Chapter 5
Health Information Exchange: The Overarching Role of Integrating the Healthcare Enterprise (IHE)

Karima Bourquard and Alexander Berler

Abstract Innovative solutions are needed in Healthcare to deliver interoperable and secure digital services. Big data and Artificial Intelligence (AI), Personalized medicine, are considered as the main priorities by the European Commission for the coming years. As such, topics are placing high demands on medical data to ensure that they are consistent, relevant, and structured. In order to achieve this degree of consistency data that is to be exchanged, needs to be underpinned with protocols and standards which need to be clearly understood by those charged with implementation. To increase data quality, integration guidelines called profiles allow a harmonious combination of standards for answering specific clinical needs and workflows. Alignment and conformity of the IT systems to the requirements is the preferred approach to build trusted healthcare IT ecosystem. The chapter describes a comprehensive process that allows reaching the goal of developing Digital Health Space. Based on two concrete examples, firstly, the Integration Healthcare Enterprise (IHE) is a profiling organization that proposes a use case driven methodology for successfully deploying interoperable systems that are tested during events called Connectathons. Secondly, The Conformity Assessment Scheme for Europe (CASforEU) designed in the European project EURO-CAS completes the process by proposing a rigorous evaluation of the conformity of products and solutions for better confidence of the interoperability implementation. This chapter initially introduces the concept of interoperability and then describes in detail how to implement the process in healthcare setting, It also provides some concrete examples of

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deployment projects, and introduces the concept and process of the conformity assessment scheme for healthcare IT products and solutions.

Keywords Digital health · Interoperability · Health information exchange Concept · Use case · Interoperability framework · Testing tools · Conformity assessment Scheme · Certification · Projectathon · Connectathon

Learning Objectives for the Chapter
Many countries in Europe and beyond are developing interoperability frameworks at the national or regional levels in order to serve their programs and objectives that include

1. Secure Access for citizens to their health data.
2. Increase interoperability among systems for sharing electronic health data.
3. Increase the quality of electronic health data.

This chapter will focus mostly on the interoperability understanding, one of the key challenges of the Digital Transformation processes of Health and Care in the Digital Single Market (Health and care in the digital single market - ICPerMed 2020). The main objectives are the following:

- Provide a common understanding of the concept of interoperability including the difference between standards and integration in eHealth;
- Introduce IHE as an international organization that collects use cases from healthcare professionals, defines IHE profiles, tests the conformance and interoperability during the Connectathon and deploys the profiles within national/regional programs;
- Provide the reader with some concrete examples of the use of IHE methodology;
- Provide insights to the reader on the data quality and how IHE impacts on better use of data in big data analysis and artificial intelligence by promoting the conformity assessment for interoperability in eHealth;
- Introduce the reader to general considerations on the use of certification and conformity assessment in digital health.

The official website of the office of the national coordinator for health information technology[1] in USA reports, the "*Electronic health information exchange (HIE) allows doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically—improving the speed, quality, safety and cost of patient care*" (What is HIE?|HealthIT.gov 2020). Even nowadays, despite the widespread existence of secure information transfer technologies, most citizens' healthcare information is still stored on paper in hospitals, primary care settings and in patients' homes. When that set of information is shared between providers, it happens by

[1] https://www.healthit.gov/topic/.

hand, mail, fax and usually by patients themselves, who have to carry their records from one point of care to another. While electronic health information exchange cannot replace patient-provider necessary physical communication, it can surely enhance the completeness of patient's medical records, as patient summaries, structured discharge letters, lab results, current medications and other information are needed during visits. Proper and well-timed sharing of vital patient information can better inform decision making at the point of care and facilitates providers to

- Avoid unnecessary readmissions;
- Avoid prescription errors adverse drug reactions;
- Improve the quality of medical diagnoses;
- Decrease or eradicate duplicate tests.

To reach the aforementioned goals listed above, it is expected that interoperable systems need to share structured (or even unstructured) information, by applying commonly accepted and used terminologies, and standards. The role of Standardization Development Organizations (SDOs) such as DICOM, HL7 Inc. and others is of critical importance. Their role is discussed in detail in Chap. 6. In addition, the role of profiling organizations such as Integrating the Healthcare Enterprise (IHE) is also of overarching importance because it introduces the terms of integration profiles and provides much needed detail for testing infrastructure to support same.

With interoperable systems, data can be exchanged and stored automatically rather than re-typed into the different point of care systems each time. Data is unfortunately today not always available in a usable format, thus hindering the integration of data from various sources in use cases for secondary use of medical information. As a solution to create widely used and accepted data format, the integration profiles process has been proposed as a way to enable end-to-end interoperability by sharing structured (and unstructured data) between the point of care systems (Hoerbst and Ammenwerth 2010). An integration profile is a guideline for implementation of a specific process called use case. The use case provides precise definitions of how standards can be implemented to meet specific clinical needs for a specific purpose. For example, integration profiles organize and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards, such as DICOM, HL7, W3C and security standards in Digital Health. Recently, the European Commission, in relation to the Article 292 of the EU (Commission implementing regulation (EU 2018) (the GDPR regulation on the lawful processing of personal data and the ability of citizens and healthcare providers to securely access and share electronic healthcare records), released the important Commission Recommendation of 6.2.2019 on a European electronic health record exchange format (EHRxF) (Transformation of health and care in the digital single market 2019; Commission recommendation on a European Electronic Health Record exchange format 2019) which set the grounds for a secure, standardized and proper set of exchange formats. These recommendations should form the basis of any future developments in the domain of lawful and legitimate reuse of clinical

data for research and Big Data analytics within the so-called Health Data Space (Digital health progressing towards more interoperability for the digital cross border exchange of health data in Europe 2020).

The achievement of Interoperability in Digital Health will facilitate the adoption of innovation when many countries are today heavily involved, by developing the medicine of the future using Artificial Intelligence and big data analysis. Interoperability is also the vehicle to ensure seamless exchanges or shared data among systems when they are distributed among public and private healthcare organizations or within healthcare providers, for example by involving a broad range of ICT systems that include medical devices (EHR, radiology Information system, modalities, laboratory information System, pump infusion) applications (appointment system), mobile applications and many other types of applications of concern.

Traditionally, ICT systems in healthcare providers have been working as standalone systems with no connection to other systems across the continuum of healthcare settings. Systems and applications were operated as silos. This is increasingly no longer the case. Health care providers and the systems they deploy from applications in silos, the systems are now more and more connected and exchange data in order to support the care processes that can involve multiple actors, healthcare professionals and patient. Behind the complexity of the health care world, the interoperability is not a simple concept but covers multiple dimensions that will be analyzed in this chapter. Implementation of interoperability cannot be a success without taking into account the end-users who will use in their daily work the systems that support their activities and tasks (Bourquard et al. 2014). This is why IHE[2] has been developing for many years a methodology that allows deployment of care systems in organizations. This methodology is presented and is followed by some concrete examples. Finally, quality of the health data is the main goal to be achieved: even if standards and integration profiles specifications are essentials (Witting 2015), vendors developing their systems have not always the same interpretation of the specifications or customize them to fit to their developments. Therefore, many countries are developing certification schema or conformity assessment in eHealth interoperability and a European project called EURO-CAS has created a Conformity Assessment Scheme for Europe which is now presented in this chapter.

In conclusion, because Interoperability is one of the key challenges in the coming years, the next section will provide oversight on the Interoperability and related concepts to better understand this challenge: Interoperability is a complex concept that impacts upon all levels of the societal health organization. It will be followed by a section on how to implement the interoperability infrastructure using IHE and its methodology with examples of deployment in various countries to complete this section. The quality of medical data will be highlighted in the last section where the conformity assessment in Europe for interoperability digital health is described based on the European project EURO-CAS and based on existing testing environment.

[2] Integration the Healthcare Interoperablity (www.ihe.net).

5.1 Interoperability and Concepts

Interoperability is a characteristic of a product or system, whose interfaces are completely understood, to work with other products or systems, at present or in the future, in either implementation or access, without any restrictions (Definition of interoperability 2020). While the term was initially established for information technology or systems engineering services, a broader definition considers social, political, and organizational factors that impact on system to system design performance (Slater 2012). Interoperability implies the use of Open standards by definition.

Open standards are publicly available and follow some principles as established by the joint meeting of several organization and standard development bodies (IEEE, ISOC, IETF, IAB[3]):

1. Cooperation between members;
2. Acceptance of the following principles:
   (a) A clear process where decisions are developed with equity and respect among members;
   (b) Broad consensus;
   (c) Transparency;
   (d) Balance: no domination by one of the groups of interest, company or person;
   (e) Openness: open to all interested parties;
3. Collective empowerment commitment;
4. Availability: standards shall be FRAND;[4]
5. Voluntary adoption of standards.

The new European Interoperability Framework promotes seamless services and data flows for European public administrations (New European Interoperability Framework 2017). This framework defines the principles and makes recommendations for interoperability by defining the minimal characteristics for a specification for open standards.

When a vendor is forced to adapt its system to a dominant system that is not based on Open standards, it is not interoperable e.g. able to exchange data with any other systems only those systems which are compatible. As a result, interoperability can be seen as an opportunity to safeguard the potential of open free markets societies.

Open standards rely on a broadly consultative and inclusive group of individuals including representatives from vendors, academics and others holding a stake in the development process which discusses and debates the technical and economic merits, demerits and feasibility of a proposed common protocol. After focused discussion, the doubts and reservations of all members are addressed, the resulting

[3] See Glossary.

[4] FRAND: FAIR, Reasonable and Non-Discriminatory.

common document is endorsed as a common standard. Then anybody is entitled to use the standard to achieve interoperability in a specific context.

