945345 – H2O

Health Outcomes Observatory

WP2 – Technical Infrastructure and Interoperability

D2.1 – Assessment of the Local and National Situation

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Definitions

- Participants of the H2O Consortium are referred to herein according to the following codes:
  1. MUW — Medizinische Universität Wien
  2. Charité — Charité - Universitätsmedizin Berlin
  3. EMC — Erasmus University Medical Center
  4. ICS-HUVH — Institut Català de la Salut - Hospital Universitari Vall d'Hebron
  5. KCL — King's College Hospital
  6. KUL — Katholieke Universiteit Leuven
  7. EPF — European Patients' Forum
  8. I-HD — The European Institute for Innovation through health data
  9. The Hyve — The Hyve
  10. TEAMIT — Teamit Research
  11. KUH — Karolinska University Hospital
  12. UniSR — Vita-Salute San Raffaele University
  13. IKNL — Netherlands Comprehensive Cancer Organisation
  14. TAKEDA — Takeda Pharmaceuticals International AG
  15. NVS — Novartis Pharma AG
  16. ABBVIE — Abbvie INC
  17. Lilly — Eli Lilly and Company Limited
  18. MDT — Medtronic International Trading SARL
  19. Pfizer — Pfizer Limited
  20. ROCHE — F. Hoffmann-La Roche Ltd
  21. SARD — Sanofi-Aventis Recherche & Developpement
  22. JDRF — JDRF International (AP)
  23. Trial Nation — Trial Nation (AP)

- 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
AKH	Allgemeines Krankenhaus der Stadt Wien
AORTA	The Dutch national infrastructure for the exchange of data between healthcare providers
app	Application
APPC	Austrian PACS Procedure Code
AQuAS	Agència de Qualitat i Avaluació Sanitàries de Catalunya
ATC	Anatomical Therapeutic Chemical
CDA	(The HL7) Clinical Document Architecture
CDM	Common Data Model
CIE10	Clasificación Internacional de Enfermedades (Spanish counterpart of ICD-10)
DICOM	Digital Imaging and Communications in Medicine
DiGAs	Digital health applications (in German, Digitale Gesundheitsanwendungen)
DHD	Dutch Hospital Data
EHDEN	European Health Data and Evidence Network
EHR	Electronic Health Record
ELGA	elektronische Gesundheitsakte (German for EHR)
ePA	elektronische Patientenakte (German for Electronic Patient Record)
EPD	Electronic Patients Dossiers
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
HDP	Health Data Platform
HIS	Healthcare Information System
HL7	Health Level Seven International
H2O	Health Outcomes Observatory
IBD	Inflammatory Bowel Disease
ICD	International Classification of Diseases
ICPM	International Classification of Procedures in Medicine
ICS	Institut Català de la Salut (in English, Catalan Health Institute)
ID	Identity
IHE	Integrating the Healthcare Enterprise

IT	Information Technology
LIS	Laboratory Information System
LOINC	Logical Observation Identifiers Names and Codes
LSP	The Dutch national switch point (in Dutch, Landelijke schakelpunt)
MeDIC	Medical Data Integration Center
MII	Medical Informatics Initiative
MIOs	Medical Information Objects
NHC	Número de Historia Clínica (in English, Clinical History Number)
OHDSI	Observational Health Data Sciences and Informatics
OMOP	Observational Medical Outcomes Partnership
PACS	Picture Archiving and Communication System
PZN	Austrian Pharmazentralnummer
RDA	Research, Documentation, and Analysis (EHR system at MUW)
RIS	Radiology Information System
SAP	Systems, Applications, and Products
SNOMED CT	Systemised Nomenclature of Medicine – Clinical Terms
TNM	Classification of Malignant Tumors
TOC	Tier One Countries (Austria, Germany, Netherlands, and Spain)
UCUM	Unified Code for Units of Measure
WP	Work Package

1. Introduction

The Health Outcomes Observatory (H2O) project (https://health-outcomes-observatory.eu/) is designed to enable a value-based approach in healthcare systems, improving their sustainability by helping them optimize care delivery and the use of their resources around outcomes that matter to patients. Patients will be provided with digital tools that will allow them to measure their symptoms in a standardized manner, to integrate their patient-generated data with clinically generated outcomes data, and to communicate with their health professionals, as well as with other healthcare providers, and align on the right course of action. National observatories will be set up in four European countries – Austria, Germany, the Netherlands, and Spain, also known as Tier One Countries (TOC), initially focused on diabetes, inflammatory bowel disease, and oncology. These will provide integrated information on patient outcomes for patients and their healthcare providers for use in clinical care.

