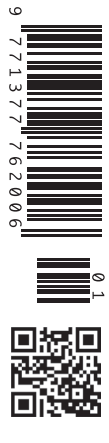




Cover Story:

Reimagined Hospitals



20 **Edward Bluth:** RSNA 2019: Radiologists Can Be Optimistic About AI

28 **Prof. Andrew Walton:** Managing Change to Improve Clinical Outcomes

36 **Adam Gale:** How Far Is the Future?

40 **Christopher Shaw:** Healthcare Design With a Long-Term View

46 **Prof. Christian Lovis:** An Alternative to Costly Tech For Future Healthcare?

50 **Prof. Marcel Levi:** Generalism as a Sustainable Model in New Healthcare Paradigm

52 **Sirpa Arvonen:** Finland's Digital Care Network: Why is it Working So Well?

56 **Marina Gafanovich:** The Empowered Patient – Capitalising on Information and Technology

60 **Chris McCahan:** Building a Better Hospital

The Reuse of Health Data: Governance and Trust As Catalysers for Quality

Summary: The European Institute’s for Innovation through Health Data (i~HD) total quality approach to data: four governance pillars designed to boost the quality of learning health systems and research to advance personalised medicine.

The value of the massively growing health data volumes to advance health-care and clinical research is beyond dispute. The question that is often posed is rather: how can we simultaneously meet the needs of health-care, research and patients? And the one posed less often is: what about the quality of the data?

Creating a neutral and independent community, after a wide consultation and engagement of many stakeholder groups, is the way i~HD went about to leverage trust and ensure that health data reuse solutions serve the collective needs.

Health Data Governance Ecosystem

Without owning any data, The European Institute for Innovation through Health Data (i~HD) has set up a comprehensive and coherent health data governance ecosystem based on four complementary pillars (Figure 1). This total quality approach to data includes not only the intrinsic data quality but also the trustworthiness of Electronic Health Record (EHR) systems and research platforms, as well as the promotion of interoperability standards to connect different systems. Furthermore, i~HD experts provide tutorials and promote codes

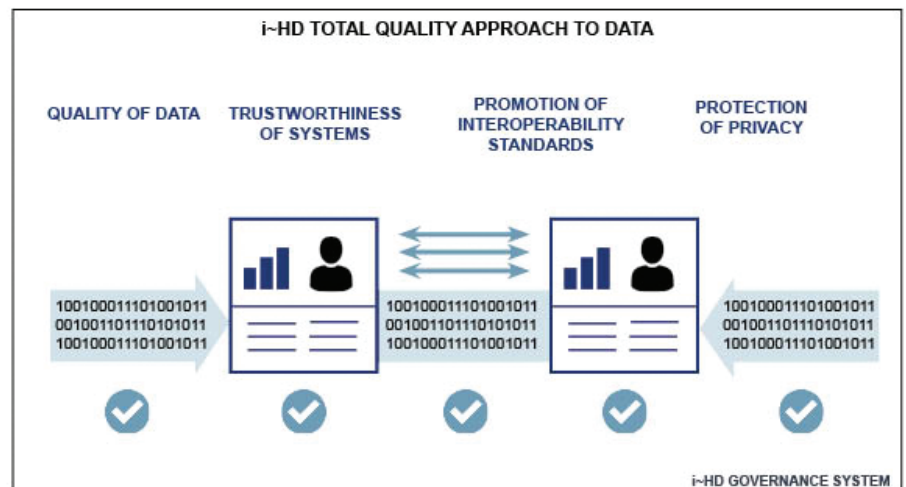


Figure 1. Four Governance Pillars Designed to Boost the Quality of Learning Health Systems and Research to Advance Personalised Medicine

of practice in data protection and the General Data Protection Regulation (GDPR) compliance.

i~HD started its activities in 2015 as a sustainable entity arising from EHR4CR (an Innovative Medicines Initiative project) and complementary EU projects supported by the European Commission. Via its founding members (EuroRec, RAMIT, empirica and TMF), it brings together over 30 years of coordinating experience and is a partner in more than 90 European projects. Its

core team is rapidly growing; the latest three recruits are listed in the ‘Contributors’ section. Its current experts are surrounded by European thought leaders in each field of governance, so that i~HD is constantly at the top through monitoring emerging legislation and R&D projects.