In the healthcare sector, HIMSS[5] provided the best current definition of healthcare interoperability as

> "the ability of different information systems, devices and applications ('systems') to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally".

Health data exchange architectures, application interfaces and standards enable data to be accessed and shared appropriately and securely across the complete spectrum of care, within all applicable settings and with relevant stakeholders, including by the individuals.

HIMSS defined four layers of interoperability (What is interoperability in Healthcare? 2013):

- Foundational (Level 1)—establishes the inter-connectivity requirements needed for one system or application to securely communicate data to and receive data from another;
- Structural (Level 2)—defines the format, syntax, and organization of data exchange including at the data field level for interpretation;
- Semantic (Level 3)—provides for common underlying models and codification of the data including the use of data elements with standardized definitions from publicly available value sets and coding vocabularies, providing shared understanding and meaning to the user;
- Organizational (Level 4)—includes governance, policy, social, legal and organizational considerations to facilitate the secure, seamless and timely communication and use of data both within and between organizations, entities and individuals. These components enable shared consent, trust and integrated end-user processes and workflows.

This definition is also in line with what has been proposed in Europe by the ISA[2] program—Interoperability solutions for public administrations, businesses and citizens, managed by the European Commission. The European position on interoperability is stated in (European Interoperability Framework for pan-European eGovernment Services 2004), communication from the commission to the European, parliament, the council, the European economic and social, committee and the committee of the regions, European Interoperability Framework—Implementation Strategy document as:

[5] The Health Information and Management Systems Society (https://www.himss.org).

> Interoperability is a key factor in making a digital transformation possible. It allows administrative entities to electronically exchange, amongst themselves and with citizens and businesses, meaningful information in ways that are understood by all parties. It addresses all layers that impact the delivery of digital public services in the EU, including: legal issues, e.g. by ensuring that legislation does not impose unjustified barriers to the reuse of data in different policy areas; organizational aspects, e.g. by requesting formal agreements on the conditions applicable to cross-organizational interactions; data/semantic concerns, e.g. by ensuring the use of common descriptions of exchanged data; technical challenges, e.g. by setting up the necessary information systems environment to allow an uninterrupted flow of bits and bytes.

Those four layers of interoperability are the foundation of the European Interoperability Framework (EIF) which is part of the reference: Communication (2017) from the European Commission adopted on 23 March 2017. The framework gives specific guidance on how to set up interoperable digital public services. It offers public administrations 47 concrete recommendations on how to improve governance of their interoperability activities, establish cross-organizational relationships, streamline processes supporting end-to-end digital services, and ensure that both existing and new legislation do not compromise interoperability efforts. The new EIF is undertaken in the context of the Commission priority to create a Digital Single Market in Europe. The public sector, which accounts for over a quarter of total employment and represents approximately a fifth of the EU's GDP through public procurement, plays a key role in the Digital Single Market as a regulator, services provider and employer. The successful implementation of the EIF will improve the quality of European public services and will create an environment where public administrations can collaborate digitally.

Standards and specifications are fundamental to interoperability. The European Interoperability Framework (EIF) distinguishes **six steps** to managing standards and specifications appropriately:

- **Identifying** candidate standards and specifications based upon specific needs and requirements;
- **Assessing** candidate standards and specifications using standardised, transparent, fair and non-discriminatory methods;
- **Implementing** the standards and specifications according to plans and practical guidelines;
- **Monitoring** compliance with the standards and specifications;
- **Managing change** with appropriate procedures;
- **Documenting** standards and specifications, in open catalogues, using a standardised description.

The European Interoperability Framework (EIF) also includes a conceptual model as presented in Fig. 5.1 for integrated public services. The model is modular and comprises loosely coupled service components interconnected through shared infrastructure.

The conceptual model promotes the idea of interoperability by design. It means that for European public services to be interoperable, they should be designed in accordance with the proposed model and with certain interoperability and

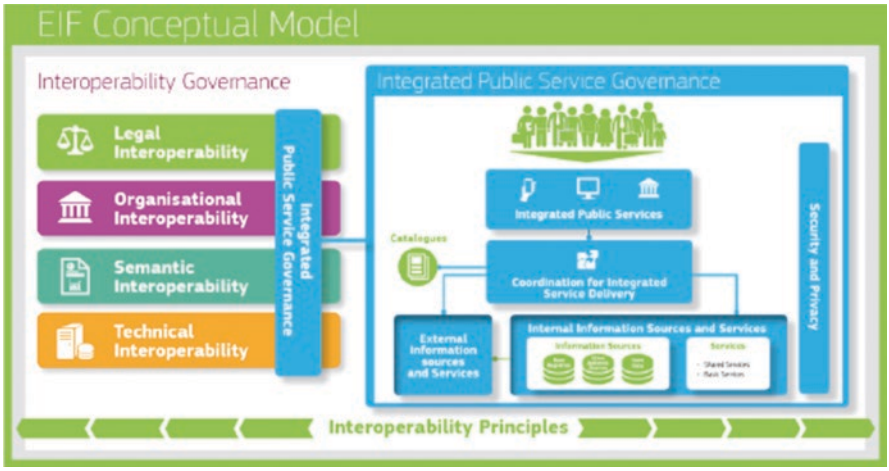

Fig. 5.1 EIF conceptual model. From ISA

reusability requirements in mind. The interoperability maturity model (IMM) developed in the context of the ISA programme can be used to assess a service's readiness for interoperability. The model promotes reusability as a driver for interoperability, recognising that the European public services should reuse information and services that already exist and may be available from various sources inside or beyond the organisational boundaries of public administrations. Information and services should be retrievable and be made available in interoperable formats. This in line with current profiling solutions for the healthcare sector as depicted in ISO/TR 28380[6,7,8] technical report.

For the Healthcare domain the European Commission adopted the Refined eHealth Interoperability Framework. The ReEIF was adopted and endorsed by the eHealth Network[9] in November 2015.

While the EIF 2017 has four layers, the ReEIF describes the organizational and technical layer. This is important because it provides details which results in six layers and takes into account security, privacy, governance principles and agreements:

[6] ISO/TR 28380-1:2014 Health informatics—IHE global standards adoption—Part 1: Process, https://www.iso.org/standard/63383.html.

[7] ISO/TR 28380-2:2014 Health informatics—IHE global standards adoption—Part 2: Integration and content profiles, https://www.iso.org/standard/46207.html.

[8] ISO/TR 28380-3:2014 Health informatics—IHE global standards adoption—Part 3: Deployment, https://www.iso.org/standard/61471.html.

[9] The eHealth Network is a network gathering European countries and Norway and created by the directive on the application of patient rights in cross border healthcare in March, 9th 2011 (https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF). One of the objective is to develop cooperation among countries.

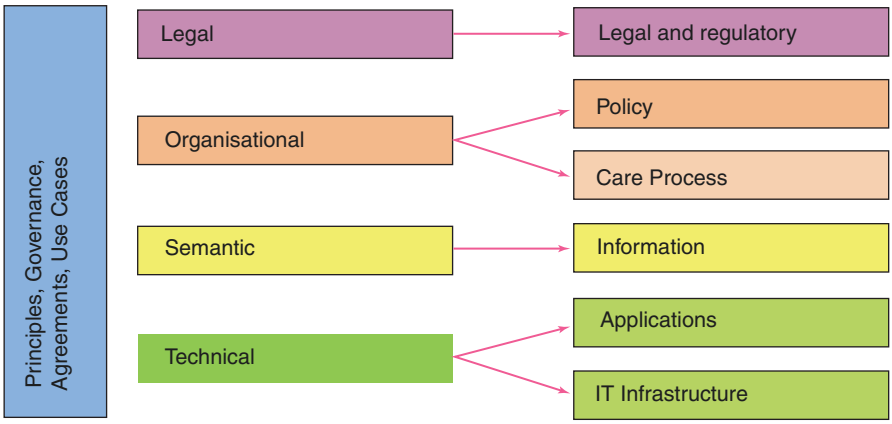

Fig. 5.2 From EIF to ReEIF with the vertical layer Principles, Governance, Agreements, Use Cases. (From Antilope project)

- Legal and regulatory level describes the legal context and constraints;
- Policy level is related to the collaboration agreements as for example healthcare network where healthcare professionals exchange medical data for given patients;
- The care process level identifies and specifies care process among healthcare professionals for alignment and development of a common vision of the processes;
- Information level describes the data and their semantic based on coding systems that are exchanges among Healthcare Professionals;
- Application level identifies the actors, structured messages and standards that will support the medical exchanges as described by the levels above;
- IT infrastructures describes the communication protocols.

These layers are completed by vertical layers for the global governance, security and patient policies and other necessary items necessary for a successful deployment (certification, interoperability framework, etc). An illustration of the EIF to ReEIF is presented in Fig. 5.2.[10]

5.2 Digital Health Strategy Efforts

As a result, the implementation of Healthcare Information Exchange network (HIE) implies a substantial policy and consensus building effort is required. Many such efforts and Digital Health strategies are globally under development. It is important to focus on some examples that have a rather important impact at the global scale. They are briefly expanded upon in this section.

[10] eHealth Standards and Profiles in Action for Europe and Beyond Deliverable 4.2r1 Interoperability Guideline for eHealth Deployment Projects, Release 1, 13-03-2017.

5.2.1 In the United States of America

The first effort is led by the Office of the National Coordinator for health information technology in the United States (ONC) (2020–2025 Federal Health IT Strategic Plan 2020) that recently released their draft 2020–2025 Federal Health IT Strategic Plan for public comments. This plan, which was developed in collaboration with over 25 federal organizations, is intended to guide federal health information technology (IT) activities.

