H_2O HEALTH OUTCOMES OBSERVATORY

Access Based on *Trust*

How to safeguard and access patient-outcomes to revolutionise health care

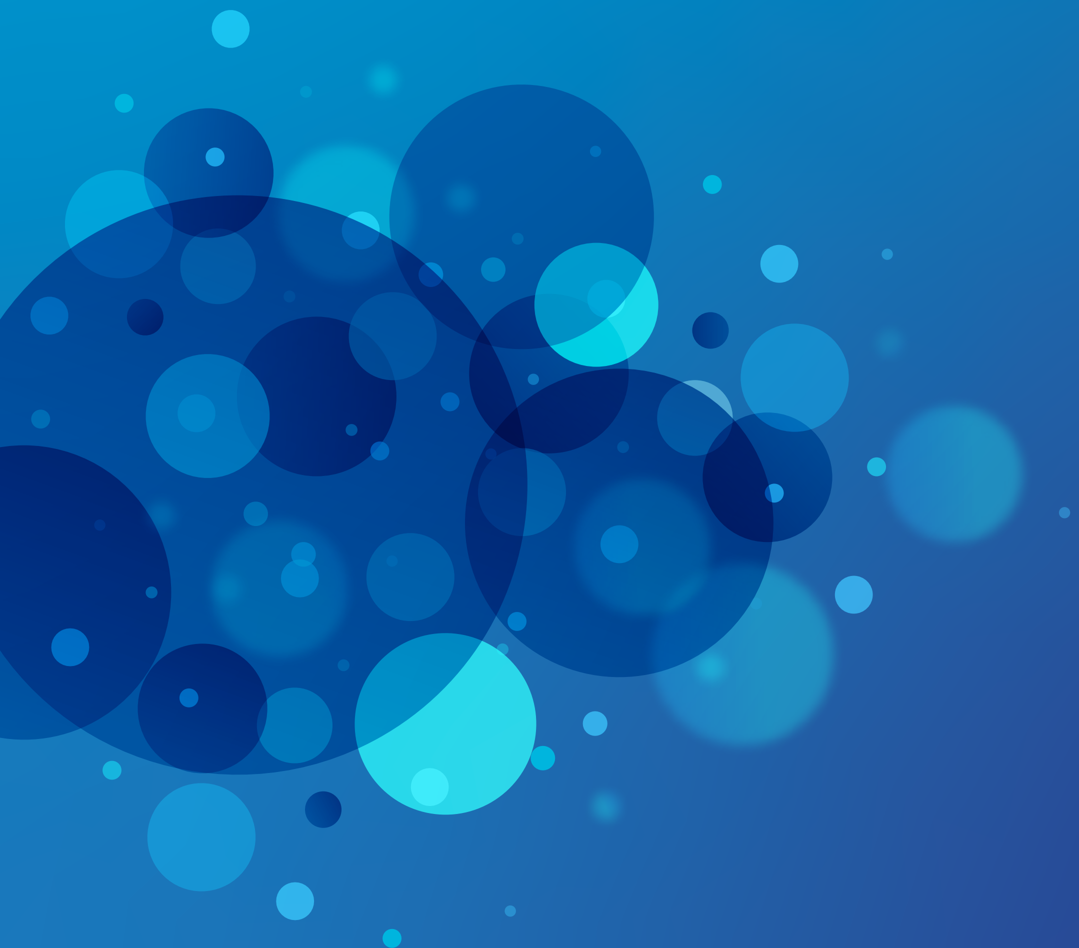


Table of Contents

The Health Outcomes Observatory 4

Unleashing the power of patient outcomes data 5

H2O's data governance and principles 6

- Balancing trust and access 8

Accessing the data 10

- Applying to access the different types of data 10
- Becoming an H2O-approved researcher or organisation 13

Annexes 14

Annex 1: The H2O Endorsed Ethical Principles for Data Use 14

Annex 2: The H2O Permitted Research Purposes 15

Annex 3: H2O Data Use Commitments regarding data protection, governance and transparency 17

Annex 4: The H2O Data Access Request Template 19

Annex 5: The H2O data access registration template (New Client Form) 24

About H2O 25

The Health Outcomes Observatory

The Health Outcomes Observatory (H2O) initiative is establishing an ecosystem in which patients are equipped with digital tools to regularly collect information about their health status and health outcomes for long-term conditions, so that they can monitor their own progress and share this standardised information with their clinical team in order to optimise their care. This ecosystem is being orchestrated through a network of national and European not-for-profit Health Outcomes Observatories.

With the agreement of patients, the Observatories will accumulate these health outcomes, complemented with selected care pathway information extracted with permission from their hospital or GP electronic health records, to provide a uniquely informative resource. In effect Observatories function as Data Trusts on behalf of the patients who have given their agreement. Through a well-defined trustworthy data access and use framework, this data can be reused for learning at multiple levels: to enable health systems to determine the most effective care pathways, for regulatory decision-makers to better understand unmet needs and evaluate the potential benefit from novel treatments, and for public and private research organisations to uncover the societal priorities for treatment innovation.

This document describes the Observatory ecosystem that H2O has established, the terms of the patient agreement that offer individuals full control over the uses of their data and the data access framework that ensures that Observatory-held data is only used for ethically acceptable purposes that advance health and care, by organisations that have provided their commitment to trustworthy data use.

Unleashing the power of patient outcomes data

The collection and sharing of health data is a key component in the advancement of healthcare. **The Health Outcomes Observatory (H2O)** offers a collaborative model whereby patients can remain in control of their data and, with their consent, allow their outcome and clinical data to be used to improve care and feed into healthcare research.

H2O empowers patients by enabling the collection of patient-reported outcomes (PROs) and the sharing by health providers of clinically captured outcomes. This combined data can allow patients to see how their outcomes compare with those of similar patients, enabling them to be more confident whether they are on a similar trajectory or to detect if their own progress is not typical for similar patients. This data can assist both patients and their clinical team to better understand the impact a care pathway is having on that individual, and whether changes should be introduced to improve the experienced outcomes.

Together, these **patient outcomes** holistically capture a patient's experience of their illness, treatment and overall well-being, offering a rich source of data in health care.

