Integrating the Healthcare Enterprise

IHE International

IHE Certified Professional Program (IHE-CPP)

IHE Foundations Exam - Syllabus

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Date: March 27, 2019
Author: IHE Education Committee
Email: ihe-edu@ihe.net

Foreword

This is the Syllabus for the

30 **IHE Foundations Exam**,

being part of the

IHE Certified Professional Program (IHE-CPP)

under the governance of the IHE Education Committee.

35 Together with the *IHE Certified Professional (IHE-CPP) – Process Definition* and the *IHE Foundations Exam* it constitutes the scheme for the

IHE Certified Professional – IHE Foundations

certification.

40 General information about IHE can be found at: www.ihe.net.

Information about the IHE Education Committee domain can be found at: https://wiki.ihe.net/index.php/IHE_Education_Committee.

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1 Introduction

This document, the IHE Certified Professional Program (IHE-CPP) Foundation Level Exam - Syllabus describes the foundation level of the certification "IHE Certified Professional" established by the Integrating the Healthcare Enterprise (IHE).

135 The purpose of this syllabus is twofold:

- It provides Training Providers with the basis for creating their course materials.

- It allows Students to prepare themselves for the examination.

The IHE-CPP is sponsored by IHE International and operates under the IHE-CPP Scheme which is defined in a companion document. It is expected in the future that other Exam Syllabus may
140 be added under the same IHE-CPP Scheme.

1.1 Purpose of the IHE Foundations Exam - Syllabus

This syllabus is designed to ensure a fair and impartial understanding between the instructor and students, setting clear expectations of material to be learned, and providing a roadmap of course organization/direction. It provides a marketing angle of the exam such that students may choose
145 this exam and whether the subject material is relevant to their professional activities.

This syllabus also contains a reading list of relevant material that expected to be familiar or professional taking this examination.

1.2 Intended Audience and prerequisite skills for the IHE-CPP Foundation exam

150 The intended audience is a person with a health IT background with a requirement or an intention to use products based on IHE profiles, either someone (contracted) to work for a healthcare provider organization, or someone employed by a software development company.

A competent IHE Certified Professional - IHE Foundations will be able to apply the IHE methodology (ISO/TR 28380) for developing interoperability specifications for an existing
155 healthcare environment. He or she will have the skills to identify and use the appropriate existing IHE profiles when faced with a healthcare interoperability project.

1.3 Educational Objectives / Cognitive Knowledge Levels

Each module of the syllabus is assigned a cognitive level. A higher level includes the lower levels. The formulations of the educational objectives are phrased using the verbs "knowing" for
160 level L1 and "mastering and using" for level L2. These two verbs are placeholders for the following verbs:

- L1 (knowing): enumerate, characterize, recognize, name, reflect

- L2 (mastering and using): analyze, use, execute, justify, describe, judge, display, design, develop, complete, explain, exemplify, elicit, formulate, identify, interpret, conclude
165   from, assign, differentiate, compare, understand, suggest, summarize!

All terms defined in the glossary have to be known (L1), even if they are not explicitly mentioned in the educational objectives.

1.4 Structure of the Syllabus

170 The syllabus consists of 5 main chapters. Each main chapter title contains the cognitive level of the chapter, which is the highest level of the sub-chapters. Furthermore, the teaching time is suggested that is the minimum a course should invest for that chapter. Important terms in the chapter, which are defined in the glossary, are listed at the beginning of the chapter.

The main chapters are:

- A_Org   Orientation on the IHE organisation
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- B_Meth   IHE Methodology
- C_Res   Locate and navigate through IHE resources
- D_Tec   IHE Example profiles, base standards, general healthcare IT knowledge
- E_Depl   Accelerate Health Information Exchange deployment

1.5 The Exam

180 This syllabus is the basis for the examination for the IHE-CPP Foundation Level Exam. A question in the exam can cover material from several chapters of the syllabus. All chapters of the syllabus can be examined. The format of the exam is a multiple-choice. Exams can be held immediately after a training course, but also independently from courses (e.g. in an examination center).

2 Content

2.1 A_Org: Orientation on the IHE organisation

Duration: 1,5 hours

Terms: Glossary IHE Board, IHE Deployment, member model vendor, user, ..

IHE is an organisation of volunteers, who cooperate to integrate IT systems in the healthcare enterprise. In order to engage in IHE one must understand the organisational structure and the tasks that each unit performs. The international committees maintain IHE as an organisation, taking care of management, processes and finance. The IHE Domain committees plan and develop the IHE technical frameworks and profiles. In all committees both users and vendors shall be represented, to balance the influence of these important groups. In order to take part in a committee, a person must be a member of IHE international, according to the IHE membership model.

Learning Outcomes
- A_Org-01: Understand IHE's vision and mission

- A_Org-02 IHE structure and governance: International Committees (e.g. Intl. Board, Global Deployment Coordination Committee, Conformity Assessment Coordination Committee)

- A_Org-03 IHE structure and governance: list of IHE Domains and their scope

- A_Org-04 IHE structure and governance: Planning- and Technical Committees and division of responsibilities

- A_Org-05 IHE structure and governance: National or Regional Deployment Committees

- A_Org-06 Understand the roles of users and vendors in the organization

- A_Org-07 Understand the membership model of IHE International

- A_Org-08 Understand the IP model surrounding IHE's body of work: Profiles & Technical Frameworks, Whitepapers, Education material

     A_Org-09 Understand the IP model surrounding IHE's body of work: Testing tools and plans, Gazelle

2.1.1 A_Org-01: Understand IHE's vision and mission (L1)

The IHE website provides a summary of IHEs vision and mission, in the "About IHE" area (https://www.ihe.net/about_ihe/):

"IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively."

It is also part of IHE's vision to "enable seamless and secure access to health information that is
220 usable whenever and wherever needed."

IHE's summarised mission according to the homepage is: "IHE improves healthcare by
providing specifications, tools and services for interoperability. IHE engages clinicians, health
authorities, industry, and users to develop, test, and implement standards-based solutions to vital
health information needs."