The plan's goals are deliberately outcomes-driven, with objectives and strategies focused on using health IT as a catalyst to empower patients, lower costs, deliver high-quality care, and improve health for individuals, families, and communities. ONC and its federal partners have taken and will continue to take steps to ensure that stakeholders in the healthcare sector benefit from the electronic access, exchange, and use of the health information. Specifically, this plan explains how the federal government intends to use health IT to impact on individuals in the following manner:

- Promote Health and Wellness;
- Enhance the Delivery and Experience of Care;
- Build a Secure, Data-Driven Culture to Accelerate Research and Innovation; and
- Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure.

5.2.2 In Europe

The second effort is led by the European Commission that is working to provide its citizens access to safe and top-quality digital services in health and care. For this, the European commission has published a Communication on Digital Transformation of Health and Care in the Digital Single Market, empowering citizens and building a healthier society (Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society 2020).

The Communication on Digital Transformation of Health and Care in the Digital Single Market identifies three priorities:

- "Citizens' secure access to their health data, this includes across borders enabling citizens to access their health data across the EU;
- Personalised medicine through shared European data infrastructure allowing researchers and other professionals to pool resources (data, expertise, computing processing and storage capacities) across the EU;
- Citizen empowerment with digital tools for user feedback and person-centred care using digital tools to empower people to look after their health, stimulate prevention and enable feedback and interaction between users and healthcare providers."

5.3 IHE (Integrating the Healthcare Enterprise) and IHE Methodology

IHE is a world-wide initiative created by healthcare professionals and industry to improve the way computer systems in healthcare share information by working together on interoperability use cases. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care.

IHE has been defined a successful process for more than 20 years that identifies four steps (IHE Process 2020):

1. Healthcare Professionals, clinical and technical experts define critical interoperability use cases for information sharing;
2. Technical experts generally originated from Industry identifies and selects established and robust standards and develop detailed integration specifications called IHE profiles for communication among systems to address these specific use cases;
3. Industry implements these IHE Profiles in their systems;
4. Vendors' systems are tested by neutral monitors at carefully planned, controlled and supervised events called Connectathons.

Figure 5.3 provides a visual overview of the IHE process activity.

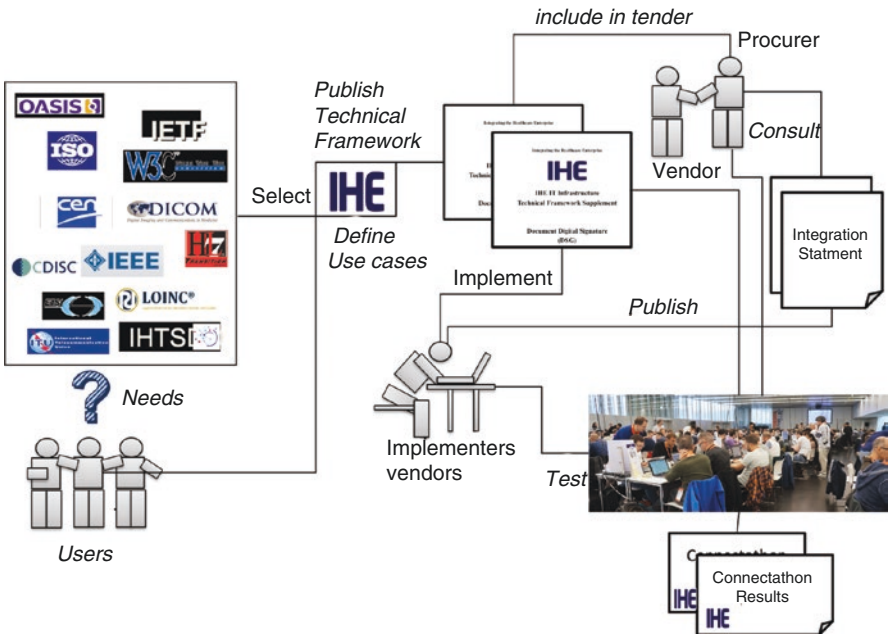

Fig. 5.3 The IHE four steps process. (From IHE)

Beginning in the Radiology Domain back in 1999, IHE has expanded into multiple domains and today 13 medical domains are covered such as Cardiology, Endoscopy, Pathology and Laboratory Medicine, Eye Care, Patient Coordination Care, ITI infrastructure, Pharmacy, Quality research and Public Health and Radiation Oncology, thereby ensuring system interoperability between suppliers and their systems on a very big scale and on an even larger world stage. Various national entities (called National Deployment Committees under IHE's governance model) were established to provide testing, education and support implementation of projects over the world, including IHE USA, IHE Europe, IHE Japan, IHE China, IHE Korea, IHE Australia and many others. They vary widely in composition, size and scope of activities.

IHE also organizes demonstrations of IHE-compliant systems working in real-world at meetings and other venues and conferences over the world. These demonstrations give a sense to the audience on how IT systems interact between them when clinical use cases are working inside hospitals or between healthcare organizations or with the shared EHR/PHR deployed at the regional or national levels or cross countries.

IHE invites clinical practitioners and technical domain experts to become leaders in this work by participating in IHE domain committees and using the IHE methodology, by identifying use cases, selecting operational and robust standards and specifying integration profiles or reviewing the documents they publish at the international level for public comments once the documents are ready. After integrating the comments received worldwide, IHE publish the specifications as supplements in trial implementation for being implementing by vendors in their systems and testing at the Connectathons. When the specifications become stable e.g. with no change proposals that impact the content, the IHE profiles are published in final text and are included in the technical framework of the domain. More than 175 organizations (IHE Member Organizations 2020) from professional societies, government agencies, provider organizations, HIT companies and others- have joined the IHE initiative worldwide.

5.3.1 Benefits of the IHE Approach

Some of Europe's largest countries are made up of autonomous regions with full authority over healthcare decisions and the information systems to support healthcare delivery. For example, Spain is made up of nine autonomous health regions, while in Italy there are 21 independent regions, and Germany is a confederation of 16 federal states. Even large nations with a single national structure, such as France or United Kingdom, have seen the development of diverse health information systems over the past 20 years built around regional university hospitals. This patchwork of regional development of IT for healthcare in Europe has created different, sometimes stand-alone systems for healthcare. Even within regions, documents created by clinical systems for patient care may not interface with administrative

systems that determine payment or citizen entitlements for healthcare. The same complexity can be seen in other countries at a global scale.

Healthcare providers, institutions like hospitals organizations or individual doctors and nurses, are working with an increasing number of information systems, all containing relevant data on the patients. Typically, these systems behave like "islands", not sharing patient-related data between systems. This leads to broken work processes, the need for repetitive data entry (with risk of mistakes) and an incomplete view on the patient's record. The same is true when caring for patients coming from abroad.

At the global scale, people are more and more highly mobile, traveling freely, whether for work or vacation, between countries. In the course of one single day, a European citizen for example, might pass through several nations. And each European citizen carries health insurance provided by his or her country of residence. In the case of an accident or a health crisis, a citizen may be treated in a foreign country by nurses and doctors speaking a different language. How can the foreign doctor determine the medications being taken by this patient, or any allergies to medications? What is the medical history of this patient? And, of course, who is paying for the often-expensive emergency medical intervention?

Europe's and other governments, both national and regional, have worked with different suppliers from the private sector to develop equipment or software for stand-alone systems. While this has resulted in a robust base of expertise and solutions for health IT in Europe, an innovative system or successful solution developed by a company often cannot be exported without significant changes to meet variations in standards and requirements in a neighboring country.

Much is at stake for national governments who spend hundreds of billions of euros/dollars each year as the primary insurer of its citizens' healthcare. As discussed in Chap. 2, there is an urgency around the globe which has a rapidly ageing population that soon countries will require greater health expenditure on, while the base for the model for health funding, for the younger working population, is shrinking. These governments see a solution in health information systems that can deliver greater efficiency and productivity, as well as supporting alternative delivery of health services for the chronically ill through community-based clinics and in-home care.

An integrated information system, with proper flow of information from one system to the other, puts the right information in front of the right doctor at the right moment to assure the right treatment.

It's that simple and applies to supporting both local and foreign patients. Adoption of common protocols and standards that are specified within IHE profiles will create a more uniform market for health IT equipment, software and services enabling manufacturers to market their products at the European and even global level with only minor variations. In addition to helping to assure compatibility between systems, a harmonized market will also lower the costs of acquiring best practices solutions for governments and citizens. Greater adoption of IHE Technical Frameworks will also enable the IT industry based in Europe to compete

internationally, thereby increasing employment and sustaining the development of this sector of activity in the Global and European economies.

5.3.2 Integration Profiles: A Framework for Interoperability

IHE Profiles provide standards-based specifications for sharing information within care settings and across healthcare networks. They address critical interoperability issues related to information access for care providers and patients, clinical workflow, security, administration and information infrastructure. Each profile identifies the system actors that are involved in the workflow (for example, the Order Filler requesting a prescription of medication), specifies the transactions where messages are described in detail using referencing standards (for example HL7 messages) with the information artefacts. The semantical information is carefully identified and selected in order to address the clinical use case by referencing appropriate terminologies.

The integration profiles that are developed by specialties and are gathered on the Technical Framework contain a number of specific volumes (IHE Domains 2020):

- The Volume 1 describes the use cases, interaction between actors by using transactions;
- The volume 2 specifies each identified transaction in detail that uses messages based on international standards;
- The volume 3 describes the content and semantic details;
- The volume 4 describes the national extensions if any.

All the technical frameworks are freely available on the IHE international website (see reference above).