The main aim of Work Package 2 (WP2) of H2O is the design and implementation of the technical architecture of the H2O project, to support data management according to the project vision. This document reports on our assessment of the local and national situation regarding data protection, access to and integration of outcomes data from existing clinical records in the participating hospitals and the TOC, which will pilot the solutions developed and drive the adoption of H2O throughout Europe.

2. Method

To assess the prerequisites and options for implementing H2O in the partner hospitals as well as in the TOCs, this deliverable describes local and national specifics and the current state regarding (i) data availability, (ii) the implementation of interoperability standards, (iii) identity management and legal frameworks for accessing health data, and (iv) the technical IT landscape and readiness for deploying the first version of the H2O architecture. In terms of data availability, we aimed to gain insights into the IT systems storing data relevant to H2O, what (structured) data has already been made accessible for primary and secondary purposes as well as information on the quality and completeness of data. In terms of interoperability standards, we aimed at identifying standard interfaces (e.g. following Integrating the Healthcare Enterprise (IHE) or Health Level 7 (HL7) specifications), support for standard data models, such as HL7 Fast Healthcare Interoperability Resources (FHIR) or the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) and the Observational Health Data Sciences and Informatics (OHDSI) tools as well as the use of standard terminologies and ontologies, such as Logical Observation Identifiers Names and Codes (LOINC), Unified Code for Units of Measure (UCUM) or the Standard Nomenclature of Medicine (SNOMED) Clinical Terms (CT). In terms of identity management and legal frameworks for data access, we aimed to identify local and national mechanisms for patient identification, legal basis and restrictions for the secondary use of data, and information on standard data protection mechanisms, such as pseudonymization, already supported. Finally, we also aimed at finding out whether the hardware and software requirements for running and maintaining observatory instances could be fulfilled by all hospitals (cf. Deliverable D2.2).

To develop this overview, a mixed-methods approach has been implemented. Firstly, two structured questionnaires have been developed in the WP2 working group and were sent out

during the first months of the project to the following partners: the Medizinische Universität Wien (MUW), the Charité – Universitätsmedizin Berlin (Charité), the Erasmus University Medical Center (EMC), and the Institut Català de la Salut – Hospital Universitari Vall d'Hebron (ICS-HUVH). Both questionnaires aimed at performing an assessment of the local and the national prerequisites and options for implementing H2O in the partner hospitals as well as in the TOCs. We decided to also put a focus on national EHR systems and eHealth infrastructures, as these have frequently been discussed as potential platforms running important components of H2O, or at least integrating with the H2O network. Secondly, the responses from the questionnaires were compiled into sections for each partner and TOC and complemented with additional information from a reference study that was conducted in 2018 by the German Bertelsmann-Stiftung[1]. Finally, the content was again reviewed by WP2 subject matter experts for final approval.

3. Results

The H2O infrastructure aims to support four important types of use cases: (1) enabling clinical decision support (e.g., outcome prediction, targeted treatment, symptom monitoring, and side-effect tracking); (2) fostering informed decision making through patient engagement and empowerment, as well as improved patient-provider communication; (3) supporting resource allocation through public reporting and quality assurance mechanisms; and (4) achieving scientific knowledge gain (e.g., by enabling comparative effectiveness and pharmacovigilance studies). The first two types of use cases are mainly based on the collection and exchange of individual patient data, whereas the latter two are mainly based on analytics over health data from certain cohorts. Hence, we put specific attention on these two general aspects.