The underlying principle of the H2O project is that **health data is an essential resource** for science and innovation. This means three things:

1. **Interlinked health data can give us invaluable insights** on the quality of life impacts a long term condition has on patients, how effective different treatments and care pathways are on those negative disease impacts and how to ensure the best possible treatment and outcomes for each individual. In order to gain these insights, H2O combines data captured in hospitals and data generated by patients in their everyday lives.
2. Since we want to link data from different sources in a way that is socially acceptable, we need the **agreement of the patient** and citizen. They need to be in control of their data and feel safe in the way their data is being utilised to create insights.
3. It will not be socially acceptable to allow any entity to control this data to derive a competitive advantage for themselves. **Much like access to water, access to health data needs to be safe, fair and based on equity.** In this way, stakeholders can derive insights when they pursue ethically acceptable goals.

H2O is a practical example of how the objectives of the **European Health Data Space (EHDS)** can be achieved and further developed. As such, H2O permits data access strictly for purposes aligned with the ethical and legal standards set by the EHDS.

Approved purposes include, but are not limited to, public health initiatives, educational activities, scientific research and innovation, and supporting healthcare institutions. H2O is dedicated to improving the healthcare system for all, from research to innovation, from patient outcomes to more evidence-based healthcare delivery.

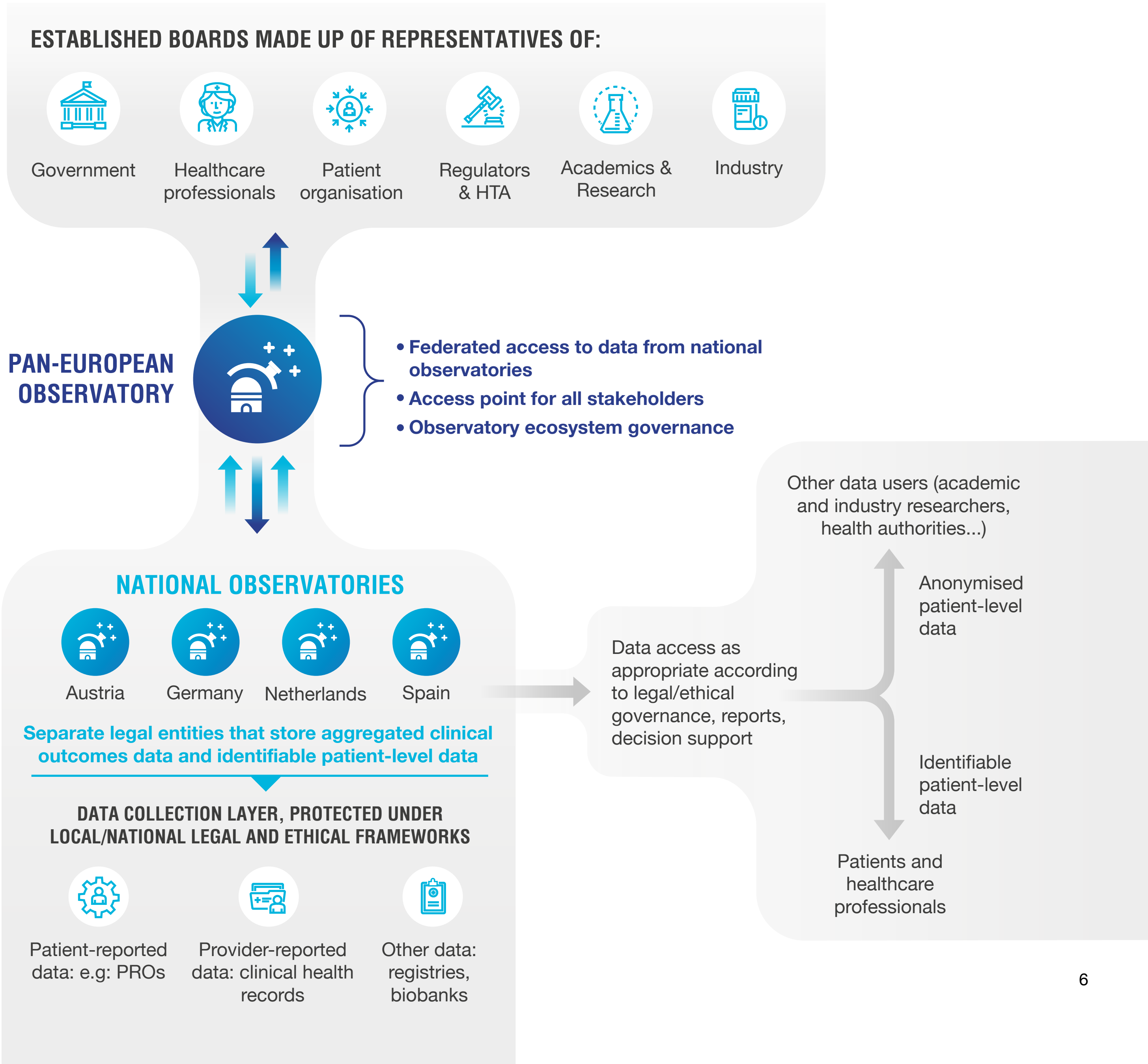
This document outlines how the H2O model can be implemented in a national context, in particular by detailing:

1. **H2O's data governance models and principles**
2. **Practical information on how approved researchers and organisations can access different granularities of H2O-held data for permitted purposes.**

H2O's data governance and principles

H2O enables patients to participate in collecting and sharing health outcomes data by collaborating with healthcare provider organisations, clinical teams, and patient organisations. To achieve this, the H2O consortium has created not-for-profit Observatories that function as Data Trusts through agreement with their registered patients, which are independent entities with boards comprising representatives of all key stakeholders.

So far, 4 national Health Data Trusts in Austria, Germany, the Netherlands and Spain have been established. These are independent legal entities with members and established boards made up of representatives of patients, clinicians, civil society, health technology assessment (HTA) authorities and the private sector. These Data Trusts can serve as libraries of health outcomes with patients always being in control of their data by providing instructions on how their data can be used to fuel a flourishing health data ecosystem. The national Data Trusts are interlinked through a pan-European Observatory in Denmark, enabling qualified researchers to securely access standardised health data across borders.



ESTABLISHED BOARDS MADE UP OF REPRESENTATIVES OF:

Government

Healthcare professionals

Patient organisation

Regulators & HTA

Academics & Research

Industry

PAN-EUROPEAN OBSERVATORY

- **Federated access to data from national observatories**
- **Access point for all stakeholders**
- **Observatory ecosystem governance**

NATIONAL OBSERVATORIES

Austria

Germany

Netherlands

Spain

Separate legal entities that store aggregated clinical outcomes data and identifiable patient-level data

DATA COLLECTION LAYER, PROTECTED UNDER LOCAL/NATIONAL LEGAL AND ETHICAL FRAMEWORKS

Patient-reported data: e.g: PROs

Provider-reported data: clinical health records

Other data: registries, biobanks

Data access as appropriate according to legal/ethical governance, reports, decision support

Other data users (academic and industry researchers, health authorities...)