5.3.3 Connectathons®: Testing Interoperability and Conformance

IHE has been testing the interoperability of Healthcare Information Technology (HIT) systems for more than a decade. At IHE Connectathons held regularly in several locations internationally, trained technical experts supervise testing of vendor systems, making use of advanced testing software developed by IHE and several partner organizations. More than 250 vendors worldwide have implemented and tested products with IHE capabilities. The IHE Product Registry (IHE Product Registry 2020) provides essential information for IT administrators and executives responsible for purchasing and integrating systems at healthcare sites and health information exchanges (IHE User handbooks 2020). Detailed results of testing at IHE Connectathons® over the past several years in Europe, North America and Asia

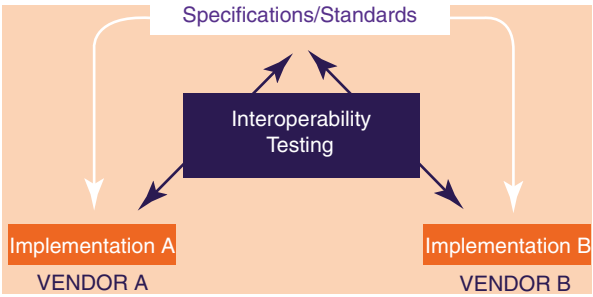

Fig. 5.4 IHE testing at a Connectathon®

are made available in this easy-to-use online database. In Europe, Connectathons has been organized for more 20 years. Each year IHE-Europe, the European deployment committee, selects a national initiative from one of the European countries for setting up the next yearly Connectathon (comparable but at its size, the selection of the city for the Olympics game!).

The main objective of the Connectathon is to test systems' conformity to IHE Profiles by using validators and the interoperability between systems or simulators in a controlled and neutral environment. Clinical workflow is guidance for testing. The Connectathon allow testing in a controlled and neutral environment. Figure 5.4 distinguishes the interoperability testing from the conformity testing:

- Conformity will be checked using validator tools where the messages that are sent/received by a system are conformed to the required standard specifications.
- Interoperability checking will show that the message sent by one system is received and treated adequately by the receiver.

It is not because a system is conformed to a specific standard that it is interoperable and vice versa. This is mainly true for a specific use case or health care context, for example when the IHE profile is applied to this use case.

The Connectathon is also called Connectivity Test Marathon and can be described as following:

- It allows week-long (5 days) face-to-face testing of the participating products' interoperability developed by industry and implementers;
- Participants implements profiles and standards in their solutions and test them with open source test tools and test plans provided in advance by IHE;
- Vendors, large and small companies, are encouraged to work closely together to solve interoperability issues for the benefit of the healthcare community;
- Participants are allowed to correct their solutions (products or prototypes) non-conformities during the event;
- Thousands of transactions are verified using both test tools and peer tests: they are recorded and the outcomes are checked and validated by neutral Monitors (subject expert matters or knowledgeable testers);
- At the end of the event, successful vendors are registered in the Connectathon Results Matrix published publicly on the IHE website;

- Sanity checks are also performed to see whether the IHE Profiles are clear enough, well understandable by implementers and can be implemented consistently.

The Connectathon test platform using test management software system is called Gazelle test bed. Essentially, several varieties of tools are used:

- Validation tools, to verify if messages/documents are in conformity with specifications and profiles;
- Simulator tools to test the interoperability of a system, not as a reference implementation but as a controlled test cases (Gazelle simulators 2020).

The Gazelle test bed provides Connectathon® participants, Monitors and the management with the tooling to run the event. The process is described in Fig. 5.5:

- Participants share configurations (1), samples and identify test partners through the Gazelle test management tool;
- The tool provides them with a list of tests to be performed and enables them to log evidences of the tests performed (2). Participants are free to run the test at their own environment following the test plan they received;
- Monitors, who are subject-matter experts, verify each test (3) using the Gazelle test management platform;
- As for the participants, they have the ability to check the conformance of the exchanged messages that are most critical, using validation services (4);
- The Management Team is provided with indicators that allow them to monitor the testing progress and grade the participants progress.

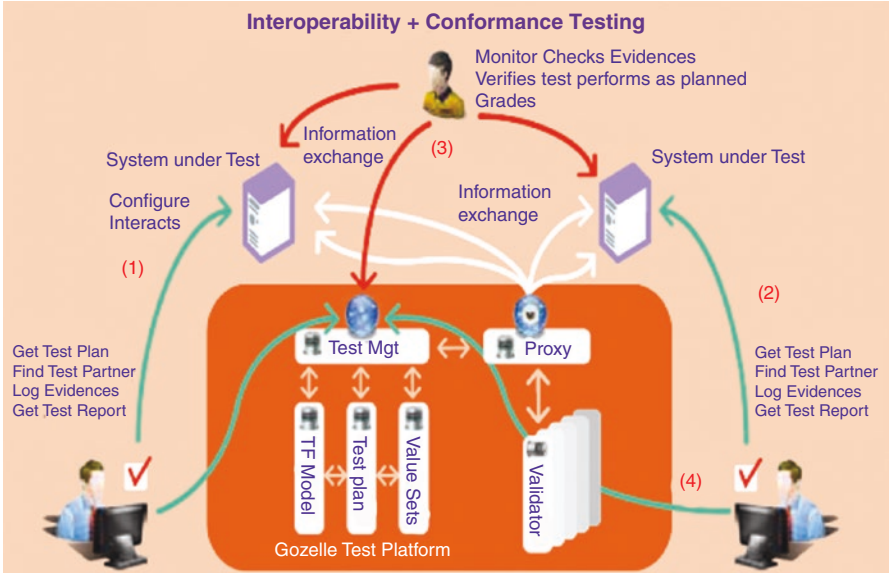

Fig. 5.5 Testing in practice

5.3.4 *Conformity Assessment Scheme*

The interoperability of healthcare information systems is one of the most important challenges facing both users and suppliers of healthcare solutions.

The accurate, timely and secure exchange of medical records requires unique technical expertise and competencies often beyond the experience of individual vendor or user deployment teams. 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 the best quality patient care. To reduce costs, delays and other risks of incorrect, inappropriate and inadequate product purchases of many products, users have come to depend on trusted, independent third-party testing, which is often called "Conformity Assessment".

To meet these challenges, IHE International is introducing the IHE Conformity Assessment Program (IHE Conformity Assessment Scheme 2014).

The IHE Conformity Assessment testing is based on an ISO/IEC 17025 quality system in accordance with the IHE Conformity Assessment Scheme published by IHE. A specific set of IHE Profiles used for sharing health records is available for testing in accordance with requests from projects users and the industry.

Products submitted must be either market-released products or expected to be released within 6 months after the Conformity Assessment test session. Figure 5.6 describes the process to be engaged in the Conformity Assessment testing:

- The vendor must have passed the IHE Connectathon tests within the prior 2 years for the appropriate IHE Profiles targeted for Conformity Assessment;
- The accredited testing laboratory, authorized by IHE International, will deliver the Conformity Assessment Report (IHE Conformity Reports 2020): it will give more trust on the results when tested by a neutral, competent and recognized testing laboratory;
- The Conformity Assessment Report is published on the IHE International website after successful completion of testing which gives transparency and an overview of qualified products to the end users.

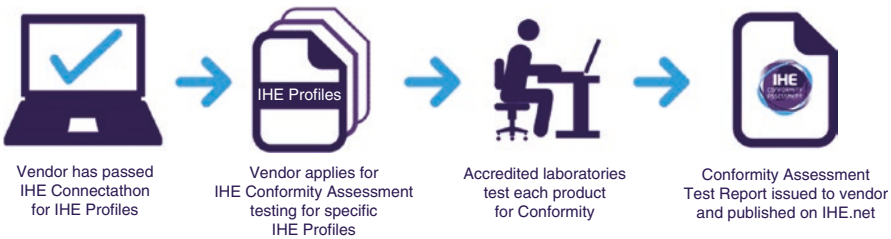

Fig. 5.6 Conformity assessment scheme**.** (From IHE)

From this, several benefits are identified for Users as well as for industry:

- Users:
  - Large eHealth projects reduce their testing and integration efforts by specifying and procuring products that have been conformity-assessed;
  - It gives confidence that a current/potential supplier has independent proof of the interoperability of their products;
  - It relies on an accredited testing laboratory to validate products before they are installed in an organization or facility, reducing risks and deployment costs;
  - It Improves patient outcome through better and more consistent product quality.
- Suppliers:
  - Interoperability readiness for systems and solutions;
  - Global market credibility by distinguishing the company and its products. For a listing of companies and products, recognized internationally and accepted for "shortlisting" (i.e. pre-qualified for purchasing programs) by being engaged in the quality process governed by the IHE Conformity Assessment Program.
  - Wealth of IHE Profiles and increase an organization's capabilities.

Currently IHE International has today 16 IHE integration profiles included in the IHE CAS program (see Fig. 5.7) that covers the most important identified needs in hospitals, at the regional and national Health Information exchanges and at cross-border. New profiles will be added in the future depending of the user demand. Procurers have to request qualified products in their tenders in order to develop this activity which is considered more and more as mandatory by various healthcare stakeholders.

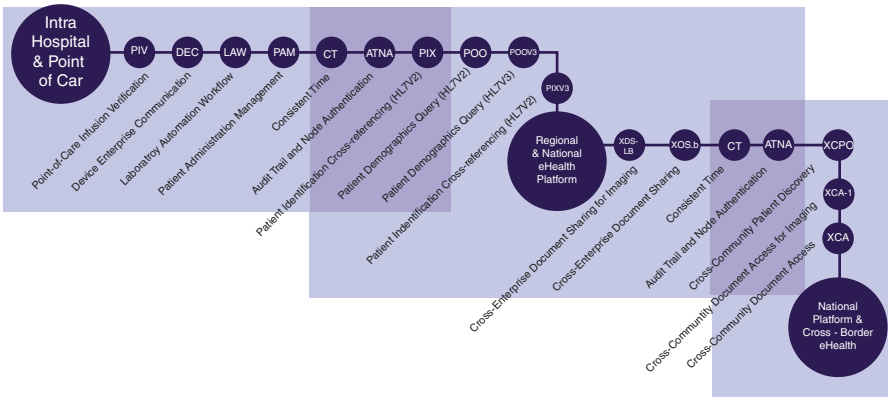

Fig. 5.7 Integration profiles of the IHE Conformity assessment scheme. (From IHE)

5.3.5 *Gazelle Test Bed and IHE Services*

IHE-Services provides the IHE competency for eHealth consultancy, training services. It organises interoperability test sessions and develops interoperability test tools, leveraging more than 10 years of experience in these domains and a community of hundreds of implementers around the world.