Connecting Is the Name of Their Game

Besides developing collective methods and guidelines, and delivering insightful

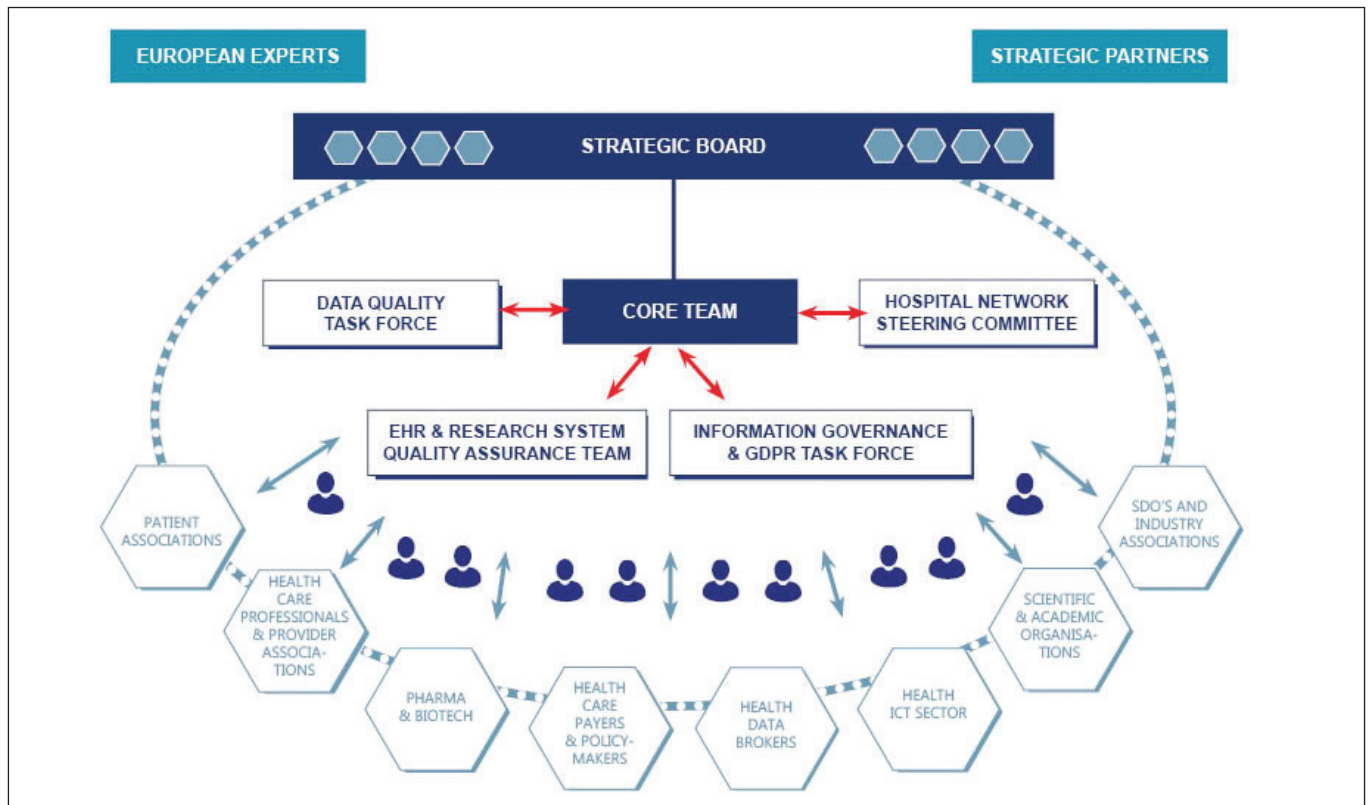


Figure 2. i-HD Eco-System

tailor-made advice, i~HD aims to boost collaboration between stakeholders and knowledge sharing through conferences and awareness campaigns, to exchange perspectives between stakeholders whose interests may not always seem aligned (Figure 2).