225 IHE's mission is described in more detail in the IHE Principles of Government
(https://www.ihe.net/wp-content/uploads/2018/07/IHE-International-Principles-of-
Governance.pdf , Section 2 – Mission)

2.1.2 A_Org-02   IHE structure and governance: International Committees (e.g. Intl. Board, Global Deployment Coordination Committee, Conformity
230 Assessment Coordination Committee) (L1)

As described in the IHE Principles of Governance, IHE runs "Development activities" and
"Deployment activities", while it also maintains and develops itself as an organisation. To
coordinate these efforts, a number of IHE International Committees are in place, see the IHE
Principles of Governance. Details on the current scope of these committees, agendas and
235 minutes, are available on the IHE Wiki, at https://wiki.ihe.net/index.php/Committees, including
the information listed here :

- IHE International Board
- Domain Coordination Committee (DCC)
- Testing and Tools Committee
240 - Conformity Assessment Committee (CAsC)
- Marketing and Communications Committee
- Global Deployment Coordination Committee (GDC)
- IHE Education Committee (Professional Certification)

As a detailed reference for further reading see the IHE Principles of Governance
245 https://www.ihe.net/wp-content/uploads/2018/07/IHE-International-Principles-of-
Governance.pdf

2.1.3 A_Org-03   IHE structure and governance: list of IHE Domains and their scope (L1)

250 Within the IHE Development activities the IHE Domains are responsible for the development
and maintenance of the IHE Technical Frameworks, that document the Profiles. Each Domain
manages Profiles in a particular sector of healthcare. IHE Member organisations can nominate
persons to participate and engage in the IHE Domains. A list of current IHE domains is available
e.g. at the IHE website and at the IHE Wiki:

255 IHE Cardiology (CARD)

IHE Dental (DENT)

IHE Endoscopy (ENDO)

IHE Eye Care (EYECARE)

IHE IT Infrastructure (ITI)

260 IHE Pathology and Laboratory Medicine (PaLM)

IHE Patient Care Coordination (PCC)

IHE Patient Care Device (PCD)

IHE Pharmacy (PHARM)

IHE Quality, Research and Public Health (QRPH)

265 IHE Radiation Oncology (RO)

IHE Radiology (RAD)

The IHE FTP space (http://ftp.ihe.net) also has sub-folders for material from each domain.

See governance document for more detailed information about membership and engagement in
270 the IHE Domains: https://www.ihe.net/wp-content/uploads/2018/07/IHE-International-Principles-of-Governance.pdf

2.1.4 A_Org-04   IHE structure and governance: Planning- and Technical Committees and division of responsibilities (L1)

For the IHE Development Activities, each IHE domain has a Planning Committee and a
275 Technical Committee. The IHE Wiki provides an entry point to the work of the Planning and
Technical Committees at https://wiki.ihe.net/index.php/Domains. This for example describes the
tasks as follows:

The Planning Committee for a domain:
- Recruits vendors of relevant information systems and users with clinical and operational
280   experience
- Develops long-term goals and roadmap
- Identifies integration and information sharing problems and priorities
- Gathers and reviews proposals for new problems/profiles.
- Selects proposals for technical/effort evaluation by the Technical Committee
285 - Approves proposals for Profile development by the Technical Committee
- Develops educational materials for the domain and profiles

The Technical Committee for a domain:
- Recruits vendors of relevant information systems and users with clinical and operational
  experience

290   • Assesses the feasibility and estimated effort of selected profile proposals

- Builds consensus on the appropriate standards-based solutions to approved proposals

- Develops Profiles to document the solutions in detail

- Maintains the Technical Framework for the domain

2.1.5 A_Org-05   IHE structure and governance: National or Regional Deployment Committees (L1)

Within the IHE Deployment activities, IHE Regional Deployment Committees and IHE National Deployment Committees are responsible for promotion and deployment of the IHE Technical Frameworks that document the Profiles. Regional Deployment Committees (e.g. Europe, North America)are open to participation by any National Deployment Committee within that region.

As part of their mission, National and Regional Deployment Committees may conduct IHE Connectathon events for their country or region.

Technical development of the Profiles is handled globally by the IHE Domains, and not by the Deployment Committees! However, the Deployment Committees are a very valuable element of the global IHE community, in that they openly welcome and support individuals and organisations in many ways. Exactly this community of organisations and individuals constitutes a large value provided by IHE. This community cooperates globally to define and resolve real world interoperability issues.

As one entry point, each Deployment Committee provides a yearly "IHE Deployment Committee Report" to the IHE International Board. These reports provide a summary of the activities in the region, including contact persons and events. This enables newcomers to quickly engage, benefit and participate in IHE activities. The reports are available via the IHE Wiki at https://wiki.ihe.net/index.php/IHE_Deployment_Committee_Reports. They can also be reached via the IHE homepage at https://www.ihe.net/ihe_worldwide/. The generation and maintenance of these reports is managed by the IHE International Board.

2.1.6 A_Org-06   Understand the roles of users and vendors in the organization (L1)

The IHE principles of governance (https://www.ihe.net/wp-content/uploads/2018/07/IHE-International-Principles-of-Governance.pdf, section 12, Selected Definitions) provide definitions for "Users" and "Developers", where Developers are also frequently termed as vendors:

- User: A Member Organization that is (and/or whose members are) actively involved in using healthcare information technology systems.   The term User should be understood broadly as it include health professionals, healthcare providing organizations, governmental authorities, national or regional ehealth deployment centers, research institutions, etc.

- Developer: A Member Organization that is actively involved in the development of healthcare information technology systems.

330 Section 10.1.3. "Membership Interest Categories" in the principles of governance describes how IHE assures that any stakeholder has the opportunity for fair and equitable participation without dominance by any single interest. Each IHE International member must choose a single affiliation to one membership interest category, "User", "Developer" or "General Interest". IHE Committees may choose to establish membership rules or voting procedures based on interest categories. The IHE International board for example must have two co-chairs, both from the
335 User interest category.

In the IHE process, users and developers (vendors) both contribute to interoperability from their specific viewpoints.
- Users define and select interoperability challenges, which have arisen in daily clinical work
340   o These are captured carefully in the form of written use cases
- Vendors then define technical specifications in the form of " Profiles", which provide a solution to the interoperability challenges defined by the users.
     o Vendors then build software that implements these profiles, test them e.g. at IHE Connectathons, and finally make conformant products available to users

345 The roles of users and vendors are a core element of the work of IHE. They are described in more detail the IHE Europe Frequently Asked Questions https://www.ihe-europe.net/about-us/faq, see for example the answers to the following questions:
- How does the IHE process work?
- What is the role of users?
350 - How does IHE support the discussion between users and vendors?

