

945345 – H2O

Health Outcomes Observatory

WP1 Governance, Sustainability and Capabilities

D1.4 KPIs and success metrics

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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
KPIs	Key performance indicators
GP	Governance principle
SMART	Specific, Measurable, Achievable, Relevant and Time-bound
Pt(s)	Patient(s)
HCP(s)	Health Care Providers
Excom	Executive Committee

Abstract

Deliverable 1.4 describes the set of Key Performance Indicators (KPIs) and success metrics that meet the H2O project's mission and ambition. Measuring and monitoring these KPIs will be responsible for ensuring that the project, its implementation and deployment and the outcomes evidence generated are of a high and trustworthy quality.

We defined a set of KPIs, in collaboration with all work packages (WPs), for monitoring the progress and success per WP and for the project as a whole to ensure sustainability (linking this deliverable closely with the work done in WP6 which focuses on implementation and sustainability). Some of the KPIs directly refer to deliverables specified in the Grant Agreement. It should prioritise the success metrics, according to the governing principals and taking into account the project's mission.

1. Introduction

Key performance indicators (KPIs) are the basis for a performance measurement process. KPIs evaluate the success of a project, a work package or a particular task. This deliverable describes the KPIs for the H2O project and the actions to be taken, if KPIs are not achieved.

Success is the achievement of pre-defined operational goals (e.g., the number of patients involved in the outcome definition process), but also determines if a project reaches its mission and/or strategic aims. To choose the right KPIs requires operationalization of the project's goals in form of measurable entities; this process may require additional prioritizing. The definition of the KPIs and what is regarded as project success might also influence the motivation of partners and external stakeholders to contribute. Next to the KPIs we are proposing a process for continuous quality improvement cycle. This is a methodology of tracking our activity progress according to our governing principles.

2. Methods

We developed a set of KPIs based on the project's mission and aims which are outlined in the Description of Action. In addition, we used the governance principles (annex I) as another source for information for the development of the KPIs. The KPIs were further advanced and refined based on the lessons learned in the first 6 months of the project. We performed the following steps:

- Select and design performance measures that correspond to the project's mission and aims and are meaningful for the consortium partners;
- Discuss them in smaller teams (e.g., WP1 collaborators, steering committee) and formulate draft KPIs;
- Circulate the document to the whole consortium to generate further input and get buy-in from partners;
- Assign ownership for the KPIs;
- Design a process for (actionable) reporting, reflecting and improving/transformation, if necessary;
- Define signals from their measures about whether performance is improving or not.

We also used certain criteria which KPIs needed to fulfil. KPIs should be

- Measurable (SMART),
- Used for reporting and monitoring progress,
- Feasible and implementable in the project,
- Not too many.

Eventually we introduced the process of continuous improvement cycle which will allow us taking action of KPIs are not achieved.

3. Results - KPIs

The mission of the H2O project is to empower patients with standardized outcomes data and insights to drive healthcare improvements. In order to achieve this, the project needs to deliver on the following key objectives:

- Create multi-stakeholder consensus on core outcome sets, including PROs, that can be measured in clinical practice across several countries:
- Equip patients with tools to measure their outcomes in a standardized manner and improve clinical care both at a patient and population level;
- Create an ethical framework around data governance to establish trust and enable data analysis to advance science and health policy.

Each objective has a number of key priorities. Progress towards these priorities is measured through the KPIs.

3.1. Objective 1: Ensure that core outcome sets, including PROs, have been selected through multi-stakeholder consensus in order to achieve broad acceptability

Metrics/KPIs:

1. Manuscripts on the selection of the four core outcome sets submitted to peer reviewed journals by the end of 2022. The timeframe for these publications (Deliverables 3.2, 4.1 and 5.1) was Month 12; however, we decided to have a larger outreach of the Delphi processes to agree on the outcomes sets and therefore delay the respective deliverables. A request has been submitted to our project officer at the IMI office.
2. Representative patients, experts (public and private) and regulators, involved in each stage of the Delphi process to select the outcome sets (Qualitative assessment regarding stakeholder categories; relevant ones to be covered); in each disease area at least four participants from outside Europe; in each disease area at least 20 participants external to the project partners; at least one regulator from each country in each disease area.
3. Stakeholders originating from at least 8 different countries involved in each Delphi process.