3.1. Local Situation at the Participating Hospitals

3.1.1. Medical University of Vienna

Healthcare and Research Systems: The University Hospital Vienna of the Medical University of Vienna is known as Allgemeines Krankenhaus der Stadt Wien (AKH). The two main information systems of AKH that manage data relevant to the H2O project are the Hospital Information System (HIS) based on SAP IS-H and Cerner i.s.h.med, and the RDA (Research, Documentation, and Analysis) platform. The RDA platform integrates research-relevant data in a central Oracle database, which is continuously and automatically supplied with routine data, laboratory data, surgery protocols/reports, and other clinical data. AKH's HIS is also connected to the Austrian national electronic health record system ELGA (see Section 3.2.1) by providing data as Health Level 7 (HL7) Clinical Document Architecture (CDA) documents and accessing data in the form of CDA documents. Moreover, selected data is exported in regular intervals into national and European disease registries. For research purposes, the RDA platform supports exporting selected data items for selected cohorts in pseudonymized form. AKH is an EHDEN data partner, currently with a focus on anaesthesiology data. An extension to further data types

[1] Thiel R, Deimel L, Schmidtmann D, Piesche K, Hüsing T, Rennoch J, Stroetmann V, Stroetmann KA. SmartHealthSystems: international comparison of digital strategies. Gütersloh: Bertelsmann-Stiftung. 2019. Link: https://www.bertelsmann-stiftung.de/de/publikationen/publikation/did/smarthealthsystems-1

relevant to H2O is currently under development. AKH is also well equipped to provide the hardware needed for running an H2O observatory or a local access node.

Data Availability and Standards: The RDA platform integrates quite a lot of H2O-relevant data in structured and interoperable form, including diagnoses; laboratory reports; histology exams; surgery reports (including transplants); medication prescriptions; breast cancer reports; radiation doses; pulmonary function measurements; heart ultrasonic reports and more. Standards currently in use include the International Classification of Diseases (ICD), LOINC, SNOMED CT, Austrian Pharmazentralnummer (PZN), Anatomical Therapeutic Chemical (ATC) codes, Austrian PACS Procedure Code (APPC), and Digital Imaging and Communications in Medicine (DICOM). The structured data available fits well with the H2O use cases on Diabetes, Breast Cancer, Lymphoma, and Myeloma. Data availability for the Inflammatory Bowel Disease (IBD) use case is limited.

Patient identification and Regulatory Aspects: In terms of patient identification and regulatory requirements for using health data for research purposes, AKH follows the usual approach. A leading patient identifier is generated by the HIS, which can be used to identify relevant data across different subsystems. The RDA supports exporting data in pseudonymized form for research purposes. The Austrian data protection law allows healthcare providers to re-use the data collected for in-house research purposes. Sharing data with further partners or processing it externally requires informed consent and, obviously, aspects of data handling are subject to the EU General Data Protection Regulation (GDPR).

3.1.2. Charité – Universitätsmedizin Berlin

Healthcare and Research Systems: Like AKH, Charité's HIS is based on SAP IS-H and Cerner i.s.h.med, which are running on an Oracle database and are connected to a range of subsystems, such as a Laboratory Information System (LIS), a Radiology Information System (RIS), and Picture Archiving and Communication System (PACS) from different vendors. Additional systems managing data relevant to H2O's use cases include the clinical cancer registry software GTDS by University Gießen and an in-house developed research and outpatient documentation system for patients with IDB. Data from the HIS and further sources are continuously replicated into Charité's Health Data Platform (HDP) and Medical Data Integration Center (MeDIC; see below) where it is fed into different data pools and platforms for downstream data use in healthcare and research settings. Important services include a Hadoop-based data lake, a FHIR repository based on specifications from the German Medical Informatics Initiative, use-case specific HL7 data streams, and a clinical and translational data warehousing platform. Recently, Charité has become an EHDEN data partner with the specific focus of transforming data relevant to H2O into the OMOP CDM and establishing an OHDSI tool chain. Charité has a range of IT offerings for research projects and is well prepared to provide the hardware and software needed to run H2O components.

Data Availability and Standards: Via the systems and services described above, a range of data items can be provided for secondary purposes, based on a range of interoperability standards. Important examples include general administrative data, such as data on administrative visits, diagnoses and procedures, patient demographics, health and medical history, body mass and height, as well as a range of LOINC-coded lab values. The IBD data collection system includes

further information on diagnoses, Montreal classification and Harvey-Bradshaw-Index for Morbus Crohn patients, Oslo classification for patients with colitis ulcerosa / indeterminate, Mayo score for colitis ulcerosa, detailed information on comorbidities, as well as prior and current medication. The clinical cancer registry contains the usual information on diagnoses, tumour localization, TNM staging, histology, operations and procedures (surgery, radiotherapy, chemotherapy, as well as a range of clinically relevant events). The availability of structured data on diabetes patients is currently limited, but a specialized outpatient documentation system is currently being established. Interoperability standards in use include ICD-10-GM, ICPM-GM, LOINC German Top 300, UCUM, TNM, DICOM. Germany has just recently become a member of SNOMED and the introduction of SNOMED CT is ongoing.