Anonymised patient-level data

Identifiable patient-level data

Patients and healthcare professionals

Implementing the patient agreement

The H2O **Patient Agreement** is one of the core pillars upon which the Data Trusts' work is founded. Patients enter into Patient Agreements with the H2O Data Trusts, specifying how their health data can be managed, who can have access to their personal data and whether their data can be part of any research query. The Patient Agreement thus empowers patients, if they so wish, to make their data accessible for ethical purposes.

When patients download H2O-accredited applications, they enter into an agreement with H2O to:

- Capture and share their PROs with their chosen healthcare provider.
- Ask H2O or its technical partner to collect their clinically captured outcomes data.
- Allow their data to be part of H2O aggregate statistics.
- Allow their data to be used for research (an opt out is possible).

With each patient's consent and agreement from their healthcare provider, outcomes data is merged with relevant healthcare data from the patient's Electronic Health Record (EHR) to achieve a valuable and unique data resource that can provide insight into the impact of healthcare interventions. This combined and standardised PRO and clinical data is referred to as the **core outcome set (COS).**

The Data Trusts partner with **technology providers** who integrate the H2O patient outcome sets in their value propositions to healthcare providers and patients, enabling them to communicate in a standardised language. These technology providers must have incorporated the H2O Patient Agreement and been validated and endorsed by H2O.

Thanks to this system, H2O enables two forms of secure health data use:

- **Primary use of data:** Identifiable forms of the COS will only ever be used to directly support patients and their clinical teams to better understand their care outcomes.
- **Secondary use of data:** Pseudonymised and anonymised COS data will be available for research by H2O-approved healthcare providers, public health agencies, regulators and a variety of research organisations, public and private.

Balancing trust and access

Trust is the foundation of H2O's data access framework: trust in the prioritisation of patient privacy and trust that the principles of ethical data use will flow throughout research, from first enquiry to post-publication. With trust, data access can be unlocked.

H2O's data access governance model includes principles and safeguards to ensure data security and ethical use. In particular, organisations may only use H2O data for agreed purposes and must respect EU and national laws, and have suitable data protection policies. In disseminating their results, organisations must also commit to reasonably make all or some of the findings from their data use accessible to other data users. (See the Annexes for more details.)

The **'Five Safes'**[1] are central to H2O's ethical principles and daily operations. This model ensures patient data is used securely, transparently and in a socially responsible manner. These safeguards consider:

1. **Safe projects** – Is the data user organisation trustworthy in terms of its governance capability, objectives, reputation and ability to pay the data access fees? Other relevant factors include whether the organisation is in a jurisdiction in which the data use agreement can be enforced and, for patient-level data requests, has EU or equivalent levels of data protection. Requests for pseudonymised data must be covered by a GDPR legal basis.

2. **Safe people** – Can the users be trusted to use data in an appropriate and approved manner? There should be a responsible officer or principal investigator who has sufficient experience, credentials and designated authority to oversee the approved data use. The principal investigator should have training in data protection, confidentiality and information security and ensure that all involved staff are similarly trained.

3. **Safe settings** – Does the organisation have appropriate policies and measures to limit data access and to prevent unauthorised use? Data access must be adequately controlled and audited. The organisation should have a secure processing environment that conforms to acceptable standards such as ISO27001.

4. **Safe data** – Does the release of the requested data itself present a disclosure risk, on its own or in the context of the history of prior data disclosures to this organisation or disclosures to other related parties?

5. **Safe output** – Has the data only been used for the approved purpose? If some analysis results are to be included in academic publications, reports or other accessible outputs, these should be statistically checked to be non-disclosing. If the output is a publication, the agreed terms on authorship and acknowledgement should be followed.

H2O is dedicated to transparency in every aspect of its operations, including how it shares patient data with research organisations. It maintains a public register of all approved data access requests, while ensuring that no personal patient information is included. To build trust within the ecosystem, the Observatory publishes information about:

- Data Access procedures and guidelines on how patient data can be accessed.

- Approved Organisations register and a list of organisations granted access to patient data.

- Its transparency register, including details of each data access, including the purpose, processing locations, type of data (whether aggregated, anonymised, pseudonymised, or identifiable), and the expected societal benefits.

This approach supports patient data being used responsibly, with a clear focus on benefiting society while maintaining patient privacy.

