IHE EUROPE
Integrating the Healthcare Enterprise

LEVERAGING THE IHE METHODOLOGY TO ACCELERATE SUCCESSFUL IMPLEMENTATION OF THE EUROPEAN HEALTH DATA SPACE

A white paper describing how IHE's Methodology contributes to the broad adoption of HL7®FHIR® in support of the EHDS

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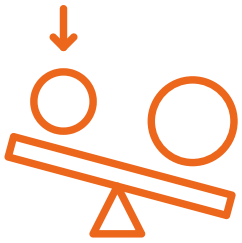
Executive Summary

This white paper is set within the context of the European Health Data Space (EHDS), a regulation that defines **rules, common standards** and **practices**, **data-sharing infrastructure**, and **governance** with an explicit goal to facilitate pan-European access to medical data for primary and secondary uses and the creation of a European Single Market for digital health systems.

The success of the EHDS relies heavily on **how it is implemented by all stakeholders** and how fast it will achieve **widespread adoption**. In this context, it is crucial to achieve ready-to-use interoperability — meaning that health systems and services should be easily connected with each other ideally through the existing infrastructure across different countries and organizations. However, realizing this vision requires overcoming several challenges.



IHE can play a pivotal role in overcoming these challenges by leveraging the **IHE® Methodology** (ISO TR28380:2014), successfully adopted by many organizations around the world.

The interoperability use cases of the **European Health Data Space** (EHDS) can effectively be defined through **IHE Profiles** which are created in full collaboration with the **Standards Development Organisations** (SDOs) of the underlying base interoperability standards. **IHE Profiles** are implementable and conformance testable building blocks with a multi-decade proven track record. Most of the eligible IHE Profiles leverage **HL7® FHIR®** and other standards for defining not only content, but all other aspects necessary for plug-and-play interoperable operation. Besides the Profiles, the IHE Methodology contains a robust **conformance testing framework** (**IHE Connectathon®**) with easy to understand ways to **demonstrate standards compliance** for products (**IHE Integration Statement, IHE Connectathon Seal**).

The requirements for standards, conformance testing and declaration of standard compliance for products are already laid out in the EHDS legislation. This whitepaper explores how using IHE's existing, reliable methodology for fulfilling the requirements, together with the aforementioned base interoperability standards, **mitigates the risks** for stakeholders on the road towards a successful EHDS.

EHDS implementation - the answer is in the details

Drawing on IHE long-standing experience in facilitating the integration of eHealth systems globally across diverse healthcare enterprises, establishing complex digital health systems like the EHDS presents valuable opportunities to address and navigate a range of challenges.

To be successful, **the EHDS needs to be implemented at large scale across Europe**:

by **Member States** in their infrastructures;

by **care providers** in their environments

by **vendors** in their products.

Beyond implementation, **user adoption** will be the ultimate measure of the success of the EHDS. Ensuring that healthcare professionals, who are the primary users of **EHR systems** and **medical software, do not have to deal with additional complexity** due to the EHDS is a must. This goal cannot be economically achieved without products forming the EHDS being **practically interoperable**, ready to use in an integrated manner out of the box.

"Practical interoperability is a journey where choosing the standard is just the first of many steps"

Plug-and-play interoperability requires easy to understand, implementable, and consistent specifications covering all aspects of the EHDS, including the various forms of **content, data transport, and security**. No single standard is capable of covering such a broad range of topics.

In addition to standards, an ecosystem is required that supports the creation of corresponding products and infrastructures through recurring **collaborative testing of the interoperability** between the various implementations.

The last prerequisite of plug and play interoperability is a simple means for procurers of products and implementers of infrastructures to **assess the availability and maturity** of the needed functionality in a given product.

"EHDS can be built on existing infrastructure, regardless of its foundation, moved forward with new technologies"

Finally, as the digital health infrastructure of Europe is already heavily developed, it is imperative to **follow an incremental approach**, where existing systems can be seamlessly integrated into the framework of EHDS, even if they cannot be updated to utilize the EEHRxF.

How IHE can contribute to the success of the EHDS

IHE is an international not-for-profit standards development organization (SDO) that brings together clinical, vendor and jurisdictional experts to create a world with seamless and secure access to health information that is usable whenever and wherever needed. This mission is implemented through the use of IHE Methodology, a comprehensive approach covering the creation, publication and refinement of standards, testing the conformance of products against these standards and the indication of the compliance status in an unambiguous, easy to understand way.

As the **first pillar of the IHE Methodology we find IHE Profiles**. An IHE Profile is a specification that narrows (e.g. Profiles) broad standards to a specific set of use cases by combining standards from various SDOs, like HL7, in a neutral way to create efficient, plug-and-play interoperable and testable implementations. Based on a well-defined structure (ISO/TR 28380:2014), IHE Profiles **guide vendors and implementers toward consistent utilization of the standards**. The creation of IHE Profiles is driven by real-world use cases and developed along processes well established for more than two decades.

Once IHE Profiles are created, conformance testing is achieved through multiple ways. On one hand, regular **IHE Connectathon** are held, which are structured testing events where vendors test their products in real-world scenarios together with products from other vendors. On the other hand, an **open-source online conformance testing framework** (Gazelle) is available, enabling vendors to test their products against various test datasets, thus expediting the road to deployment.

