IHE® | Integrating the Healthcare Enterprise
EUROPE

Frequently
Asked Questions

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What is IHE?

"Integrating the Healthcare Enterprise" (IHE) is a global not-for-profit initiative with regional and national branches. It provides a pragmatic methodology ensuring interoperability between healthcare IT systems resulting in a body of technical and semantic specifications, which are published by IHE as Technical Framework(s). IHE also organises testing events worldwide to allow vendors to verify and validate their conformance with the IHE specifications. IHE is a joint initiative of users of healthcare IT systems and providers of such systems. IHE is governed by an international board that provides strategic direction and coordinates the technical development activities of IHE. In Europe, IHE is coordinated by IHE-Europe.

Why is IHE needed?

Standards are written to support a wide range of clinical processes and include many optional features. In order to obtain interoperability with regard to a specific clinical task, IHE creates Profiles of the most relevant standards that make essential features for supporting the clinical task mandatory for those products for which conformance with a Profile is claimed. IHE Profiles specify the information that must be exchanged between systems and the actions that recipient systems must take on receipt of the information. However, they do not constrain the way in which systems are designed to enable ease of use.

What is "interoperability"?

According to ISO/IEC 2382-01, Information Technology Vocabulary, Fundamental Terms, interoperability is defined as follows: "The capability to communicate, execute programs, or transfer data among various functional units in a manner that requires the user to have little or no knowledge of the unique characteristics of those units". For IHE, IT systems are interoperable if they can properly exchange clearly defined sets of relevant information in the context of a specific clinical situation and perform appropriate actions as described by the IHE specifications.

What is the origin of IHE?

IHE was created in 1998 by users and industry in the US in order to respond to increasingly urgent issues of interoperability in the Radiology Domain. The two user organisations RSNA and HIMSS created a unique platform for users and vendors for defining specifications of healthcare IT systems that enable interoperability between complex applications. The concept of the IHE process was taken up in Europe as well as Asia shortly afterwards. European activities were started in the year 2000 by COCIR and the European Society of Radiology - ESR. Because of the nature of the European healthcare environment, national IHE Initiatives have developed in a number of European countries. These initiatives coordinate their activities at the European level within the association IHE-Europe aisbl.

How does the IHE process work?

In the **first stage** of the IHE process, users define and select interoperability challenges, which have arisen in daily clinical work. A description of the clinical process involved is written carefully. Based on this written use case, vendors define technical specifications in the form of "Integration Profiles", which provide a solution to these interoperability challenges. An "IHE Profile" includes a use case and the complete series of procedures made up of a number of individual steps. Profiles include detailed technical specifications for the use and implementation of relevant standards thus ensuring an uninterrupted flow of information between different

healthcare IT applications in support of the specific use case.

The Profiles describe how healthcare IT systems can provide integrated support for a clearly defined workflow, each of which individually supports a clinical task within a specific clinical domain. IHE Profiles can be used for a step-by-step implementation of systems in different domains and the gradual building of interoperable eHealth applications.

In the **second stage** of the IHE process, vendors implementing IHE Profiles meet for an annual test event, the Connectathon. During the Connectathon, participating systems are connected through a physical network to create virtual healthcare enterprises. This is the basis for intensive tests among systems made by different suppliers based on IHE Profiles. All tests are evaluated by independent Monitors. For a system that has successfully passed all required tests, a vendor may issue an IHE Integration Statement.

A **third stage** is IHE Conformity Assessment. The IHE Conformity Assessment testing programme is based on an ISO/IEC 17025 quality system in accordance with the IHE Conformity Assessment Scheme. A specific set of IHE Profiles is available for testing in accordance with requests from project users and the industry. Products submitted must be either market-released products or expected to be released within six months after the Conformity Assessment test session. To engage in Conformity Assessment testing, the vendor must have passed the IHE Connectathon tests within the prior two years for the appropriate IHE Profiles targeted for Conformity Assessment. The accredited testing laboratory, authorised by IHE International, will deliver the Conformity Assessment Report that is published on the IHE International website after successful completion of testing.