Developed for the annual IHE European Connectathon, these services allow specific projects to complement the product testing performed at the IHE Connectathon and include:

- The IHE Gazelle management software that supervises and coordinates testing activities;
- Unique interoperability test engines for DICOM, XML, HL7, OASIS, IETF and IHE integration profiles;
- Simulators for online, or virtual testing;
- Technical project management and results reporting services to organize and manage special-purpose interoperability testing events.

This Gazelle platform is developed under the ISO/IEC 17025 quality system (same level of quality as ISO 9001) and is composed of the main blocks below:

- Administrative, management and statistics;
- Test plan repositories and management;
- Management of test sessions;
- Management of validation tools (External Validation Service—EVS tool) and specification compliance (assertion manager);
- A portfolio of test tools: validators, simulators, objects Checker, test data sets, etc., some developed by IHE Services while many others from contributors from around the world.

This test management platform is also used remotely to realize the tests directly from the product development sites. Developed under the Apache 2.0 license, this platform can therefore be easily installed for end-users, both companies creating eHealth solutions for health projects and healthcare facilities. It supports a number of regional or national ehealth projects (Belgium, France, Finland, Luxembourg, Veneto Region, Saudi Arabia, Korea, Australia, Japan and North American Connectathons). Figure 5.8 shows that the same IHE Gazelle test platform can be used in many ways that finally provides a continuum of testing aligned with the concept of interoperability:

- At first, the IHE Gazelle test platform is used at the IHE Connectathon supporting implementers in their development of prototypes and products. The Connectathon is also a network of implementers and provides training, support and expertise from the monitors and experts to the product implementers;
- The step forward is the conformity assessment that increases the quality of products and uses also the IHE Gazelle test platform. The conformity assessment

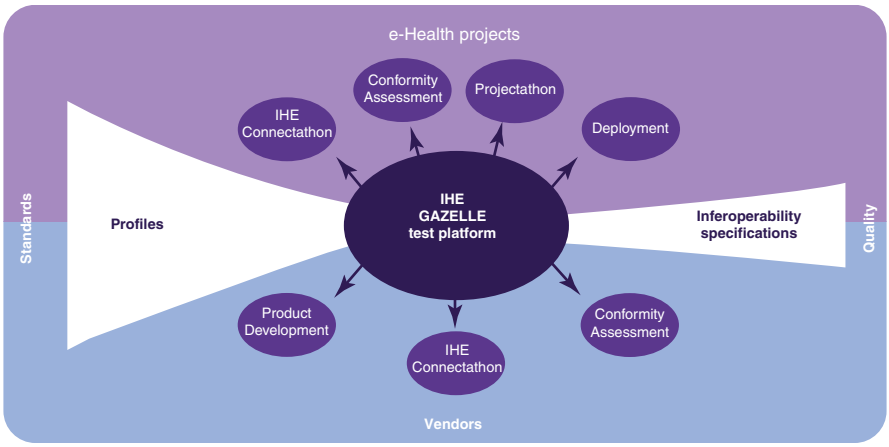

Fig. 5.8 IHE Gazelle test platform. (From IHE)

specifies a more rigorous test plan in a more controlled environment performed by an accredited testing laboratory;

- Finally, when deploying IHE profiles at the project level, the IHE Gazelle test platform is used at the Projectathon which is a type of Connectathon but dedicated to the specifications-based profiles of the eHealth project. The Projectathon has the same role as the Connectathon: it provides support, training and expertise to vendors that are selected for the project deployment.
- The ehealth project and vendors have also their own test environment (preproduction and production) that can be based on the same test bed.

Using a common IHE Gazelle test platform at different stages of development and deployment will reduce effort to build such an environment, reduce the learning phases while promoting robustness and increasing interoperability quality for medical data for their use.

5.4 Examples of Deployment

Carefully implemented interoperability standards are the foundation of the electronic Health records (EHRs), Personal Health Records (PHRs) and Health Information Exchanges (HIE) being established around the world. IHE has developed a foundational set of profiles for secure exchanges of patient information across enterprises. IHE profiles support health information networks in Canada and the U.S.A, as well as several Asian and European countries, and have been accepted as requirements by the U.S. Secretary of Health and Human Services for federal procurement of healthcare IT systems.

IHE case studies describe projects that use IHE profiles to improve systems interoperability and information access for patients and providers within and across care sites. They highlight the advantages of using IHE to improve:

- Operational efficiency in implementing and upgrading systems;
- Productivity and workflow efficiency;
- Communication among care providers and patients and access to vital medical information;
- Patient safety and quality of care.

5.4.1 French Electronic Health Record Program

The French Electronic Health Record (DMP system-Dossier Médical Partagé) developed, implemented and rolled out by the ASIP Santé (National eHealth Agency that is now renamed on ANS (National Digital Health Agency) and the CNAM/TS, the national French health insurance.

The electronic health record (in French, "Dossier Médical Partagé": DMP) system was developed based on a mandate from the French national legislature. DMP is a free service aimed to improve the coordination of healthcare in France that is supported by healthcare professionals and has become part of patient expectations for care. It makes information required for patient care available more easily and quickly and facilitates communication between healthcare professionals and patients. Launched in January 2011, the DMP is being gradually rolled out across the French territories through voluntary adoption by patients and healthcare professionals. It will form the infrastructural and technical base for numerous e-health services, whether proposed by public authorities or private sector.

DMP core specifications have been derived from IHE profiles, especially IHE XDS (Cross-Reference Document Sharing profile).

5.4.2 Hôpitaux Universitaires de Genève, Medical Imaging Facilities

Les Hôpitaux Universitaires de Genève (HUG) is the aggregation of all hospital facilities in the canton de Genève from 1856 until today. HUG is comprised of 2187 beds and a staff of more than 7865 people. HUG provides consultation services for all the Geneva region and handles more than 550,000 patients annually. The imaging workflow utilizes PACS solutions and modalities with digital capabilities.

The workflow at HUG is as follows: Images are routed to the clinical evaluation stations and the image active episode of care services for the Electronic Patient Record (EPR) upon arrival at the Image Manager/Archive. They are then queried and displayed by the Image Display workstation. Preliminary reading by residents doctors and clinical round preparation with senior residents occurs within the Radiology Department.

5.4.3 Geneva, Switzerland: Shared Medication Treatment Plan

The Canton of Geneva Switzerland has built an Electronic Patient Record system aiming at regrouping all important documents for the patient's care. Documents are provided by all stakeholders. The patient is the owner of the patient record (patient centered). An added-value service exists for 3 years now enabling care providers to manage the medication treatment plan. The goal is to have a complete view of all medications taken by the patient. The ongoing project is to link stakeholders' applications (prescription systems, dispensing systems, home care systems) directly with the core system in order to avoid any duplication of data entry and to have a true integration of all primary systems with the central shared medication treatment plan tool. The primary goal of implementing the Shared Medication Treatment Plan (Rosemberg et al. 2015; Spahni et al. 2013), is to achieve a real-time, global view of the past, current and planned medications taken by all patients. Creating this comprehensive picture of patients' medication history will create more complete and up-to-date medical histories that can be accessed anywhere that patient goes to receive care. This project uses IHE pharmacy content profiles.

In conclusion, IHE Profiles specifically implemented to this project include a set of IHE Pharmacy profiles that define the content and format of structured pharmacy documents used in planning, prescribing and dispensing of patient medications:

- Medication Treatment Plan (MTP) describes a medication document generated when a health care professional adds a medication to a patient treatment plan;
- Pharmacy Prescription (PRE) describes a prescription document generated when a health care professional decides that the patient needs a medication;
- Pharmacy Dispense (DIS) describes a dispense document generated when a health care professional dispenses a medication to a patient;
- Pharmacy Pharmaceutical Advice (PADV) describes a pharmaceutical advice document generated when a health care professional validates a prescription item against pharmaceutical knowledge and regulations or manages a medication treatment plan or a dispensation;
- Pharmacy Medication List (PML) describes a medication list document generated when a health care professional requests this information, for example when prescribing.

5.4.4 HEALTH OPTIMUM Project, Veneto Research Center for eHealth Innovation,Veneto, Italy

HEALTHcare delivery OPTIMisation through teleMedicine (HEALTH OPTIMUM) connects today all 34 hospitals in Veneto, one of the 21 Regions of Italy, to 7 specialty centers for neurosurgery., This system manages more than 2300 teleconsultations requests each year and allows 75% of patients to be treated at home medical center.

The Health Optimum network established an interoperability framework as a first common language, as an essential step first step. This framework adopted several IHE profiles such as XDS.b, XDS-I, etc. In order to accomplish information exchanges a common interoperability platform based on IHE XCA gateway (Cross Community Access profile) specifications allowed all hospitals to be linked across the region of Veneto.