KPI/ Success	Metric/ Indicator	Frequency of measurement	Owner	Time-frame
Manuscript on the selection of the four core outcome sets submitted to peer-reviewed journals	One manuscript per disease area	Once by the end of 2022	WPs 3, 4, 5	M 27 (End of 2022)

Multistakeholder outreach in Delphi processes	<ul style="list-style-type: none"> At least four participants from outside Europe, in each disease area; At least 20 participants external to the project partners; At least one regulator from each country in each disease area Stakeholders originating from at least 8 different countries involved in each Delphi process 	Once during the Delphi process to be able to adjust and once after the Delphi process is completed; will be reported to the WP leadership, ExCom and SC and described in the manuscript.	WPs 3, 4, 5	M 27 (End of 2022)
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3.2 Objective 2: Stimulate and facilitate patients with tools to measure their outcomes in a standardized manner in order to improve clinical care both at a patient and population level; empower patients by equipping them with a (prototype) app to measure their outcomes if necessary next to the system of their HCP.

To achieve this objective, one needs to successfully accomplish the following:

- Ensure that in the selected diseases, outcomes are measured and nationally centrally aggregated (PROs)
- Ensure that the tools are useful and attractive to patients and as a result patients are eager to use them regularly;
- Ensure that the tools are useful to HCPs.

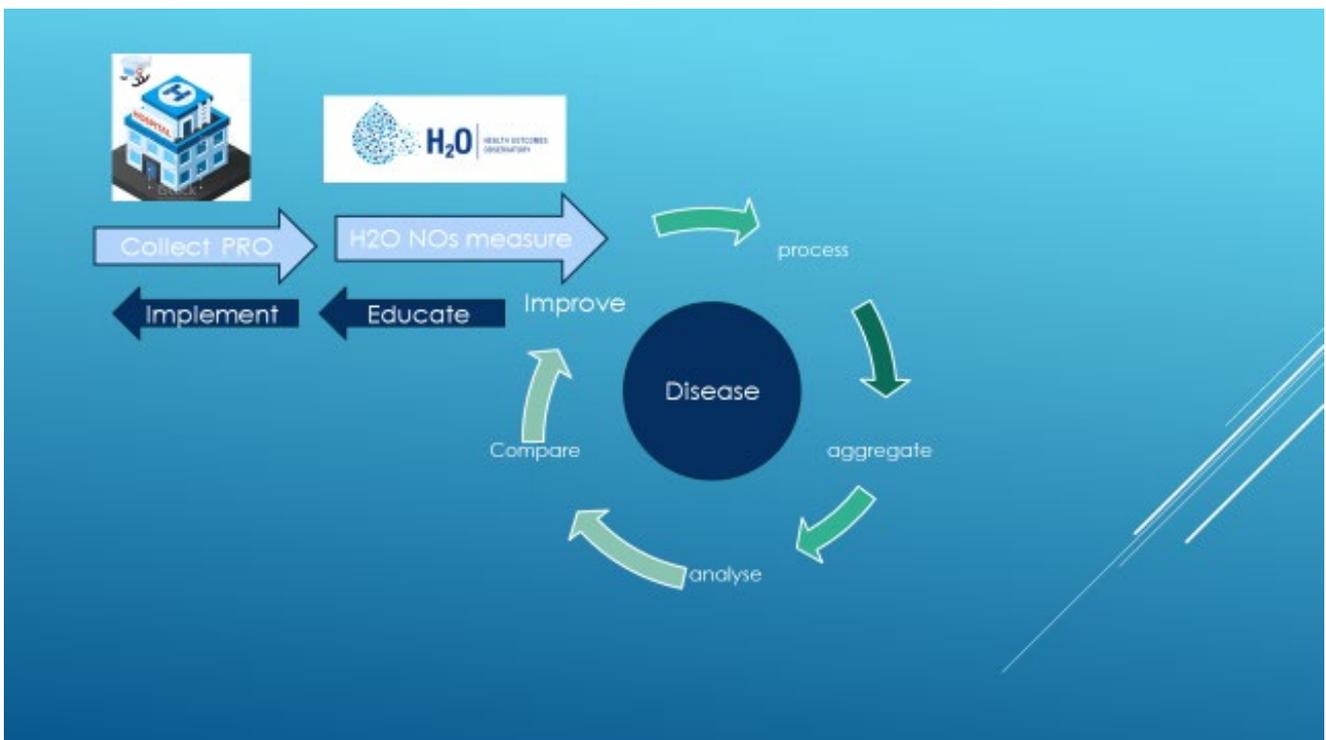
Metrics/KPIs:

- Comparable number of patients and retention rates in the four Tier 1 Countries measured quarterly; results need to be adjusted for country-specific differences; exceptions are explainable deviations
- Specific actions performed yearly per country to include patients, with the aim to increase the % as much as possible
- Comparable number of hospitals and/or healthcare providers outside of the initial partners in four Tier 1 Countries who opt in to use the tools