For which clinical areas does IHE provide Profiles?

IHE covers a number of different clinical Domains such as Cardiology, Laboratory and Radiology and also horizontal Domains such as IT Infrastructure and Cross-Clinical Domains Patient Care Coordination, including primary care. The areas of application are constantly evolving based on the needs of users. Profiles can be focussed on integration, clinical content, workflow, security and privacy. An up-to-date list can be found on www.ihe.net/Profiles.

How long does it take to develop a solution to a user problem?

IHE follows an 18-month cycle from the definition of an interoperability challenge to the publication of a related Profile. To achieve that, users and vendors within IHE may agree to break up a larger problem into separate tasks. Work on these individual tasks will then be performed on a step-by-step basis. This way of working ensures that solutions to interoperability challenges become quickly available, even if the underlying challenge is of an extremely complex nature.

What is the role of users?

The strength of IHE comes from the direct involvement of users in the process of Profile development. Users are instrumental in defining the interoperability challenges that need to be addressed. This user involvement ensures that Profiles address real-world problems in a way that users recognise as helpful. Because of this pragmatic approach, IHE Profiles find acceptance with users and are implemented quickly. IHE provides users and vendors with a communication platform for defining relevant Profiles including their technical specifications and testing to ensure interoperability between various systems.

What is the role of standards within IHE?

IHE's primary goal is not to develop base standards, but to standardise the adoption of the most common used base standards in healthcare, health IT and in the digital web. The role of IHE is to enable interoperability of healthcare IT applications and health devices through an open and transparent process, which can easily be implemented. Therefore, the resulting Profiles are based on existing standards that are already used in the relevant healthcare environment. HL7, DICOM, IETF and W3C are examples of such existing and widely accepted standards, tailored for specific use cases by IHE Profiles.

IHE Profiles specify how appropriate parts of the standards in question must be used so that relevant data can be transmitted from one application to another application within the context of a clearly defined workflow process. In the IHE process, it is not required, and in many cases not even possible, that the complete IHE Profile refers only to a single standard. Indeed, most IHE Profiles specify the precise way to combine the use of several base standards.

What is the content of an IHE Profile?

A given Profile for integration, or security, or privacy will define relevant activities in the context of the workflow of the use case in question. Communication of information is described in terms of "transactions" between "actors". An actor is implemented as part of a computer application. All relevant transactions between actors that are required to complete the workflow (clinical task) are clearly specified. The specifications describe how specific parts of standards are to be used and provide technical guidance for the computer application implementation. Some Profiles for content will cover primarily data structure and terminology-coded concepts suitable to convey the clinical information for a specific type of information exchange (e.g. provide a summary, a clinical diagnosis report, etc.).

How does IHE verify conformance at the Connectathon?

The Connectathon is a week-long test meeting. During that meeting, all participating healthcare IT systems are connected through a physical network. The Connectathon creates a virtual healthcare enterprise equipped with healthcare IT applications and devices from different vendors that provide various solutions for a range of different tasks as they are encountered in a real-life hospital or community. The correct implementation of the specifications of the Profiles is verified through a number of tests consisting of the direct exchange of data according to the requirements of the Profile between the actual systems identified as actors in the Profile. All tests are monitored and verified by independent (user side) experts recruited for that specific week based on their knowledge and experience. The experience from the Connectathon is also used to further improve the correctness and clarity of the specifications in the Profiles. When a product implementation has been successfully tested against three or more counterparts participating in the Connectathon, the technology developers are identified as part of the official Connectathon results published on the IHE website for public reference. This supplier would then issue a so-called IHE Integration Statement on the IHE Product Registry, expressing its commitment to IHE Profile compliance.

What is IHE Conformity Assessment?
What are its benefits?

Medical information details often provide crucial facts needed for optimal healthcare, whether within a hospital, across regional health IT projects, within national networks, or from a hospital to the patient at

home. It is critical that vendors and users work together, along with regulatory authorities and standards bodies, to ensure that products, systems and solutions interoperate together to bring quality solutions to the market that perform as they should and result in best-quality patient care.