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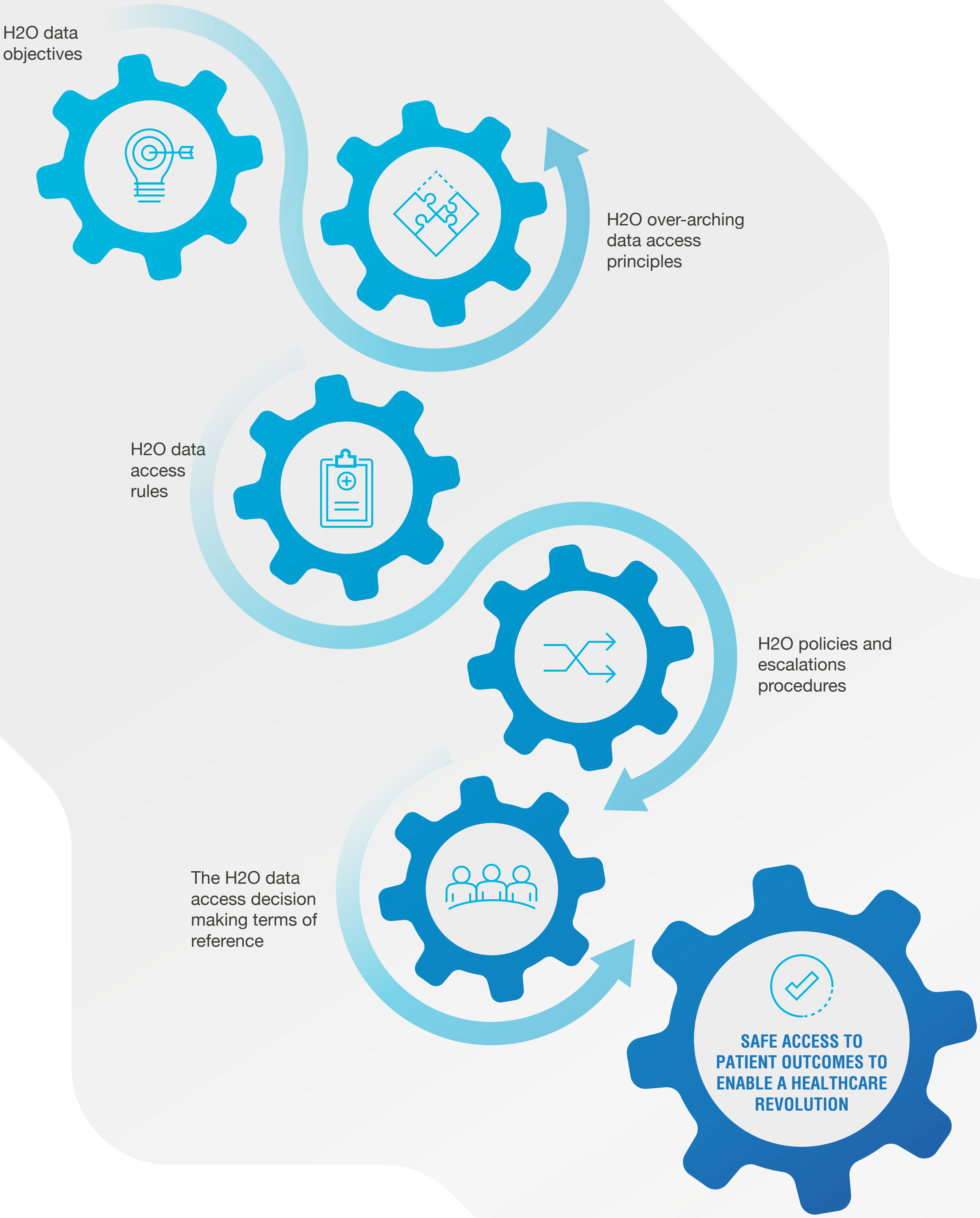
(1) Ritchie, Felix. (2016). Five Safes: designing data access for research. DOI 10.13140/RG.2.1.3661.1604

Data Access Governance

DIFFERENT STRUCTURAL ELEMENTS EACH OBSERVATORY USES



2. Accessing the data

Applying to access the different types of data

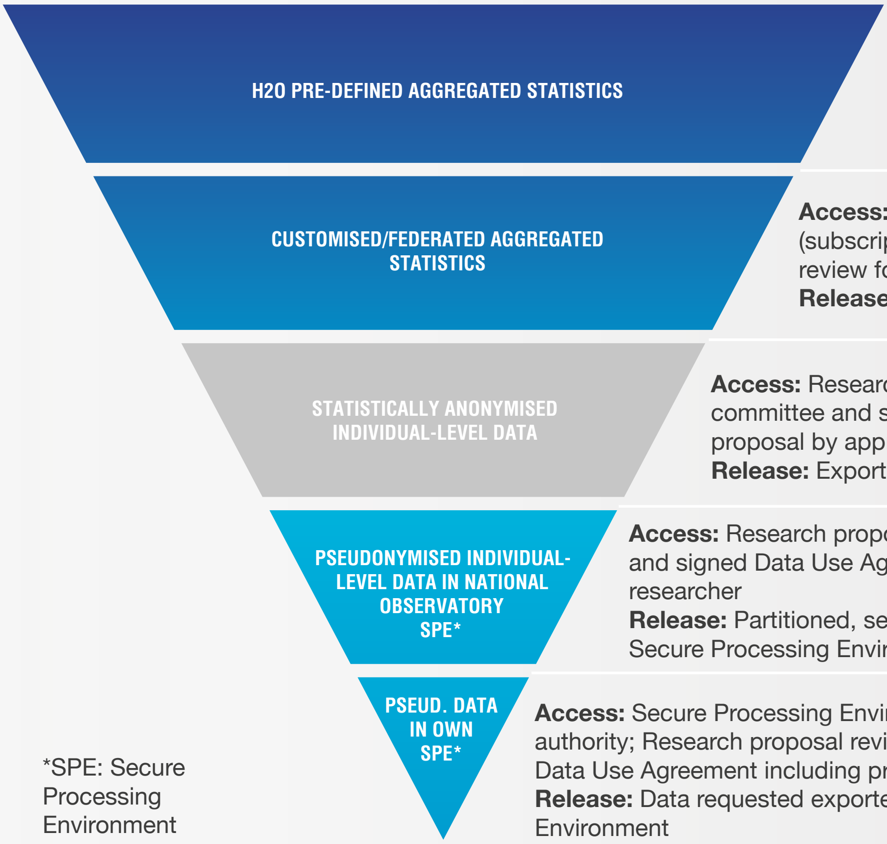
H2O's framework is designed to facilitate research while ensuring ethical and legal standards for data privacy and use. Once an organisation has confirmed its commitment to the overarching H2O principles and has been registered by an Observatory as being *bona fide* (H2O approved), it may submit data access requests. *Bona fide* status enables faster processing of data requests and access to more granular forms of data, as several elements of the five safes would be pre-approved.

By offering different levels of data granularity – ranging from aggregated statistics to pseudonymised data – H2O ensures balance between data accessibility and privacy is maintained. To avoid unnecessary data disclosures, H2O will provide data only of the minimum level of granularity needed for a given research project. This helps to maintain the trust needed to build a long-term sustainable and viable health data ecosystem.

The H2O data infrastructure has specific access pathways for each type of data request, as shown in the illustration and table below.