See for example the IHE IT Infrastructure Technical Framework, Volume 1 (ITI TF-1). Section 10 - Integration Profiles Cross - Enterprise Document Sharing (XDS.b), describes document sharing from a user perspective, in a language that can be understood by all stakeholders. The other volumes of the ITI TF then describe how interoperability shall be ensured in all necessary
355 technical detail, from a developer perspective.

2.1.7 A_Org-07   Understand the membership model of IHE International (L1)

The IHE International principles of governance (https://www.ihe.net/wp-content/uploads/2018/07/IHE-International-Principles-of-Governance.pdf, Section 10. General
360 Membership Procedures) include rules on memberships and participation in IHE International Committees. IHE International is composed of Member Organizations, there is no individual membership. Each member organisation names one single principal voting representative to each IHE International Committee on which it wishes to be represented.

365 IHE Regional Deployment Committees and IHE National Deployment Committees are affiliates of IHE International, empowered by the IHE Board to conduct testing, demonstrations and other deployment activities within their geographic areas. Regional and National Deployment Committees operate as distinct organizations, developing their own governance rules and business models, but report to and participate in the IHE Board.

370 A member organisation of a Regional or National Deployment Committee is not automatically a member of IHE International. This is relevant for participation, as only IHE International Member Organisations have voting rights in IHE International committees.

2.1.8 A_Org-08   Understand the IP model surrounding IHE's body of work: Profiles & Technical Frameworks, Whitepapers, Education material (L1)

375 The intellectual property policies of IHE International are described fully in Appendix A of the IHE International Principles of Governance. These policies include a Patent Disclosure duty for IHE Member Organizations (section A.3, https://www.ihe.net/Patent_Disclosure_Process/). Each IHE member organisation has to agree to these policies.

The Appendix A clearly states: "IHE International hereby grants to each Member Organization,
380 and to any other user of these documents, an irrevocable, worldwide, perpetual, royalty-free, nontransferable, nonexclusive, non-sublicensable license under its copyrights in any IHE Profiles and Technical Framework documents, as well as any additional copyrighted materials that will be owned by IHE International and will be made available for use by Member Organizations, to reproduce and distribute (in any and all print, electronic or other means of reproduction, storage
385 or transmission) such IHE Technical Documents."

It is a very important commitment of IHE, to make all its materials available and free to use by the general public.

The intellectual property rights of the base standards used in IHE profiles however remain with the standards development organizations who developed them.

390 The goal of the Patent Disclosure duty is to assure that any licensing issues for IHE profiles are identified during the development of the profiles. The IHE Patent Disclosure policy assures that IHE Profiles can be used under reasonable and non-discriminatory terms by developers and users of products and deployment projects that refer to these IHE profiles.

395 ### 2.1.9 A_Org-09   Understand the IP model surrounding IHE's body of work: Testing tools and plans, Gazelle (L1)

In addition to the IHE Technical Frameworks, IHE also provides test plans and test tools to support interoperability testing of software, to assess if that software supports IHE profiles. Similar to the IHE Technical Frameworks, IHE targets to make these test tools and plans
400 available under reasonable and non-discriminatory terms to users and developers, and to the general public.

The licensing information for the test tools from the Gazelle projects is available at https://gazelle.ihe.net/content/license. This states: "The Apache License Version 2.0 applies to all released components of the IHE Gazelle projects."

405 The licensing information for test plans is available at https://www.ihe.net/wp-content/uploads/2018/08/LICENSE-AGREEMENT-AND-TERMS-OF-USE.pdf . This states that applies to the IHE interoperability Test Plans for their use.

The base standards that are referenced in IHE Technical Frameworks have their own IP policies. They are therefore not the subject of IHE IP.

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2.2 B_Meth: IHE Methodology

Duration: 10h

Terms: IHE Technical Frameworks, Profiles, Actors, Transactions, IHE Annual Cycle, Final Text, Trial Implementation, Connectathon, Monitor, Testing, Conformity Assessment, Product

415 Integration Statement

IHE development activities are organized in domains. Each domain is covered by a Technical Framework specifying several Profiles, which organize and leverage the integration of health-related information by coordinated implementation of communication standards, as described in the IHE Wiki at https://wiki.ihe.net/index.php/Domains. See also in the IHE Europe Frequently

420 Asked Questions https://www.ihe-europe.net/about-us/faq: "How does the IHE process work?"

A Technical Framework is composed of a set of documents, which are annually reviewed and published by technical committees according the annual cycles of IHE. New or adapted/corrected profiles are published or republished for trial implementation according to the IHE testing processes. In case of meeting successful testing criteria, the profile is then published

425 as final text and integrated in the domain's technical framework. IHE provides a structured process of testing for vendors adopting IHE profiles in their products or ganized around the Connectathon and Conformity ASsessment. The Connectathon is a testing event for coordinated no-peer and peer-to-peer testing for vendors implementing IHE profiles in their products to enable adoption of standards-based interoperability. Monitors are technical IHE-recruited

430 specialists observing and evaluating the performed tests under the oversight of of the IHE test management. After successful testing at the Connectathon, a vendor becomes listed in the official Connectrathon results database for the profiles actors' combinations successfully tested.

Vendors are also offered the ability to register an IHE Integration Statement for one or more versions of its software product, for which the vendor claims implementation of one or more IHE

435 profiles.For buyers that may not trust the claims made by the vendors for a specific product version, IHE International offers a world-wide recognized Conformity Assessment Test Report. IHE Authorized Testing Laboratories (accredited according to ISO/CEI 17025) can assess the conformity of vendors' products with selected IHE profiles and generate a formal test reports.