HEALTH OPTIMUM applied a layered strategy where specialized hospitals in neurosurgery acted as the hub, and the peripheral hospitals extended the network out into the local communities and primary care settings. This infrastructure was implemented in seven hubs all connected so that all hubs can receive input from the peripheral hospitals, creating a safe network across the region. As a consequence, any physician in any clinic makes available to the expert neurosurgeon at the hub hospital a digitally signed teleconsultation request (HL7 CDA2 document with LOINC Codes) and a set of CT Images (based on DICOM Manifest). The neurosurgeon can then decide if a patient transfer is needed, providing the answer in a reply form. When such a decision is needed, the surgeon automatically begins preparations for therapeutic or surgical intervention while the patient is transferred from the peripheral hospital to the neurosurgeon hub, saving precious time for the patient, and increasing successful treatment and good outcome of care.

The IHE-driven interoperability of the central platform enables an infrastructure lending itself to multiple uses. Additional services have been easily added, such as teleconsultation for ischemic stroke. Extensions of the platform are expected to include laboratory and medical report sharing, e-prescription, and e-referral services for general practitioners and pediatricians (Table 5.1).

5.4.5 Keystone Health Information Exchange, Northeast Pennsylvania, USA

Keystone Health Information Exchange (KeyHIE®) is a network of healthcare providers in more than 31 counties of northeast and central Pennsylvania that serve three million patients yearly, where many of them in medically underserved areas. KeyHIE designed its Health Information Exchange (HIE) to roll out in phases, growing the system's value and capabilities and overall adoption over time. Geisinger Health System is an innovative integrated delivery network based on healthcare IT-supported care coordination, is one of the major and active participants in KeyHIE. Currently, KeyHIE interconnects already Geisinger with five other regional hospitals—Evangelical Community Hospital, Community Medical Center, Mid-Valley Hospital, Shamokin Area Community Hospital, and Moses Taylor Hospital—for a total of seven facilities. Geisinger received a $2.3 million grant from the Agency for Healthcare Research and Quality (AHRQ) to extend and innovate the KeyHIE-connected community by adding additional regional hospitals, home health organizations, long-term care facilities, and physician practices. In addition to attracting more stakeholders, this 5-year AHRQ grant helped to make

Table 5.1 Health Optimum IHE profiles used

Integration profile	System/vendor	IHE actor	IHE transaction
Cross-Enterprise Document Sharing	Solinfo, Exprivia, EbitAET, Intema (Gruppo Dedalus), A-thon	Document Source	Provide And Register Document Set—b (ITI-41) Patient Identity Feed (ITI-8)
	Solinfo, Exprivia, EbitAET, Intema (Gruppo Dedalus), A-thon	Document Consumer	Registry Stored Query (ITI-18) Retrieve document set (ITI-43)
	Solinfo, Exprivia, EbitAET, Indema (Gruppo Dedalus). A-thon	Imaging Document Source	Provide and Register Imaging Document Set (RAD-54) WADO Retrieve (RAD-55)
	Solinfo, Exprivia, EbitAET, A-thon	Imaging Document Consumer	WADO Retrieve (RAD-55)
	Solinfo, Exprivia, A-thon, InsielMercato	Document Registry	Register Document Set (ITI-42) Registry Stored Query (ITI-18) Patient Identity Feed (ITI-8)
	Solinfo, Exprivia, A-thon, InsialMarcato, Intema (Gruppo Dedalus)	Document Repository	Provide and Register Imaging document Set (RAD-54) Register Document Set (ITI-42) Retrieve Document Set (ITI-43)
Notification of Document Availability	Solinfo, Exprivia. A-thon, Ebit-AET, Intema (Gruppo Dedalus)	NAV Sender NAV Receiver	Sand Notification (ITI-25) Receive Notification (ITI-26) Send Acknowledgement (ITI-27) Receive Acknowledgement (ITI-28)
Audit Trail and Node Authentication	All vendors involved	All actors	Record Audit Event
Cross Cummunity Access	Solinfo, Exprivia, A-thon, InsielMercato, Telemedicina Rizzoli	Initialing Gateway	Cross Gateway Query (ITI-38) Cross-Gateway Retrieve (ITI-39) (RAD-55)
Cross-Community Access	Solinfo, Exprivia, A-thon, InsielMercato, Telemedicina Rizzoli	Responding Gateway	(ITI-38) (ITI-39) (RAD-55)

new innovative clinical applications and create new document types to be used within the HIE.

Leveraging KeyHIE's infrastructure is an important element in this Geisinger's $16 million projects, which aims to extend the Health information technology-driven coordinated care models to more constituents and patients. New roles such as case managers can access KeyHIE for patient information and, as a result, reduce substantially the time they spend collecting important and critical patient information locked in different systems. This new online communication is a major enhancement from their current mode of communication, which occurred via fax, email, voicemail, and regular postal service.

KeyHIE's initial phase scope was to provide rapidly critical patient information to all Emergency Department (ED) teams at the point of care—providing the right information at the right time and place. The ED is usually the place where the least information is available about a patient due to the situation of the patients, and speed is a key factor in providing the best treatment in the shortest time possible. Faced with disparate EMR systems that existed in the participating hospitals' emergency departments, it was clear that point-to-point integrations were not the proper technical solution for clinical data transparency and sharing.

KeyHIE selected a large vendor to power their community Health Information Exchange. Today, KeyHIE has successfully incorporated nearly three million patients in the Master Patient Index (MPI) across all seven active hospitals. Using the new solution, KeyHIE adhered to IHE standards, which are thoroughly tested in North American Connect-a-thons.

The use of IHE helped healthcare professionals to resolve interoperability challenges and barriers. The ability to properly and securely access and exchange patient-related health data have for long, been a substantial issue to deal with. The addition of new incentives such as demonstrating compliance to "Meaningful Use' rules and regulations in the United States, and similar regulatory mandates elsewhere in the world, IHE provides a proven and practical solution to resolve health IT interoperability problems based upon the proper reuse of international standards and terminologies. The use of IHE integration profiles creates a stable collaborative environment between healthcare providers and industry leaders to improve the secure and effective exchange of patient-related health information.

5.5 Conformity Assessment Scheme: The EURO-CAS Case

The conformity Assessment Scheme for Europe (CASforEU) is a key deliverable of the European project called EURO-CAS[11] as a mean to demonstrate that ICT systems are conformed to standards and integration profiles, thus ensuring interoperability in countries and across borders.

[11] https://www.euro-cas.eu.

5.5.1 Introduction

With the finding of the lack of interoperability that introduces discrepancies among ICT systems that uses the data that are exchanging or shared, it will directly impact of the data quality and their use by the healthcare professionals. For example, a woman coming in hospital gives the married name and the maiden name for patient identification at the entrance. The demographic data are sent to the Electronic Medical Record (EMR) where the medical record is identified by the maiden name. During the workflow exchange, because the developer misinterprets the standard used for such exchanges and the names were reversed in the structured message. When the message is treated by the EMR, a new medical record is created for the women. To avoid errors, testing the conformity is the key to enhance data quality in healthcare.

Based on recommendations from the Antilope project[12] and the state of the art in interoperability testing in eHealth, CASforEU puts in place an operational Conformity Assessment Scheme (CAS) based on ISO/IEC 17067[13] and requires laboratories to be accredited to ISO/IEC 17025.[14] This enables CASforEU to demonstrate product conformance to requirements of European eHealth projects as well as national and regional eHealth programs and provides an EU-wide platform for procurers and vendors of digital health technologies to test their products or solutions.

CASforEU is defined as a sustainable conformity assessment scheme (Fig. 5.9) that consists on a consistent and uniform policy and procedures thereof are a cornerstone for such a scheme. It gives a comprehensive vision of an organization enable to run testing session for products and ICT solutions in order to provide a trusting and confident assessment report for the evaluation of the conformity.

CASforEU specifies

- The governance based on the creation of a non-profit mutual benefit organization called ECO (EURO-CAS organization) characterized by its article of incorporation, corporate bylaws, IPR policy etc. EURO-CAS is composed by members from different constituencies gathering European organization, member states and regions, Industry and accredited test laboratories.
- The mission of the organization;
- The organization that includes the General Assembly, the steering board and technical committees;
- The process of development and maintenance of the scheme;
- The execution process that involves test laboratories, vendors and their products together executing the tests as described in the CASforEU test plan;

[12] https://www.antilope-project.eu/front/index.html.

[13] ISO/IEC 17067 Conformity Assessment—Fundamentals of products certification and guidelines for product certification schemes.

[14] ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

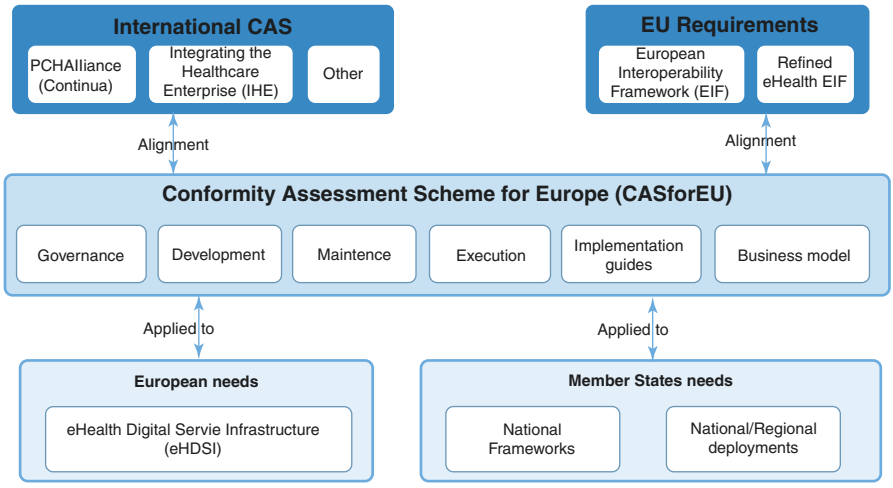

Fig. 5.9 Conformity Assessment Scheme for Europe. (From CASforEU)

- The EURO-CAS test plan that content the set of use cases, the profiles and standards and the test methodology to test product.