IHE Integration Statements are standard, simple and easy to understand documents published by vendors to demonstrate their products ability to work as specific actors in relevant Profiles. IHE Connectathons also produce a publicly available results database, making it easy to assess conformance claims. **IHE Connectathon Seals** are awarded to companies with successful testing sessions at the **IHE Connectathon**.

IHE-Europe is responsible for bringing the IHE Methodology to Europe, providing **methods**, **specifications**, and **tools** that directly address the challenges associated with EHDS adoption across the continent.

To establish implementable interoperability specifications for the EHDS IHE-Europe proposes to work together with HL7 Europe on a **two-pronged approach**:

1. Where applicable, existing IHE Profiles that align with the technological direction of the EHDS—many of which are already actively deployed by the industry in the EU—will be extended by incorporating EHDS use cases. This will be achieved through the IHE standard process for refining profiles to meet local needs, in combination with HL7 FHIR specifications tailored for the EHDS.

2. In areas where no applicable IHE Profiles exist, both organizations, in collaboration with other relevant interoperability standards development bodies, will use the IHE Methodology to develop new, testable, comprehensive standards specifications to address the corresponding requirements

This approach would effectively establish **EHDS standards bundles**, addressing all relevant aspects for the **technical implementation of the EHDS** like content, data transport, security, etc. In addition it allows to leverage the well-established conformance mechanisms of IHE like IHE Connectathons (including IHE Connectathon Seals) and IHE Integration Statements for the EHDS.

IHE-Europe and HL7 Europe are already working diligently towards refining this approach into harmonized methodologies and publication procedures.

By leveraging the entirety of the IHE Methodology based on the multi-decade experience of IHE, stakeholders can ensure that EHDS-compliant products form building blocks that can be combined into nationwide and pan-European digital health solutions. Utilizing this proven framework helps reduce the likelihood of integration challenges or costly delays, providing a reliable path for achieving secure and interoperable health data sharing across Europe.[1]

Today, IHE has already published multiple **FHIR-based Profiles** that form the first building blocks, ready for assembly to form the structure of the **EHDS**.

The availability of a wide set of IHE Profiles also supports individual Member States' EHDS journey, no matter what is their digital health "**starting point**". Member States have made large investments in infrastructure based on international standards predating HL7 FHIR or local standards. For both, IHE's FHIR-based building blocks will support EEHRxF-conformant workflows. No matter the scenario, the goal is to **progress towards the EHDS without disrupting existing infrastructures and services**, from success to success.

IHE can provide the **foundational infrastructure to scale EEHRxF** implementations across Europe. This ensures that all systems — from local clinics to national care networks — function seamlessly and efficiently, turning the ambitious EHDS vision into reality.

A unique aspect of IHE is that on international, regional and national levels **diverse stakeholders** (including clinical experts, representatives of jurisdictional authorities and vendors) are forming communities where consensus building is facilitated. A recent successful example of this is the **Multi-country Working Group (MCWG)** on Imaging Information Sharing that has already published a set of recommendations for practical interoperability in the area of sharing medical images.

[1] A copy of the recommendations proposed by the X-Net Industry team members of large and small vendors assembled by the XpanDH EU funded project on the scaling testing for EHDS interoperability, can be obtained from the position papers section on the COCIR and MedTech Europe websites . The recommendations leverage existing and mature IHE testing frameworks, used within MyHealth@EU, where vendors can validate interoperability, refine their solutions and prepare for deployment across various jurisdictions.

Successfully taking EHDS to scale

IHE-Europe, in combination with the interoperability base standards development organisations, is a trusted partner that can help address the challenges of taking EHDS to **scale across nations to form a pan-European integrated digital health infrastructure.**

Following this existing, established approach mitigates risks, maximizes the value of the billions of Euro's already invested in digital health and provides the cleanest path for all the stakeholders on their path to the implementation of EHDS throughout Europe.

EHDS is a bold step forward for Europe. It is important that **Europe succeeds with its implementation to ensure the best health outcomes for all citizens** and for the continent to regain its place as the leader in medical innovation. The IHE-Europe value proposition is simple but impactful:

Partnering with IHE-Europe in utilizing the IHE Methodology will contribute to the success of EHDS

About IHE-Europe

IHE-Europe is a not-for-profit organization member of IHE International and responsible for promoting IHE specifications, methodology and testing activities in Europe. It bridges vendors and users of health IT active throughout the continent. IHE-Europe has been the organizer of the yearly IHE Connectathon in Europe since 2001.

IHE-Europe has been an active contributor to the ECdigital health infrastructure projects since 2008 (epSOS) and was a key team member on the development of the first set of pan-European interoperability specifications (Antilope, eStandard). In 2015, the European Commission adopted a set of 27 IHE building blocks as the normative set of digital health **actor-transactions** for the **eHealth Network** (eHN). IHE's testing tools have been used since 2017 to conformance-test eHN solutions – now collectively referred to as **MyHealth@EU** as well as in many eHealth Projectathons in Europe.

More recently, IHE-Europe has participated in the development of use cases and specifications for the **EEHRxF** (on European Commission projects including X-eHealth, UNICOM, xShare and XpanDH). IHE-Europe is also actively working with HL7 Europe on the EHDS via a formal statement of understanding.

This white paper is endorsed by IHE-Europe Steering Committee, representing all its members, including clinical experts, vendors and jurisdictional authorities.

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Target audience
Positioning paper for Strategic Leadership and Senior Executives.

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