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Learning Outcomes
- B_Meth-01 Understand the main concepts and document structure of IHE Profiles (actors, transactions…) and IHE Technical Frameworks
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- B_Meth-02 Understand the annual cycle of IHE Domains and the processes to develop IHE profiles: Profile proposal
- B_Meth-03 Profiles in Public comment or Trial implementation phase and their expression in supplements
- B_Meth-04 Understand the annual cycle of IHE Domains and the processes to develop IHE profiles: Profiles in Final text phase and their incorporation in Technical Frameworks
450
- B_Meth-05 Understand the annual cycle of IHE Domains and the processes to develop IHE profiles: Change proposal / maintenance
- B_Meth-06 Understand an IHE Connectathon: Understand the purpose of a Connectathon
- B_Meth-07 Understand an IHE Connectathon: Understand the process and tooling of a Connectathon from a tester perspective
455
- B_Meth-08 Understand an IHE Connectathon: Understand the role of a Connectathon "monitor"
- B_Meth-09 Understand an IHE Connectathon: Understand the different types of testing performed at a Connectathon (Peer-to-peer, etc.)
- B_Meth-10 Understand and generate integration statements
460
- B_Meth-11 Understand and explain IHE Conformity Assessment
- B_Meth-12 Understand how to implement IHE profiles – Use case driven approach

2.2.1 B_Meth-01   Understand the main concepts and document structure of IHE Profiles (actors, transactions…) and IHE Technical Frameworks (L2)

IHE Profiles describe specific solutions to integration problems. A profile documents how
465   standards will be used by each system's Actors to cooperate in exchanging standards-based information to address the problem. A general introduction to the content of IHE profiles is available on the IHE Homepage on the IHE Technical Frameworks page under "General Introduction and Shared Appendices" (https://www.ihe.net/resources/technical_frameworks/#GenIntro).

470   The Technical Framework for each domain consists of several volumes:
- Volume 1 provides high-level overviews of each profile, the use cases it addresses, the actors involved, and references to the Transactions and Content Modules used.
- Volume 2 provides detailed technical descriptions of each IHE Transaction.
- Volume 3 provides detailed technical descriptions of each IHE Content Module.

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- Volume 4 describes National Extensions to the Technical Framework such as country specific code sets or national patient privacy requirements.

As volumes are expanded, they may be divided for maintainability into sub-volumes, such as 2a, 2b, and 2x.

See the IHE Europe Frequently Asked Questions https://www.ihe-europe.net/about-us/faq, the
480 question "How does the IHE process work?" summarises the process used for IHE Development activities. See also the answer to the question "What is the content of a 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
485 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.
490 provide a summary, a clinical diagnosis report, etc.)."

See further explanations about IHE profiles at https://wiki.ihe.net/index.php/Profiles. More detailed guidance for profile developers is available at https://wiki.ihe.net/index.php/IHE_Profile_Design_Principles_and_Conventions

More information about actors is available in the IHE Wiki at
495 https://wiki.ihe.net/index.php/Actors. This points to the IHE shared "Appendix A: Actors" (https://www.ihe.net/uploadedFiles/Documents/Templates/IHE_TF_GenIntro_AppA_Actors_Rev2.0_2018-03-09.pdf) which defines Actors as "information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise." The annex also provides a list of all current IHE actor definitions. It
500 is therefore updated regularly.

Similarly, the "Appendix B: Transactions" is part of the general introduction to the content of IHE profiles, see the IHE Homepage on the Technical Frameworks page under "General Introduction and Shared Appendices" (https://www.ihe.net/resources/technical_frameworks/#GenIntro). This list is also updated
505 regularly.

2.2.2 B_Meth-02 Understand the annual cycle of IHE Domains and the processes to develop IHE profiles: Profile proposal (L1)

The IHE Europe Frequently Asked Questions https://www.ihe-europe.net/about-us/faq: "How
510 does the IHE process work?" summarises the processes of IHE Development and Deployment. A more detailed description is available in the IHE Wiki (https://wiki.ihe.net/index.php/Process).

This includes the following steps:
- Announce Call for Profile Proposals

o The call goes out to IHE Domains Planning and Technical Committees, Domain

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Coordination Committee, and Regional and National IHE Initiatives.

- Select Short List
    - o Submitter prepares a Brief Proposal
    - o Planning Committee reviews and selects a short-list of proposals
- Perform Technical Evaluation

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    - o Submitter provides a Detailed Proposal to Planning Committee, which forwards to the Technical Committee
    - o Technical Committee evaluates, and returns to Planning Committee
- Final Profile Selection
    - o By the Planning Committee

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An overview flow chart is available on the IHE Wiki (https://wiki.ihe.net/images/d/dc/NewSupplPubProcess.pdf).
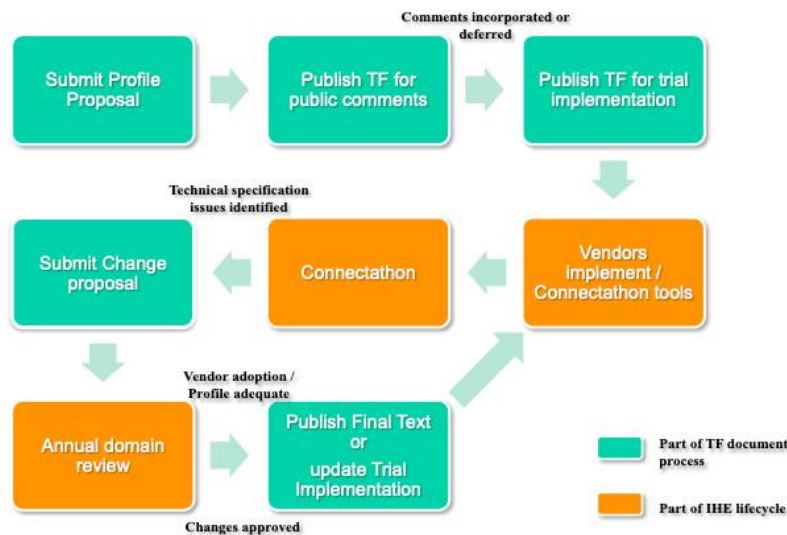
2.2.3 B_Meth-03 Profiles in Public comment or Trial implementation phase and
530 ### their expression in supplements (L1)

Once the decision has been taken to develop a profile, this then passes a series of steps, as described in the IHE Wiki:
https://wiki.ihe.net/index.php/Profile_Development_Process_for_First_Timers.

Three meetings of the Technical Committee (and optional tcons) will get the profile from
535 Proposal to Trial Implementation status.

- Kickoff Meeting (early-Novemberish)
    - o Uses a skeleton profile document to start the discussion

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- o Results in a complete idea of how you're going to draft all the text for public comment

540 - • Public Comment Preparation Meeting (Januaryish)
  - o Starts on a draft Public Comment version of the document
  - o Considers if all parts are available, not necessarily final
  - o Open Issues are clearly listed
  - o Results in a version ready to publish for Public Comment

545 - • Trial Implementation Preparation Meeting (Late March/Early Aprilish)
  - o Starts with a draft Trial Implementation version, and a consolidated list of the received comments with resolutions
  - o Committee reviews in detail and votes
  - o Results in a version ready to publish for Trial Implementation

550 IHE Technical Framework Documents for Public Comment are published on the IHE hompage at https://www.ihe.net/resources/public_comment/.