For instance, interests of healthcare, research and patients are often thought to be opposing. However, 73% of EU citizens want to share health data on the precondition that data are secure and only accessible by authorised parties (European Commission 2018). i~HD responds with a two-way plan of action:

1. Assist data users (such as research organisations) to develop quality and privacy codes of practice that give assurance to data providers (such as patients).
2. Raise awareness about these codes and the benefits of sharing health data with data providers.

Empowering Patients

To overcome the barriers to collecting a maximum of useful real world health data, patient involvement and empowerment are crucial. To keep closely in touch with patient organisations, i~HD also includes patient representatives in its team. Pieter van Galen, member of the MS Data Alliance, educates patient organisations on the benefits of sharing health data, countering fears such as privacy issues, insurances going up and data not being anonymised.

Real World Data

The explosion of interest and initiatives for reusing routinely collected health data (Real World Data) for research and healthcare improvement spans a wide spectrum of opportunities: from accelerating the design and conduct of clinical trials, to deep population stratifications using big data and artificial intelligence methods to accelerate

personalised medicine, studying clinical outcomes and advancing value-based care, optimising care pathways and empowering patients. But how reliable are the conclusions for clinical, strategic and operational decision making?

Pillar 1: What About EHR Data Quality?

Good EHR data quality is imperative for valid and reliable clinical decision-making and inference. However, most Real World Data are captured by healthcare staff who have almost never had any training in data management. As a result, several studies have demonstrated that Real World Data today are of variable quality, much of them barely fit for any reuse purpose.

In order to address this poor data quality issue, i~HD has developed a Data Quality Service for Hospitals (DQS4H). This service entails a comprehensive data quality analysis using a



set of up to nine data quality dimensions. This set has been developed by expert review of state-of-the-art literature combined with multi-stakeholder consultations.

For each of the data quality dimensions, dedicated methodology and corresponding assessment tools have been developed in collaboration with domain experts at the Valencia Polytechnic University. Moreover, i~HD has statistical and medical expertise to interpret the findings. Based on the results of data quality assessment, customised data quality improvement

EHR used for the provision of routine daily care, for the reuse of EHR data for clinical research, for big data analytics?

Assuring quality audits of systems can be approached through several methodologies, ranging from self-assessments by the system vendors to quality labelling and certification processes. The latter preferably consist of system audits conducted by third parties (so-called conformity assessment bodies), which report back to certification bodies. Depending on whether they are accredited or not by

Hence there is a need for interoperability standards, which define how clinical information, such as parts of the patient EHR held at the hospital or general practice, should be transferred to other similar systems.

There is a long history of developing international standards to enable such mappings. Bodies such as CEN, ISO, HL7, IHE, WHO, LOINC, SNOMED, CDISC and OMOP are examples of organisations that have defined relevant parts of the standards landscape for the kinds of data transfer they specialise in. However, despite

73% of EU citizens want to share health data on the precondition that data are secure

strategies can then be developed, tailored to the specific needs and problems observed within the hospital, to support hospitals in improving their data quality.

In addition, i~HD wants to raise awareness about data quality issues and potential risks of (re)using data of poor quality through collaboration in various European projects.

Pillar 2: Quality and Trustworthiness of Systems

Producing quality health data goes hand in hand with the quality of the system (software) and the level of training and awareness of the system end users. Even the best system cannot escape the aphorism 'garbage in, garbage out' when data quality is inadequate. Conversely, the system should feature the functionalities that allow the capture and management of high quality data. Finally, end users should be properly trained to use the systems correctly.