Figure 1. Overview of the types of data available and the corresponding requirements

DATA ACCESS & RESEARCH REQUIREMENTS



RESEARCH REQUEST TYPES	DATA ACCESS & RELEASE SPECIFICATIONS
H2O PRE-DEFINED AGGREGATED STATISTICS	**Access:** Standard terms and conditions (subscription) **Release:** View in national observatory with export to requestor´s own environment possible
CUSTOMISED/FEDERATED AGGREGATED STATISTICS	**Access:** Standard terms and conditions (subscription); possible need for Ethics Committee review for multiple queries on same data **Release:** Exported to requestor´s own environment
STATISTICALLY ANONYMISED INDIVIDUAL-LEVEL DATA	**Access:** Research proposal reviewed by independent committee and signed Data Use Agreement including proposal by approved researcher **Release:** Exported to requestor´s own environment
PSEUDONYMISED INDIVIDUAL-LEVEL DATA IN NATIONAL OBSERVATORY SPE*	**Access:** Research proposal reviewed by independent committee and signed Data Use Agreement including proposal by approved researcher **Release:** Partitioned, secure "room" in national observatory Secure Processing Environment
PSEUD. DATA IN OWN SPE*	**Access:** Secure Processing Environment approved by appropriate authority; Research proposal reviewed by Ethics Committee and signed Data Use Agreement including proposal by approved researcher **Release:** Data requested exported to approved Secure Processing Environment

*SPE: Secure Processing Environment

Accessing H2O data depends on the following conditions and principles:

- The conditions for accessing H2O data depends on factors such as the **granularity** of the requested data, the **nature of the research** and the **sophistication** of the applicant's data processing environment.
- In certain cases, third-party auditors may be consulted to ensure that the data platforms utilised by the data requesters meet the necessary security and privacy protocols.
- H2O aims to enable a straightforward process for accessing patient outcome data with **requirements increasing in proportion to requested data granularity.** This encourages researchers to only request the minimum amount of data needed for their projects.
- It is hoped that most requests will either be included in a **standard organisational agreement** or via a **"fast track" process.** For example, to access H2O's vast library of pre-defined standardised aggregated population-level statistics, it is sufficient to be a registered user of an approved organisation and agree to standard terms and conditions.

Summary[2]: Accessing different data types

Data type requested	How to access the data	Minimum requirements for the requester
Pre-defined aggregated statistics	• The easiest and fastest data to access. • Aggregated data is derived by an accountable Observatory person or task group and may be generated through a federated query. • The researcher may view the request in an H2O-hosted platform or export the statistics to their own environment. • Observatories may accept less details on the scientific, analysis plan and data protection detail in the request. • Observatories may agree to process such applications more rapidly through a fast-track procedure.	• Sign standard terms and conditions. • Submit Data Access Request (fast-track sections).
Customised aggregated statistics	• Identical process as above, but may require an independent ethics committee or an institutional review board review in case of multiple queries on the same dataset.	• Sign standard terms and conditions. • Submit Data Access Request (fast-track sections). • Possible Ethics Committee review.
Statistically anonymised individual-level data	• Requires a more detailed request in the Data Access Form, including a lay summary, of the intended study, study protocol, statistical analysis plan, and details of the requested data categories. • The Observatory will then determine the data inclusion / exclusion criteria and what level of EHR and patient outcomes should be included.	• Apply to become an H2O-approved organisation / researcher by submitting the New Client Form (Annex 5). • Submit Data Access Request in full. • Submit CVs.

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(2) Each data access request will be subject to national observatory access rules.

Pseudonymised data, accessible in the National Observatory's Secure Processing Environment (SPE) or the researcher's SPE	• Pseudonymised data is the most sensitive data available for researchers in the H2O ecosystem. At the same time, this data can provide the most insights into lived patient experiences. • Several special safeguards are introduced and extra requirements are placed on the requester of such data. • For data accessed via the National Observatory's Secure Processing Environment researchers must submit a full Data Access Request and sign the Data Use Agreement – a contract regulating the access to the agreed H2O dataset and the corresponding rights and obligations. • Access to such data generally entails a review of ethics, compliance and privacy by an independent ethics committee. • Pseudonymised data exported to a Secure Processing Environment (SPE), hosted or contracted by the requesting organisation may be acceptable, if evidence of its information security and governance safeguards has been provided and approved by the Observatory.	• Apply to become a H2O-approved organisation / researcher by submitting the New Client Form (Annex 5). • Submit Data Access Request in full. • Submit CVs. • If data is to be exported to the researcher's own or sub-contracted SPE, additional evidence of information security and governance safeguards must be provided and approved by the Observatory.

Note: All data requests must comply with H2O's ethical principles for data use and permitted research purposes.

Becoming an H2O-approved researcher or organisation

Only organisations committed to H2O's ethical principles for data use, permitted research purposes and commitments on data protection, governance and transparency (detailed in Annexes 1-3) will be approved to submit data access requests and be granted access beyond the level of pre-defined statistics as shown in Figure 1.

Researchers and organisations approved within the H2O ecosystem may be granted **access to a digitised, multinational and standardised data set,** reducing the economic and administrative burden of research. Approved organisations and researchers may also enjoy significant benefits in the processing and speed of handling data requests, and will have access to more granular health data.

Becoming an approved organisation/researcher

Organisation applies to become H2O approved by:

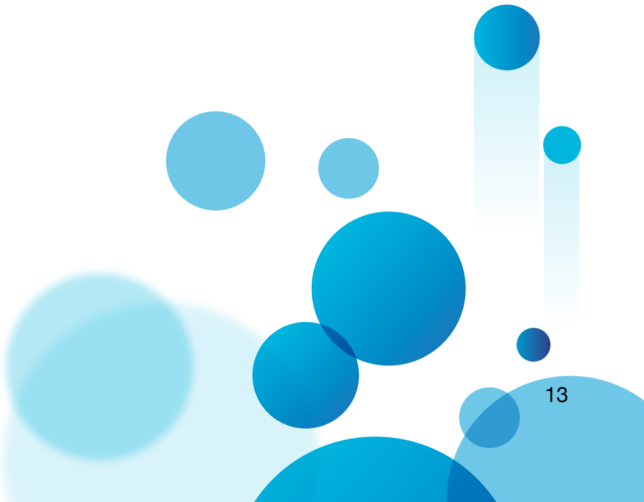
- Submitting New Client Form (Annex 5).
- Confirming adherence with:
  - H2O Endorsed Ethical Principles for Data Use.
  - H2O Permitted Research Purposes.
  - H2O Data Use Commitments regarding data protection, governance, and transparency.

After a new organisation has completed the New Client Form:

1. H2O National Observatory Secretariat will assess the application for completeness;
2. H2O National Observatory's (NO) entrusted individual will review the application;
3. New applicant passes vetting and becomes approved;
4. H2O updates the public register of the approved organisations.

It may be appropriate for Observatories to additionally approve one or more principal investigators within approved organisations. Proposing more than one investigator may be particularly relevant if the organisation is anticipated to request access to micro-data or pseudonymised data, to allow for appropriate verification of the suitability of a lead to oversee the information governance and scientific validity of data use. In this case:

1. The researcher submits a CV (and additional training certificates e.g. on GDPR).
2. H2O National Observatory (NO) assesses CV & experience.
3. H2O NO may suggest collaboration to gain experience.
4. Confirm researcher has the required training/experience.
5. Approval of (individual) researcher.