An overview flow chart is available on the IHE Wiki (https://wiki.ihe.net/images/d/dc/NewSupplPubProcess.pdf).
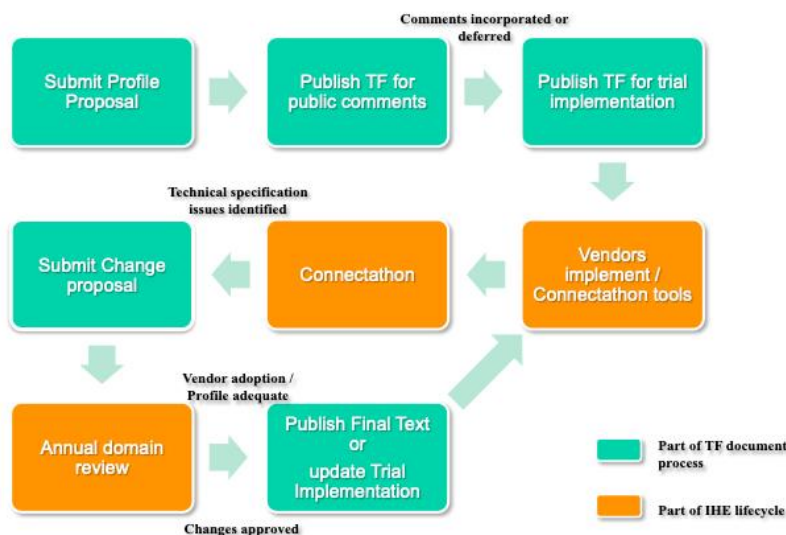
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2.2.4 B_Meth-04 Understand the annual cycle of IHE Domains and the processes to develop IHE profiles: Profiles in Final text phase and their incorporation in Technical Frameworks (L1)

The IHE Technical Frameworks page provides all IHE profiles that are in Final Text and Trial
560 Implementation status. These profiles may already be integrated into the applicable Technical Framework documents, or still be available in the form of Supplements for Trial Implementation.

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Supplements for Trial Implementation still combine content into one single document that is only later distributed among the different volumes of the applicable Technical Framework documents.

565   It is important to note that as soon as a Change Proposal becomes Final Text, it carries the same weight as published Technical Frameworks and Trial Implementation Supplements (i.e., it is 'testable' at a Connectathon from the time it is approved for Final Text, even if it will not be integrated into the applicable Technical Framework document until several months later.

The Technical Committee of a Domain performs an assessment of the trial implementation
570   supplement, using the established criteria for profile maturity and decides whether to move it to final text. Concretely, a supplement in TI becomes Final Text after testing in three Connectathons without any new significant change proposal.

2.2.5 B_Meth-05   Understand the annual cycle of IHE Domains and the
575   **processes to develop IHE profiles: Change proposal / maintenance (L1)**

Change Proposals (CPs) are the way stable, published technical documents (Final Text Profiles in Technical Framework volumes, or Supplements in Trial Implementation) can be modified. Change Proposals may be submitted by users, vendors or Technical Committee members, and usually result from experiences implementing Profiles, deploying and using Profiles or testing
580   them at Connectathons.

CPs are considered by the Technical Committee of the IHE Domain. They are assigned one of the following statuses:

- Rejected
    - CP is rejected by the Technical Committee and will not be assigned, e.g. because
585   this is an inappropriate or duplicate change
- Assigned
    - A member of the Technical Committee further investigates the CP with the goal
        to produce adequate clarifications or corrections
- Cancelled
590   - After investigation by the Technical Committee the CP will not be completed
- Completed
    - The CP is completed by the Technical Committee, and published
        - for public comment, and
        - for letter ballot by Domain Technical Committee members
595 - Final Text
    - CP has passed letter ballot and the comments resolved to the satisfaction of the
        Technical Committee.
- Incorporated

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   o CP has been folded into an updated version of a Technical Framework or Supplement

2.2.6 B_Meth-06   Understand an IHE Connectathon: Understand the purpose of a Connectathon (L1)

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The IHE homepage describes the purpose and methods of IHE Connectathons (https://www.ihe.net/participate/connectathon/):

IHE Connectathons provide a detailed implementation and testing process to enable the adoption of standards-based interoperability by vendors and users of healthcare information systems. During a Connectathon systems exchange information with corresponding systems in a structured and supervised peer-to-peer testing environment, performing transactions required for the roles (IHE actors) they have selected to perform in carefully defined interoperability use cases (IHE profiles).

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Connectathons are held annually in Asia, Europe and North America. Thousands of vendor-to-vendor connections are tested each year. The results of testing are published in the Connectathon Results Database.

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The Connectathon provides detailed validation of the participants' interoperability and compliance with IHE profiles. Participating companies prepare for the event using either testing software developed for this purpose or release commercial software. Connectathons offer vendors a unique opportunity for connectivity testing, removing barriers to integration that would otherwise often need to be addressed on site, at the customer's expense. Companies taking part have responded overwhelmingly that the IHE process addresses important issues in their product development plans."

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The IHE test management platform Gazelle provides more detail (https://gazelle.ihe.net/) and links to training material and further resources.

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2.2.7 B_Meth-07   Understand an IHE Connectathon: Understand the process and tooling of a Connectathon from a tester perspective (L1)

The IHE 2019 Connectathon White Paper describes the Connectathon in summary (https://www.ihe-europe.net/sites/default/files/WP_Connectathon_2019_0.pdf). The IHE test management platform Gazelle provides more detail (https://gazelle.ihe.net/).