Patient identification and Regulatory Aspects: In terms of identity management, Charité's IT landscape follows the usual approach with a leading patient identifier being managed by the HIS. Additional pseudonymization services via a Trust Center have been established and are used to create stable pseudonyms for secondary data use in research settings. On the regulatory side, clinical data that has been collected within a specific treatment context may be used for research purposes in pseudonymized form by physicians directly involved in that treatment according to the Berlin State Hospital Law. Further aspects are regulated by the GDPR or Germany's implementation in the German Data Protection Act, respectively. As part of the Medical Informatics Initiative (MII; see below), a broad informed consent for using healthcare data for research purposes is currently being established throughout Germany and Charité is implementing according pilot studies.

3.1.3. Erasmus Medical Center

Healthcare and Research Systems: The Erasmus Medical Center maintains a range of information systems that are relevant to the H2O project. These include the HIS HiX by Chipsoft, which maintains the electronic health record, the LIS Labtrain and the Pathology Information System SymPathy. For using this data for secondary research, EMC is currently establishing a platform (also) called Health Data Platform (HDP) that aims at integrating and making available all structured data collected at EMC through standardized FHIR-based interfaces. EMC is coordinating the EHDEN project and has established a comprehensive OMOP/OHDSI platform.

Data Availability and Standards: Through the services and solutions mentioned above, EMC can provide a range of data items to the H2O project. Important examples include discharge summaries, data on allergies, patient records, functional examinations, medication, measurements, imaging, laboratory values, surgery reports, radiology images, radiotherapy, and emergency care, but also patient reported outcomes (PROMs). Usual interoperability standards for representing such structured data are only partly implemented by the various systems.

Patient identification and Regulatory Aspects: EMC also follows the usual approach of having the HIS manage a unique and leading patient identifier. No specific rules or regulations on data use for healthcare and research settings have been reported, which makes the GDPR or the Dutch implementation – Algemene verordening gegevensbescherming (AVG) – the most important legal framework. No information has been provided on specific protection measures (e.g., pseudonymization) for research data use, but the HDP that is currently being established is expected to provide such functionalities.

3.1.4. Hospital Universitari Vall d'Hebron

Healthcare and Research Systems: Like AKH and Charité, the HIS of Institut Català de la Salut - Hospital Universitari Vall d'Hebron is based on SAP IS-H and Cerner i.s.h.med running on an Oracle database and is connected to the usual subsystems from different vendors. Relevant data to the H2O project can be extracted from these systems into a data warehouse, as well as into an Hexadata platform. Hospital Universitari Vall d'Hebron is an EHDEN data partner and has established an OMOP database and the OHDSI tool chain. This database is being created and populated since January 2021 and is expected to be completed by the end of October 2021. The data relevant to H2O that is being transformed into the OMOP database includes patient demographics, episodes, diagnoses (including allergies), procedures, inpatient data, emergency data, laboratory test results, medication, and clinical measurements.

Data Availability and Standards: The usual structured data is available in healthcare as well as research settings. Standard interfaces based on HL7 v2.x are available for accessing data from the HIS as well as a FHIR-ready integration bus (InterSystems IRIS). On the terminology level, LOINC has been implemented for some laboratory values, as well as SNOMED CT for pathological anatomy (PA) and ICD-10 (CIE10 in Spain) for procedures and diagnostics.

Patient identification and Regulatory Aspects: Analogously to the other sites, patients are identified by a leading identifier maintained by the HIS, which is known as the Clinical History Number (NHC). On the legal and regulatory level, the national data protection laws that regulate data access and sharing procedures are subject to the GDPR to an organic law on protection of personal data and guarantee of digital rights (in Spanish, *Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales*[2]). Systems providing data protection mechanisms for structured data (e.g., anonymization and pseudonymization) have been established and can be used by research projects provided ethics approval.