To reduce costs, delays and other risks of inadequate purchases of products, users and vendors have come to depend on trusted, independent third-party testing offered by IHE Conformity Assessment:

- Give confidence to the end user that a current/potential supplier has independent proof of the interoperability of their products.
- Reduce testing and integration efforts for large eHealth projects by specifying and procuring products that have been conformity-assessed. They can focus their testing investment on the specifics of the project.
- Rely on an accredited testing laboratory to validate products before they are installed in an organisation or facility, reducing risks and deployment costs.
- Improve patient outcome through better and more consistent product quality.
- Gain global market credibility by distinguishing the company and its products. For a listing of companies and products, please visit: http://conformity.ihe.net/summary-reports.

Does IHE provide certification?

With the Product Conformity Test Report, IHE delivers the substance that could enable certification. IHE believes that the IHE Conformity Assessment Test Reports have the legal strength with international acceptance due to the ISO/IEC 17025 Testing Laboratory Accreditation and are sufficiently simple that they provide the proof of interoperability quality needed. Some deployments have added their own certification process, where the IHE Conformity Assessment Test Report is used as input to deliver a project- or country-recognised certification or label.

IHE offers multiple levels of testing scope and rigor that complement each other:

- Connectathon, as a basic-level testing open to all implementers but with a focus on testing between systems. When successful, developing organisations have their results for the specific Profiles tested made publicly available by IHE.
- Product Integration Statement, a self-declaration by the developer, that a product supports specific Profiles. Vendors can be held liable for the content of their IHE Integration Statement.
- Conformity Assessment, specific to a particular product and of the highest level of rigor.
- Only companies that implement IHE Profiles within their products may make reference to IHE. The market expects that such statements are backed-up by the Connectathon results. Products that passed IHE Conformity Assessment may advertise their summary Test Reports and use the IHE Conformity Assessment logo.

What are the benefits to users?

Healthcare IT applications that have successfully passed the Connectathon are easy to integrate with each other, saving time and money during the implementation process at a user's site. Furthermore, the IHE Profiles provide a description of basic functionalities that the user can expect from a relevant application. Profiles can therefore also be used as a starting point for the development of requests for proposal. By combining the published vendor Connectathon results and the Integration Statements' claims for specific products, users can quickly generate an overview of available healthcare IT systems that are in conformance with a given Profile.

How does IHE support the discussion between users and vendors?

IHE Profiles summarise the actual state of knowledge regarding technical and other issues affecting the clinical process in question. They contain relevant definitions that enhance understanding among users and vendors. This helps users and vendors to reach a common understanding concerning requested services and functionalities quickly, even if they have not been involved in the development of the Profile. In this way, IHE facilitates the discussion between users and vendors about the interoperability goals and content of specific IT projects.

Finally, IHE helps to protect previous investment in existing IT systems. IHE opens a way to upgrade existing systems, when necessary, and integrate such systems with new applications from a different provider. This reduces the need to replace existing and working IT systems just because a new application is being introduced in one department of the healthcare enterprise.

What are the IHE Domains and what's the Annual Work Cycle?

IHE is organised across a growing number of clinical and infrastructure Domains, such as Cardiology, Laboratory and Pathology, Public Health, Radiology, Patient Care Coordination, IT Infrastructure, just to name a few. Each Domain produces its own set of Technical Framework documents, in close coordination with other IHE Domains. Committees in each Domain review and republish these documents annually, often expanding with supplements that define new Profiles. Initially each Profile is published for public comment. After the comments received are addressed, the revised profile is republished for trial implementation: that is, for use in the IHE implementation testing process. If criteria for successful testing are achieved, the Profile is published as final text and incorporated. More information can be found here: http://www.ihe.net/Profiles/

Does IHE address sharing of health information?