In addition, the implementation guidelines provide guidance for the ecosystem that allow stakeholders to implement and to be part of the conformity assessment ecosystem, for example, implementation entities (organization wanted to launch a conformity assessment for their own eHealth program or project, vendors, test laboratory, etc). The business model provides scenarios for sustaining the Euro-CAS Organisation (ECO) at the European level starting by the adoption of CASforEU by European countries (the main goal of the year 2019).

5.5.2 The Content

The CASforEU developed under the supervision of the EURO-CAS organization, is compliant with the deliveries of the international standard bodies (SDOs), which develop and specify standards in eHealth and other domains such as HL7 international,[15] DICOM,[16] IEEE,[17] W3C,[18] ISO,[19] etc) as well as international profile organizations (IHE, PCHAlliance[20]) which develop implementation guidelines. By

[15] http://www.hl7.org.

[16] Digital Imaging and Communication in Medicine: https://www.dicomstandard.org.

[17] https://www.ieee.org.

[18] https://www.w3.org.

[19] International Standard organization: https://www.iso.org/fr/home.html.

[20] Personal Connected Health Alliance: https://www.pchalliance.org.

Table 5.2 Examples of standards used for CASforEU

Level	Standards	Description
Organization and process	ISO/IEC 17065	Requirements for bodies certifying products and services
	ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
Semantic	LOINC ((Logical Observation Identifiers Names and codes)	Nomenclature providing identifiers for medical observations in laboratory
	SNOMED/CT	Codified language that represents groups of clinical terms
Application	IHE profiles	Profile organize and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards, such as DICOM, HL7, W3C and security standards
	HL7 (Health Level Seven)	standards in eHealth such as HL7v2, CDA release 2 or FHIR

this alignment CASforEU ensures continuity and recognition with the international level and benefit of the up-to-date standards. Note that these standards and profiles have a large coverage including processes, organizations, semantic and technical aspects (see Table 5.2).

At the European level, the European Interoperability Framework (eEIF) described principles that apply in Europe. All these inputs are used directly on the specifications of the EURO-CAS test plan (CASforEU CATP).

Based on the recommendations of the European Commission on a selection of 27 profiles, the test plan identifies

- The interoperability use cases;
- The profiles specifications, implementation guidelines;
- The test scripts that will be used to test the conformity of the system to the identified actors;
- The test tools mostly the simulators and validators. Most of them are developed by IHE services and used at the Connectathon or for the IHE Conformity Assessment Scheme (IHE CAS).

The CASforEU CATP provides also recommendations on

- How to extend the scope;
- How the laboratory can access to the test plans and test methods;
- The uniform templates of test reports that include detailed and summary test reports.

One of the expectations is to encourage alignment with the international level and more specifically with the IHE Conformity Assessment Scheme (IHE CAS) and the Continua Alliance certification. This is why the test plan reuses the test methods developed by those organizations for their own needs.

Table 5.3 Use cases examples

Scale	Use case	Short description
International/ Cross Border	Patient Summary exchanging across international borders	Providing medical background and history of a patient to a Healthcare Professional in another country
Cross Border	ePrescription and eDispensing exchanging across borders	To support the processes of prescription and dispensation through the electronic exchange for citizens travelling in Europe
National and regional	Discharge report of the patient from secondary care	Providing all relevant medical information of the patient to GP after a treatment in hospital
	Request and results sharing workflow for laboratory	Providing laboratory results and reports to the prescriber
	Request and results sharing workflow for radiology	Providing radiology reports to the prescriber
At home	Remote monitoring and care of people at home or on the move using sensor devices	Collecting information from devices at home to healthcare application
	Involvement of chronic patients in electronic documentation of healthcare information	Registration and monitoring of patient-generated health parameters

When the EURO-CAS organization will be set up, agreements with the IHE international CAS committee will be discussed in order to mutualize efforts for mutual recognition among the issued seals.

The test plan is the heart of the CASforEU and identifies requirements from a selection of use cases (see Table 5.3), applicable profiles and standards, test cases and test methods that are used to test products and ICT solutions.

The initial scope was validated during a meeting held in Paris in June 2017. The stakeholders (National centers of competencies, vendor associations, end-users, SDOs) select a set of profiles and standards that support use cases described on the Antilope Refined ehealth Interoperability framework and available in the use case data repository (Use case repository, see https://usecase-repository.ihe-europe.net) (Fig. 5.10).

The applicable profiles for the first version of the EURO-CAS Test Plan supporting such use cases were selected according their current deployment in several countries in Europe. They cover.

- Security aspects and more specifically confidentiality, integrity and traceability with
  - IHE CT Consistent Time
  - IHE ATNA audit Trail and Node Authentication
- Patient demographic information
  - IHE PDQ Patient Demographics Query
  - IHE PIX Patient Identifier Cross referencing
  - IHE XCPD Cross Community Patient Discovery

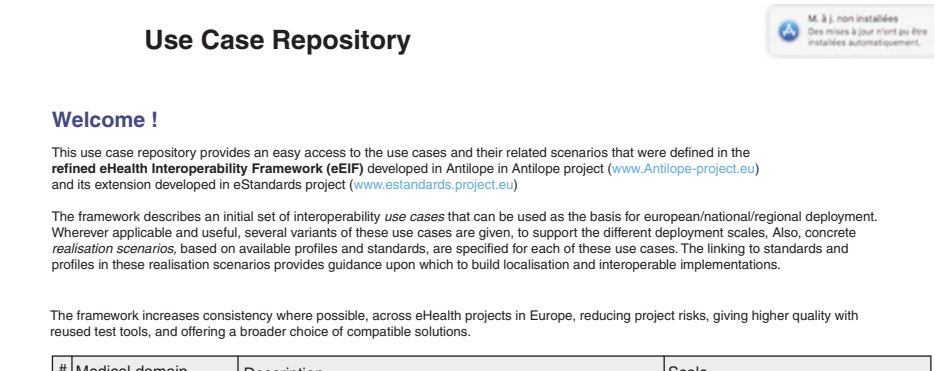

Fig. 5.10 Use case data repository

- Cross community infrastructure
  - IHE XDS.b Cross Enterprise Document Sharing
  - IHE XDR Cross Enterprise reliable Interchange
  - XDS-I.b Cross Community Imaging Sharing
  - IHE XCA Cross Community Access
- At home
  - Personal Health Devices Interface
  - Services Interface
  - Health Information System Interface

Finally, the CASforEU requests that the testing of products shall be performed by an accredited ISO/IEC 17025 test laboratory in order to increase the liability of the results of the testing and therefore increase the trust and confidence on those products having passed the conformity assessment.

The test plan was elaborated taking into account existing international conformity assessment such as IHE CAS[21] and certification process from PCHA with the objectives to align their processes for better adoption of the interoperability specifications in eHealth. The alignment covers also the use of same testing tools and test plan at the two levels, European and international to enforce closed relationships.

The next step will be the establishment of a mutual recognition between the International Conformity Assessment and the European one. It will allow any product has been assessed at the European level to be recognized as assessed for the international level for the benefit of the vendor and buyers.

[21] https://www.ihe.net/testing/conformity-assessment/.

5.6 Benefits for the eHealth Stakeholders

The benefits are presenting by categories of stakeholders *(from Euro-Cas project)*

- Healthcare Professionals and patient:
  - Having applications that are compliant on interoperability specifications and tested, will provide better quality of clinical data, for their treatment and usability by increasing confidence and trust;
  - Better time to market of innovative solutions;
  - Enhanced patient's engagement and mobility through innovative solutions;
- Vendors and IT companies:
  - Reduction of effort in interoperability testing: having one conformity assessment scheme over Europe allow vendors to sell products that integrate the European interoperability specifications in all European countries (see Fig. 5.11);
  - The investments will be redirected to innovative features;
  - Broaden market opportunities in a European Digital Single Market (and beyond);
- ehealth initiatives, policy makers, procurers, payers:
  - Provide an independent benchmark;
  - Provide reduced effort and expenses in specification and testing;
  - Conform to the European regulation.

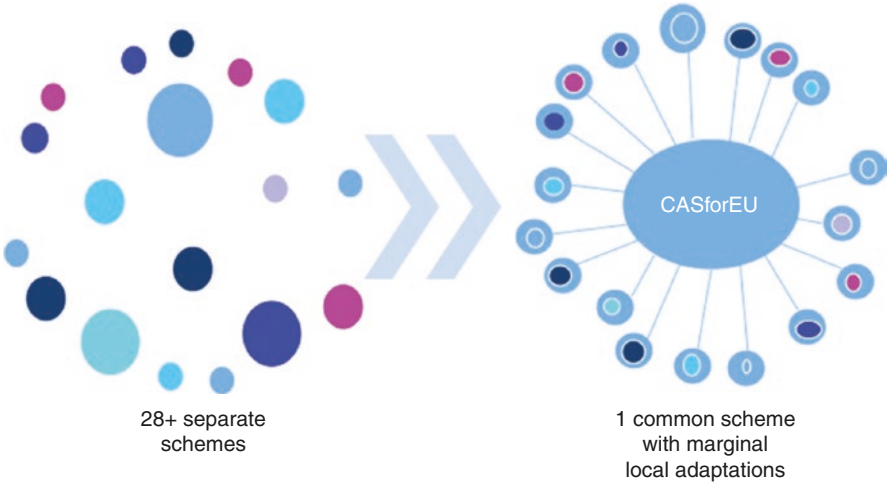

Fig. 5.11 CAsforEU in Europe. (From EURO-CAS)

5.6.1 *Certification vs Conformity Assessment*

Based on ISO 9001:2000 (or ISO 9001:2008) and ISO 14001:2004, certification could be defined as an independent accredited external body issuing written assurance (the "certificate") that has audited and verified the product or software is conformed to the specified requirements." [HITCH, 2011]. The conformity assessment demonstrates that specified requirements related to a product, process, system or body are fulfilled [ISO/IEC 17000].

