outcomes of my constituency, national comparisons • Education on measuring and using outcomes • Engagement on promoting the outcomes culture • Ability to better influence HTA and decision makers
Scientific and informatics bodies	• Updated standards, methods, innovations	• Outcomes evidence and experience of collection and benefits • New outcomes and measurement needs

	• Potential for research collaborations	• Uncover research opportunities

This set of value propositions and data value chains represent a starting point of defining and communicating value propositions within the supply side organisations and for working out a business model for stimulating the supply side, primarily through in-kind and freely offered services. They are expected to mature and culminate into a solid set of validated value elements that will be delivered to patients and data providers, through specific services and channels. These will be also a starting point for elaborating the business model of H2O.

3.5. Supply capacity

It is important to recognise that the initial product and service offerings from H2O will be based on the available data obtained through the patient and clinician networks of the initial sites in the four project countries, in the first three disease areas. It will be important to understand the current capacity for providing the breadth and depth of data that will satisfy an as-broad-as-possible demand; it is equally important to understand the expectations in terms of capacities and services that the H2O needs to develop in order to support a transparent, efficient and trustworthy flow of data within the H2O ecosystem.

A supply capacity model will be created and supported with data from the data providers that would allow at any time an approximation of the capacity of the supply side to meet requirements of new requests. These competitors should be also continuously monitored and assessed.

What would the data provider be able to provide and under what conditions of use and re-use? The list below comprises examples of success factors from the demand side section. The supply side implications of these points relate to capacity, any barriers to providing data meeting these demand side expectations, and in particular the costs of providing data on a sufficient scale and of a sufficient richness to meet the demand side expectations.

- Data availability and quality (responsible data)
- Data access rules, legitimate and prohibited re-use of data
- Geographical coverage of data
- Number of diseases data can be collected for at the required quality standards
- Diversity of patients with each condition
- Frequency of patient outcomes collection
- Longitudinal linkage
- Complementary outcomes data items from EHRs
- Complementary care pathway data from EHRs
- Supplementary data from registries
- Granularity of data
- Longitudinal trends of consistently captured data.

4. Sustainability Strategy

It is too early at this stage of the project to describe sustainability strategies in a conclusive way. What is however possible and important to do at this point is to formulate a short list of sustainability building blocks and an accompanying list of guiding questions that need be addressed by all work packages to their appropriate scope and relevance over the different stages of the project development.

4.1. Sustainability Building Blocks

The above initial analysis of the demand and supply side has highlighted several areas where decisions taken today will have a major impact on the future sustainability of the H2O Observatory ecosystem. These are presented here under five topics (strategic building blocks) together with a several questions that H2O has to examine. They do not all need immediate answers, nor definitive answers, but they need to be kept in mind as we elaborate and instantiate the national and European observatories and establish their partnerships and business relationships. These guiding questions have been formulated as a form of self-assessment against sustainability considerations. This list and the respective questions will be also subject to further validation within the consortium and regular updates.

4.2. Guiding Sustainability Questions

H2O as a pioneer operating in the European Health Data Space

H2O has the potential to set up proactively operational models that will benefit from legal certainty and enablers set forth in the EHDS, including its infrastructure and governance.

- How does the chosen operational approach map to the governance of a (health) data space?
- What is the legal basis for each and every critical data sharing process in the operational area of data processing that the national and ~European Observatories will engage in?

Patient driven data supply – care impact, learning systems and innovation driven demand

Data supply will be a valuable persistent resource, as long as it can provide back to those that have contributed data a clear added value: to patients, to their care teams, to health systems and society.

- What value will H2O bring to the patients and their treating care teams? In which form will these concrete benefits be delivered? Through which means and feed-back loops? Are they pertinent and compelling?
- What is the competition to H2O and its relevant penetration at national and EU levels?
- What are the H2O unique advantages and unique value propositions that will assure sustainable relationships with patients and their care teams?
- What secondary uses of data are being supported and whose demand expectations will be addressed?
- What is the collective capacity of the data suppliers to provide the data needed to the specified level to serve the needs of the demand side, and how can that best be strengthened?

Mutualisation and subsidiarity

A collective effort, shared assets and infrastructure, and mutualisation of costs at EU level will maximise the likelihood of a thriving self-sustaining ecosystem. How can the subsidiarity and mutuality principles of European health systems best be leveraged by H2O to maximise its sustainability and impact, in particular in its relationships with the supply side and the public sector demand-side actors?