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The IHE Europe Connectathon General Training resource provides guidance for the necessary steps (https://gazelle.ihe-europe.net/training#GenlTraining):

- Registration for a Connectathon
  - o managing gazelle user accounts (logins) & company/organization details, entering contact information

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   o System registration

- - - ▪ entering system(s), profiles, actors, and options you want to test
    - o Connectathon contract
      - ▪ how to generate your connectathon contract
    - o Participant registration
640 - - ▪ register staff who will attend
  - • Perform Pre-Connectathon tests & submit results
  - • Share samples with your test partners
    - o (eg documents, images) and perform sample validation
  - • Enter and share your configuration parameters
645 - • Perform and review Connectathon tests
  - • Report the results on the official Connectathon Results database. Browse at: https://connectathon-results.ihe.net
    - o This database allows to find which profiles and actors have been successfully tested, either by vendor, Connectathon event, or overall.

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2.2.8 B_Meth-08   Understand an IHE Connectathon: Understand the role of a Connectathon "monitor" (L1)

The IHE 2019 Connectathon White Paper describes the role of Monitors (https://www.ihe-europe.net/sites/default/files/WP_Connectathon_2019_0.pdf):

655 During the Connectathon, testing is performed using the Gazelle Test Bed. The tool enables to log evidences of the tests performed. Participants are free to run the test at their own pace. When they finished a test, they mark it as ready for checking by the Monitors. Monitors, who are subject-matter experts, then verify each test.

There needs to be a sufficient number of monitors to cover the scope of testing at the
660 Connectathon in terms of profiles and systems under test. Whilst the Monitors are there to help, they are also totally independent and objective in their decisions. Ultimately, they have to carry out testing checks that are a pass or a fail. Monitors are assigned to tests based on their own competencies and skill set. Vendors have to convince them that the work they are effectively grading is soundly based; successful vendors will always have their logs ready to run, replay and
665 replay again if necessary.

The Monitors are not looking to fail anyone, and the "help-each-other-mentality and stay-until-it-works-mentality" are paramount amongst those present. After all, problems one vendor may experience today may invariably arise for another vendor tomorrow.

The IHE Gazelle Homepage provides information about Monitors
670 (https://gazelle.ihe.net/content/connectathon-monitors).

2.2.9 B_Meth-09 Understand an IHE Connectathon: Understand the different types of testing performed at a Connectathon (Peer-to-peer, etc.) (L1)

At the IHE Connectathon the main activity are peer-to-peer tests, where two or more participants test against their software for interoperability according to a specific IHE profile. Participants will be required to perform three instances of each specific test with a different test partner to demonstrate interoperability. After each Connectahon, IHE publishes the IHE profile/actor pairs that each company successfully tests during Connectathon week.

During No-peer tests vendors test their software against a testing tool only. This typically takes place during software development at home and when a vendor team performs Pre-Connectathon Testing to prepare for the event. During the Connectathon some no-peer tests are performed, e.g. during setup of the software, to assure correct configuration of the software and the Gazelle test bed.

The IHE Gazelle homepage provides more information (https://gazelle.ihe.net/content/connectathon-test-process).

2.2.10 B_Meth-10 Understand and generate integration statements (L2)

The IHE Product Registry provides information about IHE Integration Statements (https://product-registry.ihe.net/PR/pr/introPR.seam):

IHE Integration Statements are documents prepared and published by vendors to self declare the conformance of their products with the profiles from the IHE Technical Frameworks. They identify the specific IHE capabilities a given product supports in terms of IHE actors and profiles. The integration statement is under the responsibility of the vendor and does not engage IHE. It is a compliance commitment made by the vendor for a specific product version.

Users familiar with these concepts can use Integration Statements to determine what level of integration a vendor asserts a product supports with complementary systems and what clinical and operational benefits such integration might provide.

An IHE Integration Statement for a product shall include:
- The Vendor Name.
- The Product Name (as used in the commercial context) to which the IHE Integration Statement applies.
- The Product Version to which the IHE Integration Statement applies.
- A publication date and optionally a revision designation for the IHE Integration Statement.
- The following statement: This product implements all transactions required in the IHE Technical Framework to support the IHE Integration and Content Profiles, Actors and Options listed below.

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- A list of IHE Integration and Content Profiles supported by the product and, for each profile, a list of IHE Actors supported. For each profile/actor combination, one or more of the options defined in the IHE Technical Framework may also be stated. Profiles, Actors and Options shall use the names defined by the IHE Technical Framework Volume I. (Note: The vendor may also elect to indicate the version number of the Technical Framework referenced for each Integration Profile.)

Integration statements can be generated in different ways:
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- The vendor generates the IHE Integration Statements using the template provided by IHE, and publishes it e.g. on the vendor homepage, as a pdf document
- The vendor enters organisation and system information into the IHE Product Registry. The vendor then generates its product's IHE Integration Statement using the online tool of the IHE Product Registry

720 The IHE Product Registry is a tool offered by IHE under the vendor's responsibility. It is important to note that there are many more products with an integration statement published on the vendor website, than those registered by the IHE Product registry.

2.2.11 B_Meth-11   Understand and explain IHE Conformity Assessment (L1)

725 The IHE Homepage provides information about IHE Conformity Assessment (https://www.ihe.net/testing/conformity-assessment/):

IHE International administers the IHE Conformity Assessment Scheme (CAS), which forms the basis for IHE Conformity Assessment Program and any official report of conformance of a product to IHE Profiles associated with such testing program.

730 The CAS Scheme consists of two volumes:
- IHE CAS-1 defines the necessary processes for establishing and managing an IHE Conformity Assessment Program and for accrediting and operating testing labs.
- IHE CAS-2 defines the standardized test methods for assessing conformity to individual IHE Profiles.

735 On the basis of the Conformity Assessment Scheme, test laboratories are accredited in accordance with the ISO/CEI 17025 standard, General Requirements for Competence of Calibration and Testing Laboratories. Test reports produced in accordance with this standard are recognized worldwide. IHE International authorizes designated test laboratories accredited under this standard to assess the conformity of products with selected IHE profiles. Providing an IHE
740 Conformity Assessment Test Report for the Profiles implemented in a product is a robust and objective proof (ISO 17025 Accredited Test Laboratories) of conformance based on the test plans and tools required by IHE-CAS-2.