3.2. National Electronic Health Record Systems in the Tier One Countries

3.2.1. Austria

The national electronic health record system in Austria is called ELGA, which stands for 'elektronische Gesundheitsakte' (German for "electronic health record"). ELGA provides a central access point to health records for patients and healthcare providers, as well as other care facilities and pharmacies. Due to the federal structure of the Austrian healthcare system, ELGA has been designed as a distributed system with central components for patient and healthcare provider identification and authorisation management, as well as a central database for e-Medication. ELGA is based on a central master patient and provider index, which can be accessed by patients through a central application and each patient is empowered to decide which data is available to others (e.g., to the physicians) and to revise at any moment the given consent. The ELGA system retrieves the required information on individual patients from the information systems (e.g., HISs) of the different care providers connected to it using IHE

[2] https://www.boe.es/buscar/doc.php?id=BOE-A-2018-16673

integration profiles. Security is ensured by state-of-the-art measures, such as encryption protocols and strong authentication mechanisms. Data is semi-structured and encoded into HL7 Clinical Document Architecture (CDA) documents using, to some degree, international terminology standards (e.g., LOINC) as described in ELGA-specific specifications. Currently, it is not permitted to use the data stored in ELGA for secondary analytical purposes (e.g., research) and discussions are ongoing. ELGA is well established in Austria and can provide a solid solution for exchanging structured and semi-structured clinical and outcomes data across sites and securely identifying patients. It could also be used to host H2O's patient app when a dedicated ELGA section ("ELGA-Bereich") is created for the project.

3.2.2. Germany

In Germany, the gematik, a German company with limited liability founded by the leading organizations of the German healthcare system, leads the development of the national electronic health record ePA, which stands for "elektronische Patientenakte" (in English, "electronic patient record"). It is being offered by all statutory health insurance companies as of January 2021. Recently, also private health insurances have decided to introduce the system to their customers. Each insured individual in Germany has an electronic health insurance card for use when interacting with the healthcare system (e.g., medical appointments, hospital visits, and examinations). The ID number of the insurance card is used to uniquely identify the insured individual. As reflected in Germany's eHealth Act, since the beginning of 2021, any (publicly) insured individual has the right to be provided with a cross-provider electronic health record, which can be used to store data concerning medical appointments, medication, and other relevant data. Additionally, patients may decide which data can be disclosed and to which care provider. This functionality will however only be added at a later point in time and is currently not available. ID cards are also provided to healthcare professionals and are needed to authenticate at the system through secure terminals. The data in the ePA are securely stored in the central telematics infrastructure, the German national network for electronic health information. Currently, the data managed is mostly unstructured, but so-called Medical Information Objects (MIOs) based on HL7 FHIR and terminologies (e.g., LOINC and SNOMED CT) are currently being specified and coordinated with a wide range of stakeholders, and will be integrated in the future for capturing data in structured form. As of January 1st, 2021, Germany has also become a member of SNOMED International. MIOs will also be important for establishing interfaces between the ePA and the recently introduced range of DiGAs, which stands for "Digitale Gesundheitsanwendungen" (in English, "digital health applications") and which are apps that can be prescribed to patients like other approved medical aids or medicines[3]. In terms of analytical access to the data managed in these national systems, the current situation is heterogeneous. Regulations surrounding access to the data have been established (e.g., through a trusted third party – called "Forschungsdatenzentrum", which means "research data center"), but their exact implementation and scope of data managed is yet to be defined. In parallel, Germany is establishing a large-scale data sharing infrastructure with the aim of making patient data more accessible for healthcare and, in particular, for medical research purposes through the MII funded by the German Federal Ministry of Education and Research. How this

[3] For more details see Section 87(5c) of the German Social Security Code, Book V.

infrastructure will connect to the national electronic health record system and which data flows will be supported under which governance structures is still being sorted out.