- What are the current and emerging needs for the adoption of EU level interoperability assets, necessary to equip the national H2O observatories?
- What are the economies of scale achieved through mutualisation of operation at EU level? Are there any adverse implications of choices made?
- Which is the most appropriate level for operationalising any given activity, in terms of its proximity to the relevant stakeholders that determine critical acceptability, and taking into account costs and efficiency factors?
- What are the available alternative operating models and the sharing of labour between the local, national and EU levels?

Maximising quality and re-usability of data at the source

H2O is uniquely positioned to establish win-win partner relationships with local data providers, progressively shifting effort from data curation to promoting and supporting a culture of data quality and interoperability standards, and certification, to increase the value of the generated data flowing into the Observatories. What is the prevailing culture, national policies and legal enablers in each of the countries for clinical data quality and interoperability standards adoption?

- Taking into account country specific profiles, what is the best strategy in terms of efficiency, costs and scalability considerations for maximising the generation of “responsible data”, promoting standards adoption and certification of data providers, linking patient outcomes to clinical data at the source?
- What are the costs and what is the added value (per case) of the residual curation needed by the H2O?
- For each of the associated data providers:
    - How do the data sets at each site measure against the quality and interoperability specifications set by H2O?
    - What is needed to reach an acceptable level of conformance to these requirements?
    - What are the respective needs for further data collation and synthesis to be performed by the national H2O?
    - What are the access policies to data? Do these policies allow for access to data sets that hold sufficient value for re-use within the H2O ecosystem and stated objectives?
    - If not, are there additional safeguards that could mobilise access to sufficient data sets?
    - Is this a good practice that would merit considering as part of the improvement cycle of H2O services and trust framework?

Securing critical infrastructure and other essential resources

H2O can leverage its existing networks and partnerships to pursue the most efficient means of securing trusted, secure and efficient infrastructure and critical interoperability assets such as standardised data models and data sets.

- What is the market and what is the relevant maturity of

    - Data Sharing platforms within the partners' networks and outside these networks (e.g. EHDEN)?
    - patient PROs supporting Apps?
    - Other tools and services needed by H2Os
- What is the potential of lab-fabricating the whole array of H2O requirements, including flexibility for evolving and expanding needs and requirements on the platforms selected for consideration?
- What is the cost-benefit of alternative infrastructure capacity building models?
    - Own development and maintenance – sub contractors
    - Partnering with infrastructure provider - lab fab approach
    - Infrastructure services – pay as you go

5. Roadmap to the H2O Sustainability Plan

At this stage, much of the design elements of the services and decisions on the functioning of the H2O observatories are unfolding within the various work packages. It is the intention to maintain this document as a living document, internal to the project to be updated as necessary for it to stay current and consistent with on-going strategic choices made across the project.

The Sustainability Plan itself is due on month 36 (D6.8). However, given the intention to have national observatories and a nascent European level entity established and operating prior to this date, incremental versions of the content will be regularly generated and used prior to this deliverable milestone date. On the other hand, the setting up and running of the observatories well in advance of this project milestone (MS23) will provide for the collection of actual data on costs, resources and level of uptake of the H2O reports by the demand side, so as to create a realistic and evidence-based sustainability plan.

	Sustainability Milestones	Completed by	Pre-requisites
S-MS 01	Sustainability Strategy	M06	
S-MS 02	Fine tune value propositions and DVCs with the consortium level supply and demand partners	M08	Acceptance criteria for entities to run the 4 nationalH2Os (MS2) M06
S-MS 03	Validate the above through a consortium level interviews and EU survey	M10	Consortium level survey completed(S-MS 02)-M10
S-MS 04	Compose business models for the national and the EU observatories	M12	Specification of infrastructure (MS04) M06
S-MS 05	Design and assess alternative operational and cost models	M12	Operational Plans for H2Os (MS 07) - M12
S-MS 06	Final buisness models	M30	D1.8 - M30
S-MS 07	Populate cost and revenue models with real data	M30	n-H2Os set up or selected MS(12) - M18
S-MS 08	Sustainability Plan: 3 year business plans for H2Os and EU-H2O for sustainable operations (MS 23)	M36	Deployment of infrastrcture and services (M24)

The Gantt chart below provider a finer grain view of the specific activities that need be implemented up to the end of the year, to establish well informed, important sustainability foundations for H2O.