Annexes FOR ILLUSTRATIVE PURPOSES ONLY

Annex 1:

The H2O Endorsed Ethical Principles for Data Use[3]

Any organisation applying to register with an H2O Observatory as a *bona fide* organisation must agree to uphold the following principles regarding its intended uses of data provided via one or more H2O Observatories.

1. Health and health related data must only be reused for purposes that aim to directly result in, or contribute to bringing, benefits to society in terms of improved opportunities for better health and care.
2. Health and health related data must never be reused for purposes that are unethical, violate human rights, will directly disadvantage or are very likely to directly disadvantage individuals or groups of individuals, or will exclusively further individual or organisational interests without bringing benefits to some parts of society.
3. The reuses of health and health related data must always safeguard the privacy of individuals whose data are being reused, by complying with all applicable data protection laws (such as the EU GDPR), by adopting robust information security and privacy preserving measures, and by using aggregated or anonymised data whenever possible. These limits must be balanced against benefits that may be achieved by using identifiable or pseudonymised data.
4. The reuses of health data must be respectful to the holders of the data being used, and adhere to data use terms agreed with the data holders including the purposes for which their data may be reused.
5. The results from reusing health and health related data should be published, or shared in some other way unless the results are (i) personally damaging to identifiable participants, and (ii) may be used to discriminate against groups, (iii) subject to commercial use for products and services.
6. Organisations that reuse health and health related data must make every effort to be as transparent as possible to the public about their use of health data and the outcomes of each data use.

H2O will ensure that these principles are upheld when defining decision making rules and be transparent to the public about those rules, the data access decisions that they make and the societal benefits that those data reuses have enabled.

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(3) Main principles of Annexes 1- 3 derived from iHD & the digital health society (2023) "Proposal for a Societal Compact for the secondary use of health data", available at: https://www.i-hd.eu/wp-content/uploads/2023/09/Round-Table-6-Proposal-for-a-Societal-Compact-for-the-secondary-use-of-health-data.pdf

Annex 2:

The H2O Permitted Research Purposes[4]

Any organisation applying to register with an H2O Observatory as a *bona fide* organisation must agree that it will only use data provided via an H2O data use agreement for one or more of the following categories of purpose. These categories are identical to those listed in Article 34 of the Regulation on the European Health Data Space (COM 197/2022).

a. Activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices.

b. To support public sector bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates.

c. To produce national, multi-national and Union level official statistics related to health or care sectors.

d. Education or teaching activities in health or care sectors.

e. Scientific research related to health or care sectors.

f. Development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices.

g. Training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices.

h. Providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.

A non-exhaustive list of research purposes is given below as an illustration of the interpretation of purpose e) above.

- Epidemiology and observational research studies.
- Disease understanding, disease burden, unmet need and stratification.
- Outcomes research, comparative effectiveness research.
- Predictive analytics and identify patient sub-groups that respond better to certain treatment.
- Digital innovation: devices, sensors, apps (including understanding patient experience and PROs).
- AI development conforming to the new AI Regulation.
- Quantify deeply stratified populations, for targeted therapies and personalised medicine.
- Biomarker discovery and validation.
- Diagnostics development.
- Accelerate the conduct of clinical trials.
- New treatment indication areas.
- Adaptive trials and licensing.
- Patient characterization and optimal treatment sequencing.
- Testing and improving outcome sets.
- Assessing the feasibility of planned research and implementation.

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(4) Main principles of Annexes 1- 3 derived from iHD & the digital health society (2023) “Proposal for a Societal Compact for the secondary use of health data“, available at: https://www.i-hd.eu/wp-content/uploads/2023/09/Round-Table-6-Proposal-for-a-Societal-Compact-for-the-secondary-use-of-health-data.pdf

Any organisation applying to register with an H2O Observatory as a *bona fide* organisation must agree that it will not use health or health related data for any of the following categories of misuse purposes. These categories are identical to those listed in Article 35 of the Regulation on the European Health Data Space (COM 197/2022).

a. Taking decisions detrimental to a natural person based on their electronic health data; in order to qualify as "decisions", they must produce legal effects or similarly significantly affect those natural persons.

b. Taking decisions in relation to a natural person or groups of natural persons to exclude them from the benefit of an insurance contract or to modify their contributions and insurance premiums.

c. Advertising or marketing activities towards health professionals, organisations in health or natural persons, unless in strict compliance with the applicable law for drug advertising.

d. Providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit.

e. Developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services which are designed or modified in such a way that they contravene public order or morality.

Any organisation applying to register with an H2O Observatory as a *bona fide* organisation must additionally agree that that it will not use health or health related data for purposes that would violate the European Convention on Human Rights, nor use health or health related data for any of the following misuse purposes:

- Research uses of data that would require but have failed to achieve ethical approval.
- AI development that would not be permissible in the EU.
- Weapons development and research, including development of biological weapons (but OK for research into treatments following biological attack).
- Drugs for use in capital punishment, interrogation or torture.
- Eugenics.
- Political projects where there is party political gain motivating the research.
- Discrimination and profiling of persons.
  - Using data to develop profiles intended for marketing, service access or financial purposes.
    - » e.g. the exclusion of guarantees from insurance contracts and the modification of insurance contributions or premiums of an individual or group of individuals presenting the same risk.
  - Unless the population profiling is solely to target appropriate therapies and to assess health risks.
- Advertisement or marketing activities.
- Research where the sole outcome is a financial interest.
- Research which would be deemed illegal in the country in which the data user organisation is based, the country of data processing or the country from which the data originates.

Annex 3:

H2O Data Use Commitments regarding data protection, governance and transparency[5]

An organisation signing an H2O Data Use Agreement must comply with to all of these commitments, as further defined in the H2O Data Use Agreement.

Declared purposes

1. The organisation commits to only use health data and health related data to which access has been granted according to an H2O Data Use Agreement for one or more of the purposes listed as permitted uses. It commits never to use health data and health related data for any of the listed prohibited purposes.

2. If data access has been granted to the organisation by H2O for explicitly specified purposes, the organisation commits to only use the data for those specified purposes.

3. The organisation will only permit its personnel to use data for the purposes that have been approved, and will have appropriate governance mechanisms to ensure that data are not used for non-approved or prohibited purposes.