3.2.3. Netherlands

Health information exchange in the Netherlands is supported by AORTA, which is the Dutch national infrastructure for the exchange of data between healthcare providers, but not at the national level. . By means of this network, hosptals can ask community pharmacies to supply a medication summary of patients. Technically, the infrastructure is based on HL7 specifications. Amongst other components, the AORTA infrastructure has a registration system used to identify and authenticate its users, and the LSP reference index system. Each patient is identified by his/her citizen service number (BSN) and, according to regulations, has control over his/her data. Semantic interoperability is ensured through international standards, such as SNOMED CT. However, as specifications are not necessarily implemented on a national level but more on a regional level, data exchange is often limited to regional networks. On the analytical level, DHD (Dutch Hospital Data: https://www.dhd.nl) is a not-for-profit organisation which collects data from all the hospitals, including episode/admission oriented, administrative, clinical, and financial information. Individuals and organisations can request data in aggregated form. Currently, DHD is developing towards a more longitudinal view, also collecting patient-reported outcomes and data from other healthcare providers besides hospitals. More and more people want to better understand their health status. The official nationwide initiative MedMij, ensures that anyone who so wishes has access to their health data in a personal health environment of their choice (PHE). This could be an app or a website, for example. To do this, such an app or site must be able to communicate securely with all the locations where the information is stored. These could be the healthcare information system of a hospital, the physician, the well-baby clinic or the pharmacy. MedMij is the standard in the Netherlands for the secure exchange of health data between care users and care providers. Anyone that meets MedMij's criteria may use the MedMij label. This label is available for apps, websites or personal health environments (PHE) that demonstrably meet MedMij's criteria. The label is also visible to health care providers or other healthcare professionals who exchange details through MedMij.

3.2.4. Spain

In Spain, there is no common implementation of an EHR system at the national level. For instance, at the time of writing, Catalunya is transitioning toward a new electronic health record that will be based on OpenEHR (https://www.openehr.org/)[4]. Therefore, cross-provider electronic health records are typically restricted to the region of residence of patients. For example, the government of Catalonia has commissioned the Agència de Qualitat i Avaluació Sanitàries de Catalunya (AQuAS) to access all data generated by the public healthcare system and to be responsible for the correct use of data. Data from Catalonia's public healthcare system, which includes providers (primary care, hospitals, mental health, social care) and public-funded services (such as pharmaceuticals public dispensation), are collected at individual level and managed from AQuAS for improving healthcare system quality and provision. Public

[4] https://catsalut.gencat.cat/web/.content/minisite/catsalut/actualitat/2021/documents/2021-05-14-Catalonias-new-electronic-health-record-openEHR.pdf

consortium partner Hospital Vall d'Hebron University Hospital (HUVH) is a key provider for community and tertiary level, part of the Catalan Health Institute (ICS) that manages data for 75% of the primary care sector and 8 of the largest hospitals in Catalunya. As a part of the public system, HUVH and ICS are key for the development of the innovation and health management of the region. The model developed in Catalonia will be potentially extended or reproduced in other Spanish regions, but this has not been decided at the time of writing. Each patient has a unique ID number which is used to create, access, and maintain his/her EHR. A physician does not require express consent from the patient to create his/her EHR. Despite the availability of functionalities concerning data protection, security, and processing, the patient cannot grant or deny others (e.g., healthcare professionals) access to his/her data. However, a patient must give express consent for his/her data to be used for research purposes. Several cross-regional datasets (e.g., cancer registry data, diabetes registry data, cardiovascular registry data, medication and prescription information, and administrative data registries) are fed by aggregated patient data from regional systems and used for quality assessment, for example. However, the amount of interoperable data using terminology standards (e.g., SNOMED CT) is still less than half of the entire data stored in the regional EHR systems.

4. Conclusions

From the information provided on the local and national situation above, it can be concluded that the participating hospitals have already integrated comprehensive solutions for connecting their systems with external platforms, such as H2O, and to use the data collected for secondary purposes. The hospitals are therefore well prepared to participate in H2O on the technical level, although local integration efforts will be needed due to differences in the respective system landscapes and interfaces. On the legal and regulatory level, the implementation of the consent model and the governance structures which will be established as part of H2O project will be equally important.

Regarding national electronic health record infrastructures, it can be concluded that developments in Europe have picked up speed and that selected national infrastructures might be able to serve as pilot environments for integrating H2O-specific solutions for individual-level health and outcomes data collection and exchange. Further developments will be required regarding the use of the data collected in national health records for analytical purposes and some challenges will need to be overcome (e.g., regarding the regional focus of the Spanish system and the early development stage of the German infrastructure). Currently, many countries are either still discussing legal frameworks for these use cases or are implementing heterogeneous solutions (e.g., mandating access through trusted third parties). The full integration of H2O into national infrastructures may therefore only become realistic in the future.