The main goal of IHE is to achieve interoperability between healthcare IT applications and devices. In doing so, IHE also addresses the issue of the exchange of medical records between different applications and different health and healthcare environments. As IHE considers health data exchange in the context of the workflow of the sending and receiving systems/organisations, it has developed different Profiles that are suited for use within hospital departments, others across entire hospitals, others at the regional or national level, others for home health, others for mobile environments. Attention for consistency across those environments ensures that these Profiles can be easily combined and support national eHealth strategies. IHE provides these interoperability building blocks that have been designed so that they could be arranged in a variety of ways or architectures depending on the eHealth deployment constraints.

Can I become an IHE member?

IHE has members, who provide special support, direction and commitment to the development and deployment of IHE. Members understand that supporting IHE is an efficient way to support their needs for interoperability. That is why membership fees at the international level (supporting development and maintenance of Profiles) and at the national level (supporting communication, deployment and testing) are

needed. Specific Domains are sponsored by not-for-profit benefactors (clinical professional associations, IT associations, national or regional eHealth projects, competence centres etc.). In return, the access to and implementation of Profiles is open to all. The participation in the Connectathon, on the other hand, is open to all interested developers of healthcare IT applications. Participants (users and vendors) simply need to accept and respect the open rules and procedures of IHE (including its IP policies), but do not have to enter into any other commitments.

Is IHE promoting openness?

Yes, as a not-for-profit initiative, IHE publishes the Profiles and releases its Testing Tools for free. Users of IHE-compliant healthcare IT applications procure IHE conformant products in the usual way.

Can I use any IHE intellectual property for free?

IHE Profiles and the IHE Testing Tools can always be freely used by everyone. However, rules for the protection of intellectual property rights do apply (e.g. logos, trademarks) and the use of any IHE intellectual property is restricted to "fair use".

What is the specific role of IHE-Europe?

IHE-Europe is a not-for-profit association under Belgian law (aisbl) with the goal of coordinating European input to international IHE development activities and IHE activities in Europe. A first goal is to ensure that the needs of European users of healthcare IT systems are taken into account in the development of the IHE Profiles. A second goal is the organisation of the annual IHE-Europe Connectathon and support for national IHE Initiatives in Europe. A third goal is to offer services (https://www.ihe-europe. net/deployment/IHE-Services) that help accelerate projects by reusing methodology, best practices and tools to accelerate deployment initiatives. These services include the definition of national use cases, the development of IHE Profiles-based interoperability specifications, the establishment of a high-quality and customised test platform based on the IHE Gazelle toolbox (https://www.ihe-europe.net/sites/default /files/Flyer_Gazelle_03.pdf) and the establishment of testing policies that leverage IHE Conformity Assessment. IHE-Europe is regarded by the European Commission as the lead organisation that has established an efficient methodology to ensure that healthcare systems can interconnect and communicate together across Europe (see https://www.ihe-europe.net/sites/default/files/Flyer_27_profile.pdf).

Organising some of the testing for the European eHealth Digital Services Infrastructure (eHDSI) in conjunction with the annual IHE-Europe Connectathon, contributes to achieving the objective of cross-border exchange of healthcare information in Europe (https://ec.europa.eu/cefdigital/wiki/display/ EHNCP/OpenNCP+Community+Home).

What is the specific role of National IHE Initiatives?

National IHE Initiatives promote the use of IHE specifications and testing in their respective countries (https://www.ihe-europe.net/participate/national-initiatives). They do this by proposing and promoting Profiles that are relevant in the context of the national healthcare environment, supporting the discussion between users and vendors about requirements at the national level, encouraging vendors to participate in the IHE-Europe Connectathon, evaluating the existing IHE Profiles in the context of the national

healthcare environment and developing proposals for national extensions or amendments when required as well as by developing extensions to the Profile specifications to support unique national requirements.

Is the IHE logo and other IHE trademarks free to be used?

Yes, they are. Although there are limitations to what you can do or which uses are permitted. IHE has established a usage policy which address the fair use of its logos and trademarks. The policy is available here: https://www.ihe-europe.net/sites/default/files/inline-images/Trademark%20Policy%201.4.pdf

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