Legal basis

4. The organisation commits to verify with H2O that a suitable legal basis exists for the intended data access and data use by the organisation, if the data falls under the scope of the GDPR or any other applicable data protection legislation.

5. H2O and data user agree that all health data sharing will comply with all European Union and Member State laws applicable to such health data sharing.

Permissions

6. The organisation commits to verify with the data custodian that where ethics committee or other research governance permissions are required for the intended data use, such permissions have been applied for or obtained. If the permission is still at the application stage and the organisation will not use the data until such permission has been granted.

7. If H2O has itself obtained the data from other originating data sources, the adopting data using organisation commits to verify, and may seek evidence, that H2O has the necessary permissions to provide the data access to the organisation for the intended purposes.

Data protection

8. The organisation commits to having suitable data protection policies and codes of practice that ensure that its personnel have sufficient knowledge of the GDPR and other data protection legislation, and know how to apply these within their job responsibilities and activities, so that they enable the organisation to meet data protection compliance obligations.

9. The organisation commits to initial training and regular update training in data protection to all staff who process personal health data as defined by the GDPR and has appointed officers who are responsible for data protection and for investigating any issues that arise with the way the data are used or misused.

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(5) Main principles of Annexes 1- 3 derived from iHD & the digital health society (2023) "Proposal for a Societal Compact for the secondary use of health data", available at: https://www.i-hd.eu/wp-content/uploads/2023/09/Round-Table-6-Proposal-for-a-Societal-Compact-for-the-secondary-use-of-health-data.pdf

Data handling

10. The organisation commits to having information security policies, and technical and organisational information security measures (including trained staff), to a level that safeguards the use of personal health data as defined by and as required by the GDPR, by relevant national Data Protection Authorities and by the data custodian.

11. The organisation commits to requiring the obligations of an H2O Data Use Agreement to be complied with by any other permitted party with which it shares the data it has been granted access to, pursuant to the H2O Data Use Agreement.

12. The organisation commits to agreeing with H2O and specifying in the Data Use Agreement if its copy of the data must be destroyed (and when) after the permitted purpose of use has been completed.

Analysis and results

13. The organisation will state how it plans to use the findings it obtains from the data, in terms of whether the results are intended to be published as scientific findings, used to develop or validate or monitor the use of a healthcare product or service, to guide future internal strategy, to test hypotheses prior to conducting a more substantive study or any other legitimate purpose.

14. The organisation will negotiate and agree with H2O whether any enhancements to the data that are made through the course of conducting the purpose, such as statistical data enrichment or cross mapping to additional terminology systems, will be provided back to H2O and under what terms, including with regard to intellectual property ownership and access.

Transparency of use

15. The organisation commits to maintaining a public inventory (possibly through its web site) of data reuses being made according to an H2O Data Use Agreement, at minimum containing the information specified by H2O, and to keeping this up-to-date.

16. The inventory should specify the data sources that are intended to be used, the intended purpose, the intended time interval for undertaking that purpose, and at a high level how the findings will be used by the organisation (to be described by the researching organisation in the Data Access Request Template).

Declaration of intended societal benefit

17. The organisation commits to publishing, either as part of the above public inventory or elsewhere on its web site, a brief lay summary of the intended data use and the expected eventual societal benefit from the data use and, once the intended purpose has been completed, the outcome from such data use.

Dissemination of results

18. The organisation commits to the principles of open science and to reasonably make all or some of the findings from its data use accessible to other data users.

Annex 4:

The H2O Data Access Request Template

This table lists the information to be provided by a registered H2O *bona fide* organisation for each data access request. A formal (online) template will be created later. The final H2O approved Data Access Request will be incorporated into the final Data Use Agreement.

For applications requesting access only to aggregated data, or to utilise a federated query approach to generated statistically checked aggregated data (if available) a fast track procedure may be introduced by Observatories, requiring only completion of the fields in this form that are marked with this (Bullet Train) symbol:

APPLICABLE TO FAST TRACK

Applying Organisation details

- Name of the organisation
- Full legal name
- Registered address and registration number

Requester details

Requesting organisation APPLICABLE TO FAST TRACK	Must be an H2O approved organisation: *[COMPLETE]*
Senior investigator leading on the data study	Name, designation, contact details Designation must be senior enough: *[COMPLETE]*

Data study details

Title of the data study and name of requesting organisation APPLICABLE TO FAST TRACK	Forms part of the Transparency Commitment and requesting organisation agree that this description will be used in organisation's own and H2O publicly accessible transparency register together with requestion organisation's name: *[COMPLETE]*

Category of data use purpose APPLICABLE TO FAST TRACK	Specification of the purpose category from the H2O list (to be further aligned with the EHDS Regulation, when finalised): *[SELECT]* ☐ activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices; ☐ support public sector bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates; ☐ produce national, multi-national and Union level official statistics related to health or care sectors; ☐ education or teaching activities in health or care sectors; ☐ scientific research related to health or care sectors; ☐ development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices; ☐ training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices; ☐ providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons; ☐ Others? Describe: ....
Details of the research purpose and intended use of study results APPLICABLE TO FAST TRACK	Short description of the data study objective and intended use: *[COMPLETE]*
Add information in case of an interventional and/ or prospective study (e.g. if any data subject access requests are part of this application and why)	Describe study design if prospective in nature and if contacting patients for recruitment is required, e.g. to collect additional data, to collect samples and describe process to procure patients’ consenting steps (ICF) including any eventual publication commitments
Research protocol (if applicable)	Attached or a link, if required, e.g. for access to a patient level data set: *[COMPLETE]*
Approvals obtained or in progress (if applicable)	Document or the provision of any information of any ethics committee approval or application in the pipeline, internal organisational approval or other permissions required and obtained or pending: *[COMPLETE]*

Intended dissemination of the study outputs (form, channels, timing) APPLICABLE TO FAST TRACK	e.g. if the knowledge obtained is intended for direct publication or other form of open access, or is intended to be used within products or services for the public good, but will not necessarily be published: *[COMPLETE]*
Intended organisational exploitation of the study outputs APPLICABLE TO FAST TRACK	Requesting Organisation: Including details of the handling of intellectual property, publication, authorship, acknowledgement: *[REQUESTING ORGANISATION TO COMPLETE A DESCRIPTION OF SUCH OUTCOME WHICH WILL BE MADE TRANSPARENT ON H2O TRANSPARENCY REGISTER]* *[ADD APPROVED CITATION HERE]* H2O Response: H2O standard acknowledgement and contribution text must always be used, which is dependent on the actual contribution: *[To be completed by H2O as part of the approval process]*
Scientific abstract of the proposed study	~250 words *[COMPLETE]*
Lay abstract of the proposed study, including anticipated societal value APPLICABLE TO FAST TRACK	~ 100 words *[COMPLETE]*