2.2.12 B_Meth-12   Understand how to implement IHE profiles – Use case driven approach (L1)

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The following articles provide information about the concepts used in the IHE methodology:
1. Bourquard K, Orlova A, Parisot C. Understanding User Needs for Interoperability: Collaborative Approach. JAHIMA. 2017. 88(10): 58-61: URL: http://bok.ahima.org/doc?oid=302323

750
2. Orlova A, Bourquard K, Parisot C. Understanding User Needs for Interoperability: Standards for Use Cases in eHealth. JAHIMA. 2017. 88(9): 40-44.
    URL: http://bok.ahima.org/doc?oid=302252

3. Orlova A, Bourquard K, Parisot C. Understanding User Needs for Interoperability: Standards for Business Cases in eHealth. JAHIMA. 2017. 88(7): 34-37.
755
    URL:http://bok.ahima.org/doc?oid=302184

4. Bourquard K, Orlova A, Parisot C. Understanding User Needs for Interoperability: Defining Use Cases in eHealth. JAHIMA. 2017. 88(6): 42-45.
    URL: http://bok.ahima.org/doc?oid=302159

760 Understand the concepts of business case and interoperability use cases and hierarchy. Implementation of the concepts with two examples of Clinical imaging and ePrescription.

"In computer science, a use-case driven approach is the foundational methodology for documenting user needs. This has been adopted by national and international digital health efforts to support IT systems and devices interoperability and health information sharing across
765 systems." Because the concepts are generally used in several ways, the objective is to define the concepts and their relationships to facilitate better deployment of the standards-based technical solutions called IHE profiles.

Driven by eHealth priorities, business use cases or **interoperability use cases** are selected.

For each interoperability use case, information flows between business actors are identified and
770 documented at a high-level in a **Use Case Specification**

These information flows are further analysed and mapped onto Profiles and their supporting technical transactions. The resulting high-level specification is called **a realization scenario** for the selected Use Case.

Then an **Interoperability Specification** is derived with all necessary technical details on the
775 way one combines these Profiles across transport, services, semantic content, security and privacy. Although the largest part of this Interoperability Specification is based on generic IHE Profiles, it adds all the specific details necessary for an operational deployment.

Finally, test plans and tools, such as a customized version of the generic IHE Gazelle Test Platform can be easily developed and will ensure that infrastructure systems or point of care
780 systems can be designed independently but be tested to conform to the project Interoperability Specification, and thus have a high chance to interoperate successfully when deployed.

2.3 C_Res: Locate and navigate through IHE resources

Duration: 4h

785 Terms: Domains, TFs, WIKI, FTP, White papers, product registry, CAS testing reports

IHE offers a large variety of artefacts to be used by the community. On the IHE homepage the technical frameworks are available as the main source of information for those who plan and implement IT systems in healthcare. Additionally, on the FTP site there are development materials and educational materials. In the Connectathon result matrix one can research which

790 company has tested which profile at which Connectathon. This enables to identify companies who are actively engaging in IHE, and to see which profiles are used over time. The IHE Conformity Assessment testing reports of a specific product show to which IHE profiles this product conforms, as tested in an accredited CAS testing laboratory.

Learning Outcomes

795 • C_Res-01 Draw knowledge from IHE Domain material (Meeting information, Current work items, educational material)

• C_Res-02 Draw knowledge from IHE Technical Frameworks, Profiles (Supplements) and White Papers

• C_Res-03 Draw knowledge from the IHE Homepage, Wiki, FTP

800 • C_Res-04 Perform simple and advanced browsing in the Connectathon result matrix

• C_Res-05 Perform simple and advanced browsing in the Product registry

• C_Res-06 Perform simple and advanced browsing for Conformity Assessment testing reports

2.3.1 C_Res-01   Draw knowledge from IHE Domain material (Meeting
805 information, Current work-items, educational material) (L2)

The development activities in IHE are driven in the IHE domains. The Domain Committees record their work on the IHE wiki https://wiki.ihe.net. You can find meeting information, agendas, minutes, planning outcomes, and many other traces of their activities there.

Introduction material on the domains is also available on the IHE homepage:
810 https://www.ihe.net/ihe_domains/ . This also links to the committee wiki, education and implementation material.

The IHE FTP site also offers a large volume of material: ftp://ftp.ihe.net/ . You may need to browse there, and explore.

2.3.2 C_Res-02   Draw knowledge from IHE Technical Frameworks, Profiles (Supplements) and White Papers (L2)

The main source of information for deployment of IHE profiles is the IHE Technical Frameworks page: https://www.ihe.net/resources/technical_frameworks/

This has the Current Technical Frameworks, in Final Text status, as well as the Supplements for Trial Implementation. It also has the IHE White Papers. Make sure you find your way into the technical Frameworks. Find information about the use cases and the profile actors-transaction diagrams the in the Volumes 1. Find detailed specifications of the transactions in the further volumes 2 and up.

2.3.3 C_Res-03   Draw knowledge from the IHE Homepage, Wiki, FTP (L2)

Make sure you browse the IHE Homepage https://www.ihe.net, wiki https://wiki.ihe.net, and FTP site ftp://ftp.ihe.net/.

Find the IHE TFs, profiles, in the different statuses, change proposals, event information, Connectathon results, reports from regional and national deployment committees, minutes, agendas from all IHE committees, educational material,

2.3.4 C_Res-04   Perform simple and advanced browsing in the Connectathon result matrix (L2)

Arrive at the Connectathon result matrix (https://connectathon-results.ihe.net) via the IHE homepage, in the Testing space. "Simple browsing" for Connectathons, vendors, actors and integration profiles gives you quick overviews.

Advanced browsing gives you more detailed information, e.g., how often was a specific profile tested over time, at different connectathons? At which Connectathons did a specific company test a specific profile? Were they keeping up the effort, or was this just a one-timer?

Test some filter combinations to understand what the market offers, and which profiles have been implemented most often.

2.3.5 C_Res-05   Perform simple and advanced browsing in the Product registry (L2)

Arrive at the Product Registry (https://product-registry.ihe.net/PR/home.seam) via the IHE homepage in the Testing space, then on via the IHE Gazelle page. The Product Registry provides the Integration Statements that vendors registered there.

Via the "TF" menu, the HE Product Registry also provides a browser for the technical frameworks. This browser uses a database, enabling you e.g. to filter for actors, profiles, transactions. This is helpful if you need to assemble information that is distributed among

multiple documents in the Technical Frameworks, e.g. about possible groupings of actors, and about transactions that are defined in different profiles for the same actor.

This browser also provides a mind-map type of overview on the IHE Technical Frameworks, enabling an additional access to the information contained in the IHE profiles. This browser
855   enables to click through the TFs, following a direct line of existing connections between the items in the IHE profiles, that are not so obvious in the Technical Framework documents themselves.