Quality assurance of systems is essential to ensure the presence of a number of correctly implemented functionalities. These comprise security, confidentiality, trustworthiness, etc depending on the use-case: is the

an accreditation body – these certification bodies can grant a certificate or quality seal to the EHR system.

i~HD has followed the latter methodology and has developed a strategic partnership with its sibling, the European Institute for Health Records (EuroRec). EuroRec has a longstanding history in quality labelling and certification of EHRs in Europe. It has developed a repository of functional quality criteria for EHR systems and several tools (web applications) to assist in the quality labelling and certification process. The i~HD Quality Seal for Research Platforms is the latest example of the collaboration between i~HD and EuroRec.

Pillar 3: Interoperability Standards

In a digitally connected and collaborative health environment, sharing health data is vital to enable the safe continuity of care for individual patients between different care actors. At a more collective level, pooling data at a population level can show how well a health system is performing. Large quantities of pooled health data, on thousands or millions of patients, are also very valuable for research.

this rich array of available standards, the experience of most healthcare professionals and patients is a lack of connectivity. People undertaking large-scale research struggle to bring together the data they need, on enough patients, and their data harmonisation costs are a substantial part of the total cost of undertaking research.

This landscape is changing, thankfully. Healthcare funders (health ministries, health insurance) increasingly want care to be connected. They are starting to demand better clinical outcomes and to financially incentivise those outcomes. This stimulates, for the first time, a business case for hospitals to be more interoperable. Secondly, countries are now making substantial investments in research infrastructures that aggregate the data at large population levels. These investments are gradually also trickling down to healthcare organisations as incentives to have better connected and better quality data.

i~HD and its member organisations play an important role in the development and promotion of interoperability standards, and in promoting the importance of good quality

interoperability data across the health ecosystem.

Pillar 4: Data Protection

Sharing and pooling of health data inevitably raises questions as to protection when reusing it for health-care and research. These questions have always been of the highest importance to the health data innovation community. The recent arrival of the GDPR was a rallying cry for the innovation community to not only redouble our efforts, but also to ensure that we could demonstrate our excellence and commitment to this area.

The GDPR put data protection centre stage of societal discourse, but it also tried to help clarify various complex areas and provide consistency across EU and EEA states in how data were protected. As it has arrived, we are nevertheless seeing divergence across member states and uncertainty around how to honour consent to participate in research, understand the regulatory impacts of artificial intelligence, uphold newer rights like erasure and portability, and to truly understand how data uses can be made transparent for patients and the wider public.

To answer these challenges, i~HD has formed a GDPR Taskforce composed of leaders across Europe in law, information governance and security, engineering and regulatory oversight. Together, they are helping to provide best practice as it develops and emerges through tailored workshops and tutorials, supporting an Observatory of how different member states and regulators are handling GDPR as it lands. They are actively engaging with the health data innovation community as a sounding board to help understand the challenges that are surfacing and how to meet them.

Be Part of a Responsible Health Data Community

Collating and studying millions of quality-checked health data currently

stored in separate silos, in secure ways, is expected to lead to a growing number of new insights, which can speed up diagnosis and the development of new medicines, new medical devices and smart applications.

Leading the way to a responsible and trustworthy health data community by breaking down the existing governance barriers, that is i~HD's mission. Therefore, we call all health data providers and users alike to liaise with, contribute to and benefit from dialogue and thought leadership on data sharing and reuse. ■

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Key Points

- The reuse of health data is crucial for enhancing healthcare and speeding up clinical research.
- Poor data quality, untrustworthy and disconnected systems, and misunderstanding of data protection issues can jeopardise optimal clinical, strategic and operational decision-making.
- A comprehensive and coherent health data governance ecosystem is an essential condition for quality and trust.
- Connecting all stakeholders in a responsible and united health data community will boost a collaborative ecosystem where the needs of data providers and users alike can be met.

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