KPI/ Success	Metric/ Indicator	Frequency of measurement	Owner	Time-frame
Comparable number of patients and retention rates in the four Tier 1 Countries adjusted for country-specific differences	Instead of defining concrete numbers upfront, a continuous, transparent measurement process is proposed; we believe that this will stimulate recruitment (incentive through comparison with other countries)	Quarterly monitored; TEAMIT will prepare a google form and send the link to the project managers of the Tier 1 Countries and the disease WP leaders. We will measure the number of newly recruited patients, patients will regular follow-ups and complete data sets. We will report the results in the H2O Bulletin and discuss them in WP and	WPs 3,4,5 and Tier 1 Countries; TEAMIT to collect information and report back	Continuous, quarterly measurement after "first patient in"

		management meetings. Based on the results, we will propose appropriate activities to increase participation in H2O, if needed (the process is depicted in Figure 1).		
At least 2 specific actions performed yearly per country to include patients	Number of action performed	Yearly	WP1, Tier 1 Country Leaders	Yearly
Comparable number of hospitals and/or healthcare providers outside of the initial partners in four Tier 1 Countries who opt in to use the tools	Same as for the comparable number of patients (row 2)	Quarterly monitored; Same as in row 2	Same as in row 2	Same as in row 2

Figure 1. Continuous measurement and improvement process of the participation in H2O



3.3 Objective 3: Create an ethical framework around data governance to establish trust and enable data analysis to advance science and health policy.

To achieve this objective, one needs to accomplish successfully the following:

- a) Set up successfully the Observatories as independent entities that operate as guardians of patients’ health data in a sustainable but not-for-profit manner.
- b) Implement a data governance framework, respecting FAIR principles, that creates trust with patients and stakeholders to enable data collection and importantly insightful data analysis that

advances health science and health policy in an ethical and legal - including GDPR - proof manner.

Metrics/KPIs:

1. Concept paper published in a peer reviewed journal (already achieved)
2. Set up four National Observatories as independent non-for-profit entities and attract persons with adequate expertise in the respective countries as Board members within the first 3 years of the project.
3. Set up the pan-European Observatory as a not-for-profit entity and attract a highly respected public body with regulatory competencies within the first 4 years of the project
4. Collaboration with at least one registry (document signed until project end)
5. Ensure sustainability by generating income from year 3 of the project for at least one observatory (this could be the pan-European Observatory) outside of the IMI funding
6. Collaboration interest set up with at least four other international initiatives (document signed until project end)
7. At least one submitted manuscript (on the H2O data) per disease area to peer-reviewed journals
8. Ensure that the data insights from the H2O observatories are widely used in health policy debates in the press and/or patient organization publications or by publication of governments/authorities)

KPI/ Success	Metric/ Indicator	Frequency of measurement	Owner	Time-frame
A legal entity (Health Outcome Observatory) exists in each of the four Tier 1 Countries	Local, not for profit entities with a supervisory multi-stakeholder board comprising representatives from all key stakeholder constituencies.	To be reached by months 18	WP 1 and Tier 1 Countries	M 18
The pan-European Observatory exists as a legal entity	Hosted by a highly respected public body	Once	WP1	End of year 2
Collaboration with at least one registry	Document signed until project end	Project end	WPs 1 and 6	Project end
Income from year 3 of the project for at least one observatory (this could be the pan-European Observatory) outside of the IMI funding	Income for at least one Observatory	End of years 3, 4 and 5	WPs 1 and 6	End of years 3, 4 and 5
Collaboration interest set up with at least four other international initiatives	Document signed until project end	Project end	WPs 1 and 6	Project end
At least one submitted manuscript (on the H2O data) per disease area to peer-reviewed journals	Manuscript submitted	Project end	WPs 3,4,5	Project end
Data insights from the H2O observatories used in health policy debates in the press and/or patient organization publications or by publication of governments/authorities	Number of uses of data insights; at least one per country.	Project end	WPs 1, 3,4,5 and 6	Project end

ANNEXES

ANNEX I. H2O mission and Governing principles

The H2O Mission:

- a) **Empower patients:** engage patients and equip them with digital tools that allow them to monitor their outcomes, to improve their communications with the HCPs and in the long run feel more empowered in the management of their conditions. At the same time, collected data will help to advance science and to create supporting evidence for the development of better health policy.
- b) **Provide patients with full control and ultimately full portability 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 their reported outcomes from the start, even if they switch between healthcare providers and ultimately proceed towards full portability of all their health data.
- 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 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 outcomes¹ 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.

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.

4.2 H2O governance principles

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

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.

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.

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.

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.

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.

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.

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.

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.