Data request details

Data access date interval APPLICABLE TO FAST TRACK	Start and end data for authorisation to access the data, or date of providing the data if being hosted by the requester: *[COMPLETE]*
Geographical scope of the request (e.g. from which observatories, sites) APPLICABLE TO FAST TRACK	*[COMPLETE]*
Specification of the subject population to be included APPLICABLE TO FAST TRACK	e.g. disease, age groups, other inclusion/exclusion criteria. Initially to judge the suitability of the request, later when performing data extraction, needs to be specified relevant to the proposed study: *[COMPLETE]*

Specification of the data item categories requested APPLICABLE TO FAST TRACK	Probably from a list of data categories that we maintain: *[COMPLETE]*
Any requirement for longitudinal linkage (with justification)	H2O may be requested to provide e.g. for serial data access and use over time: *[COMPLETE]*
Any linkage to external data requested for H2O to undertake	H2O may be requested to provide this service: *[COMPLETE]*
Requested form of the data (i.e. extent of de-identification: anonymised, pseudonymised, aggregated data generated by H2O…) APPLICABLE TO FAST TRACK	*[ADD HERE A DESCRIPTION OF WHAT TYPE OF DATA IS REQUESTED AND THE UNDERLYING JUSTIFICATION FOR THE REQUESTED FORM OF THE DATA. H2O MAY SUGGEST A DIFFERENT CATEGORIZATION]*
Specification of any data quality requirements (e.g. minimum quality score of certain dimensions) APPLICABLE TO FAST TRACK	H2O aims to offer quality label its data holdings: *[COMPLETE]*
Any data enhancing activities requested for H2O to perform prior to data release	H2O may be requested to provide this, as a service: *[COMPLETE]*
Requested hosting facilities for the data	Requesting Organisation: *[COMPLETE e.g. H2O SPE, own SPE, including supplementary security details about the requesters own SPE]* H2O Response: *[To be completed by H2O as part of the approval process]*

Data usage details

Analysis plan (if appropriate or requested by H2O)	Add a full statistical analysis plan: *[COMPLETE]*
Any third parties (e.g. subcontractors, data processors) that will access and process the data	Requesting Organisation: *[COMPLETE]* Additional H2O requirements: *[To be completed by H2O as part of the approval process]*
List of countries in which the data will be processed	*[COMPLETE]*

If any data enriching activities such as cleaning, variable derivation and/or analysis will be undertaken by the data user, and if any enhanced data sets will be provided back to H2O	*[COMPLETE]*
Data retention	
Requested duration of data access beyond the above study duration, with justification APPLICABLE TO FAST TRACK	Especially important if the data will not be hosted by H2O. Requesting Organisation: *[COMPLETE]* Additional H2O requirements: *[To be completed by H2O as part of the approval process]*
Any request for H2O to archive the data set (e.g. for research governance purposes and to regenerate data sets with historic accuracy) APPLICABLE TO FAST TRACK	Requesting Organisation: *[COMPLETE]* Additional H2O requirements: *[To be completed by H2O as part of the approval process]*

Annex 5:

The H2O data access registration template (New Client Form)

This annex lists the information to be requested from an organisation seeking new client registration with a national or European H2O Observatory, as a data user. It also lists the commitments that the organisation agrees to as part of its registration request.

A formal (online) template will be created later.

Organisation details

Name of the organisation

Full legal name

Registered address and registration number

URL

National or European office, if applicable

Contact details for legal and contractual matters (name, address, email, telephone)

Contact details for scientific, research, and data related matters (name, address, email, telephone)

Contact details of the DPO (name, address, email, telephone)

Representations

The organisation agrees that it meets the criteria of being an H2O *bona fide* organisation. It agrees to adhere to all existing H2O Data Access Rules & Procedures, the H2O Endorsed Ethical Principles, to only use data provided by any H2O Observatory for H2O Permitted Research Purposes and never for prohibited purposes, to adhere to the H2O Data protection, governance and Transparency Commitments, and to adhere to the terms of H2O data use agreements for every approved access to data provided by or via an H2O Observatory.

The organisation represents and warrants that it complies with all applicable laws and regulations, including applicable data protection and privacy laws and applicable guidelines of the International Council on Harmonisation (“ICH”), as adopted by applicable regulations and that it complies fully at all times with all applicable anti-bribery and anti-corruption laws. It further represents that it has not and it will not use in any capacity the services of anyone debarred, disqualified, blacklisted or banned or under investigations or threat of investigations by any regulatory authority for debarment, disqualification, blacklisting or any similar regulatory action in any jurisdiction anywhere in the world.

About H2O

The Health Outcomes Observatory (H2O) is a public-private partnership funded by the European Union's Innovative Medicines Initiative (IMI) and members of the European Federation of Pharmaceutical Industries and Associations (EFPIA). It was launched on 1 October 2020 and will run for 60 months, through September 2025.

H2O brings together the public and private sectors to create a standardised data governance and infrastructure system across Europe to incorporate patients' experiences and preferences in decisions affecting their individual health care and those of the entire patient community. With H2O infrastructure and tools, patients will be able to measure their outcomes in a standardised way, whilst keeping full control of their data. This framework aims to foster innovation in health care in Europe and beyond to deliver better outcomes for all.

H2O Partners

H2O's 23 partners include Medizinische Universität Wien (coordinator) and Takeda Pharmaceuticals International AG (project leader); Charité – Universitätsmedizin Berlin, Erasmus Universitair Medisch Centrum Rotterdam, Institut Català de la Salut – Hospital Universitari Vall d'Hebron, Novartis Pharma AG, F. Hoffmann-La Roche Ltd, and Eli Lilly International as Executive Committee members; and King's College London, Katholieke Universiteit Leuven, Forum Européen des Patients / European Patients' Forum, the European Institute for Innovation through Health Data, The Hyve BV, TEAM IT Research, Karolinska Universitetssjukhuset, Università Vita-Salute San Raffaele, De Stichting Integraal Kankercentrum Nederland, AbbVie INC, AstraZeneca AB, JDRF, Pfizer Ltd, Sanofi-Aventis Recherche & Development, and Trial Nation as consortium members.

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