EURO-CAS does not define a certification scheme but organizes the interoperability assessment of the products. This best practice identifies on one side the test laboratory that provides the assessment report and on the other side the body issuing the certificate at the European or national level.

EURO-CAS is complementary to the certification body: the validation test reports provided by the test laboratory can be sent and used by an identified certification body that will issue the certificate after review according to the requirements, with the validation test reports. Each organization has a clear role that avoids any conflict of interest. The certification body follows the policy and rules defined by the authority generally a governmental authority, seeking to submit products to certification (Fig. 5.12).

Clinical Pearls

EURO-CAS is a means to increase interoperability among products in Digital health. It gives more confidence and trust on those products implemented with profiles and standards. To facilitate the understanding of the end-users requirements to procure such products, EURO-CAS provides a set of use cases that are supported by the CASforEU test plan. A first draft was published in 2019 and will be maintained

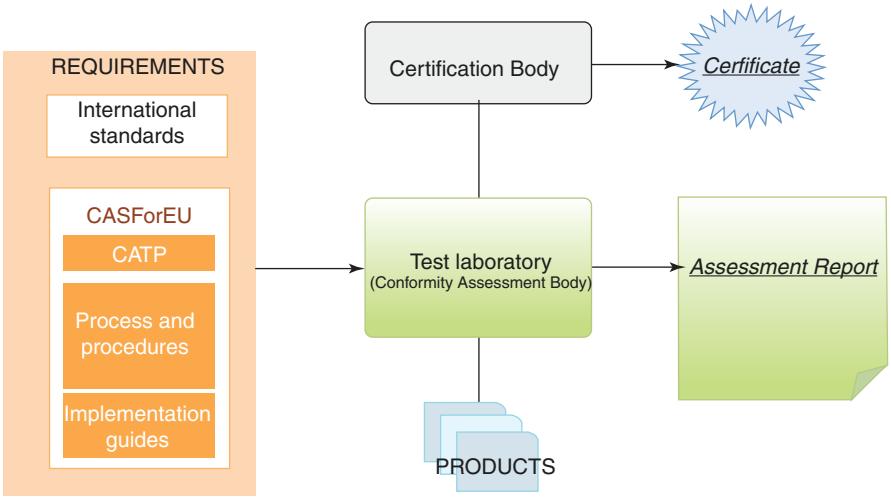

Fig. 5.12 Certification and Conformity Assessment best practices

by extending the current test plan with new use cases that healthcare professionals, authorities, vendors and other actors of the ecosystem will choose with consensus following the governance and the maintenance process.

CASforEu provides for clinicians and patients.

- More transparency when procuring or choosing healthcare products or solutions: when procurers specify the tender for specific products or solutions; at first, they will review the set of use cases available on the CASforEU test plan and select the one corresponding to their needs and secondly request for profiles, standards and their conformity validation test report according the specifications that the CASforEU covers. Finally, the vendors are able to answer to the tender with the proof of their conformity by providing their validation test report (or the certification seal if any) and when available the integration statement of their products;
- For vendors it provides solutions and a clear direction on the future development of the Digital Health allowing vendors to invest in interoperability with less risks: knowing what the interoperability demands are and what the requirements are that the products shall be compliant with, vendors are able to anticipate their development roadmap, which is often called "interoperability by design".

Acronyms

DMP: Dossier Médical Partagé (Electronic Health Record)
EHR: Electronic Health Record
GSPS: Grayscale Softcopy Presentation State
IAB: Internet Architecture Board
IEEE: IEEE Advancing Technology for Humanity
IETF: Internet engineering Taskforce
ISOC: Internet Society
MRI: Magnetic Resonance Imaging
PACS: Picture Archive and Communication System

Review Questions

1. You are working on your tender because you are building an EHR repository that will support exchanges of patient summaries among Healthcare Professionals (GPs, Hospitals, etc) in your region. Describe your use case (see examples on the use case repository: https://usecase-repository.ihe-europe.net)
2. Best practices are now available on the implementation of such an EHR repository. Analyze them and identify the main profiles that are implemented. What do those profiles cover in terms of functionalities?
3. Many of the projects presented in this chapter agreed that testing the conformity to profiles is one of the key elements for the success of the project. What are the main testing tools which are needed for your project (see https://gazelle.ihe.net/content/gazelle-user-guides)?
4. How can you compare products that will be offered by various vendors, what can you include in your tender as a means of validation. Explain why this appraoch will provide more confidence to the products that will be selected.

Answers

1. Use the template provided by the Antilope project. Example is given in the use case repository
   The sections to be filled are

   (a) Purpose: describe in one sentence the use case
   (b) Relevance: why this use case has to be deployed in your environment
   (c) Domain: Patient Summary
   (d) Scale: regional
   (e) Context: describe with sentences your use case, ecosystem and context. It will allow any end-user the functional requirements of the use case for validation
   (f) Information: provide the set of data needed to realize the use case (for example, Patient demographics, patient identifier, allergies, current prescription medication, etc)
   (g) Participants: Patient, GPs, other HCPs
   (h) The functional process workflow: describe the interaction between human actors using systems, for example the GP is requesting the last patient summary for his patient that was admitted at the emergency setting of the regional hospital

2. Examples provided in this paper demonstrates that this use case is currently broadly deployed in many countries. A common set of profiles are used in various projects over the world. See for example Table 5.1.

   In synthesis, the main profiles are CT, ATNA, XDS, EUA, PIX and PDQ and CDA r2 for structuring the documents. Terminology should be chosen by clinicians. In the case of cross community, XUA and XCA are also used. The profile XDS (Cross Border Document Sharing) manages the exchange of documents between Healthcare organization. ATNA (Audit Trail Node Authentication) defines security audit logging and secured network. PIX (Patient identification Cross Referencing) provides the means to cross identify a patient. PDQ (Patient demographics Query) allows queries by patient demographics. The EUA profile enables single sign-on inside an enterprise. See https://wiki.ihe.net/index.php/Profiles for more information.
3. The testing tools that can be used are (list non exhaustive). More information at https://gazelle.ihe.net/content/gazelle-user-guides

Type	Testing tool	Description
Validators	Gazelle External Validation Front-end (EVS)	To allow the user to use a user-friendly interface to access to validator
	HL7 Validator	Web services to validate HL7v2 and HL7v3 messages exchanged in the IHE context
	Schematron based validator	Web service to validate xml documents
	Gazelle Object checker	Web service to validate a large set of CDA documents using a model-based architecture
	XDS metadata validator	Web service to validate metadata of XD* profiles
Simulators	Patient Manager	Emulates actors for PIX/PDQ
	XD* Client	Emulates the initiating actors of XD* profiles

4. An organization which provides a Scheme on conformity validation will maintain
   (a) A test plan that users can refer to in their tender;
   (b) A public website where products having passed the conformity assessment and will be available (see for example https://conformity.ihe.net/summary-reports for IHE CAS);
   (c) A list of accredited test laboratories enables users to test products against the test plan in a neutral and rigorous environment.

   It will allow procurers to have a better overview on the interoperability functionalities and capabilities of the products (more transparency) with confidence and it provides an easy way to compare products. In counterparty, the procurer and his team should maintain their skills on interoperability architecture and IHE specifications to better address their needs.

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Glossary

CDA Clinical Documentation Architecture
CEN European Standards Organisation
Conformance The level of adherance to an agreed rule or standard
Connectathons Planned events by IHE to test new implementations
DICOM Digital Imaging and Communications in Medicine
DMP Dossier Médical Partagé (Electronic Health Record)
EHR Electronic Health Record
epSOS European Patients—Smart Open Service
European Interoperability Framework Four layers of interoperability (Foundational, structural, semantic, and organizational) are the foundation of the framework
FRAND FAIR, Reasonable and Non-Discriminatory
GSPS Grayscale Softcopy Presentation State
HIE Health Information Exchange
HIT Health Information Technology
HL7 Health Level Seven
HPD Healthcare provider directory
IAB Internet Architecture Board
IEEE IEEE Advancing Technology for Humanity
IETF Internet engineering Taskforce
IHE Integrating the Healthcare Enterprise

ISA Interoperability Standards Advisory
ISO International Organization for Standardization
ISOC Internet Society
LOINC Logical Observation Identifiers Names and Codes
Mandation A term that groups categories of mandatory, condition, or optional
Metadata Information that provide facts about one or more aspects of a data element
MPI Master Patient Index
MRI Magnetic Resonance Imaging
OASIS Organization for the Advancement of Structured Information Standards
PACS Picture Archive and Communication System
PCC Patient Care Co-ordination
Projectathon Projectathon, when deploying IHE profiles at the project level, the IHE Gazelle test platform is used at the Projectathon which is a type of Connectathon but dedicated to the specifications-based profiles of the eHealth project. The Projectathon has the same role as the Connectathon: it provides support, training and expertise to vendors that are selected for the project deployment
SDO Standards Development Organisation
Standard A rule that enables consistent and repeatable use, performance, and outcomes
Use Case An integration profile used as a guideline for implementation of a specific process called use case. The use case provides precise definitions of how standards can be implemented to meet specific clinical needs for a specific purpose. For example, integration profiles organize and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards, such as DICOM, HL7, W3C and security standards in Digital Health
VA United States Department of Veteran Affairs
W3C World Wide Web Consortium
XCPD Cross community patient discovery

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