2.3.6   C_Res-06   Perform simple and advanced browsing for Conformity
860   **Assessment testing reports (L2)**

Arrive at the Conformity Assessment (CAS) page (https://www.ihe.net/testing/conformity-assessment) via the IHE homepage in the Testing space. This provides an introduction into CAS. It also links to a repository of test reports for products that have completed Conformity Assessment testing administered by IHE Authorized Testing Laboratories
865   (https://conformity.ihe.net/summary-reports). The page enables to filter for profiles, for a faster search.

2.4 D_Tec: IHE Example profiles, base standards, general healthcare IT knowledge

870   Duration: 8h

Terms: HTTP, SOAP, JSON, XML, HL7, HL7 V2, HL7 CDA, HL7 FHIR, DICOM, SNOMED-CT, Security & Privacy Profiles, ATNA

IT systems communication using IHE profiles is based on several standards from HL7, DICOM or other SDOs. These standards define requirements from syntactical and semantical point of
875   view to share information. Therefore, a basic understanding of the differences between HL7 V2, HL7 V3, HL7 CDA, HL7 FHIR and DICOM is necessary to understand the technical environment of selected IHE profiles. These standards leverage base technologies like HTTP, XML, JSON, SOAP and RESTful architecture to a high degree, which requires knowledge of the basic concepts. Promoting semantic interoperability includes the application of code-lists and
880   value-sets, and therefore knowledge of code-lists like SNOMED-CT, LOINC or ICD and its application, based on examples for HL7 V2, HL7 V3/CDA, DICOM and HL7 FHIR, is necessary. Implementation of IT solutions requires the coverage of Security & Privacy needs and IHE provides several profiles to cover basic requirements. A general overview about the most prominent Security & Privacy profiles shall be given. Knowledge of the top ten tested profiles on
885   the level of Vol. 1, shall prove a general knowledge and understanding of IHE profiles and its application.

Learning Outcomes
- D_Tec-01 Understand and explain the usage of base technologies in IHE profiles: HTTP, SOAP, RESTful, JSON, XML services

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890   •   D_Tec-02 Identify the base standards used by IHE profiles: HL7 V2, HL7 V3/CDA®, HL7 FHIR, DICOM

•   D_Tec-03 Understand and explain the basic concepts of terminologies, ontologies, coding systems and value sets used by IHE (LOINC, SNOMED CT, ICD and HL7 code lists)

•   D_Tec-04 Understand and explain the basic concepts of semantic interoperability on the

895   examples of HL7v2.X, HL7v3/CDA, DICOM, HL7 FHIR: where does which content go and how

•   D_Tec-05 Identify IHE Profiles and White Papers which address the topic of security or privacy (ATNA, BPPC, ITI Access Control Whitepaper)

•   D_Tec-06 Understand and explain the 'top 10' most tested profiles' (as determined by looking

900   at Connectathon statistics) on the level of Volume 1: Use-case covered by the profiles, actors and the transactions between them without options

2.4.1   D_Tec-01   Understand and explain the usage of base technologies in IHE profiles: HTTP, SOAP, RESTful, JSON, XML services (L2)

905   Depending on the different requirements of an IT system one can select specific integration profile(s) to fulfil interoperability requirements. Each of this integration profiles are based on using well known and widely used base technologies. Several different scenarios are using profiles based on web-communication technologies, taking the exchange of clinical documents on a cross-enterprise level as a very frequently used application in healthcare. For this purpose,

910   IHE specified the Cross-Enterprise Document Sharing (XDS) profile, which uses HTTP and SOAP as communication technologies to transfer for example XML-based clinical documents defined according HL7 Clinical Document Architecture (CDA) specifications.

At present there is strong movement to integrate data from mobile devices, like personal health devices (PHDs), smartwatches and mobile phones. It is an important requirement to integrate this

915   data in existing infrastructure to foster sustainability without forcing new procurements. HL7 Fast Healthcare Interoperability Resources (FHIR) is a recent standard supporting mobile environments and efficient data sharing using RESTful architecture and JSON/XML. IHE is working intensively on profiles using FHIR (see https://wiki.ihe.net/index.php/Profiles) for example to integrate mobile platform data to Electronic Health Records based on XDS with the

920   Mobile Access to Health Documents (MHD) profile. Therefore, it is a requirement to have a basic understanding of the following technologies:

•   Hypertext Transfer Protocol (HTTP): HTTP is a state-less protocol for the exchange of data in the application layer of the OSI-model. It is used in the World Wide Web

925   (WWW) for representation of web-sites, but also for machine-to-machine communication (e.g. web services). HTTP(s) includes transport layer encryption (TLS).

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- Simple Object Access Protocol (SOAP): SOAP is a network protocol for the exchange of data between IT systems and is defined by the World Wide Web Consortium (W3C). SOAP uses XML for the representation of the data transported and Internet-protocols of the transport- and application-layer level of the OSI-model, mainly by HTTP(s) and TCP. A SOAP-message has an element called SOAP-Envelope compound of a SOAP-Header and a SOAP-Body. The SOAP-Header incorporates meta information for routing, encryption or identification of the transaction and is optional. The SOAP-Body includes the data itself and is mandatory.

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- Representational State Transfer (REST): REST is a paradigm for distributed systems especially for web services. REST defines principles on using communication protocols (mainly HTTP and HTTP(s)) in the application layer level of the OSI-model. For example, it defines to use stateless communication based on standard HTTP methods like GET, POST, PUT, etc. for the exchange of data. Data shall be linked together (distributed

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  resources) and different resource representation can be used, like for example JSON or XML. An advantage of REST, compared to SOAP, is the support for efficient communication on mobile environments like smartphones or tablets.

- JavaScript Object Notation (JSON): JSON is a compact, text-based data format for the platform independent exchange of data between IT systems. JSON is often used by web

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  applications and mobile devices using JavaScript but can be used with other languages through using corresponding parsers.

- Extensible Markup Language (XML): XML is a markup language with the aim to represent data in a hierarchical structure in a text file. These files can be read by humans and machines. It provides a platform independent language for exchange data between IT

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  systems via the internet and is defined by the W3C. The structure of an XML document can be described by an XML-Schema. With a Schematron (XML-Schema), which is a rule-based validation language, content as well as structure of an XML document can be validated.

955   **2.4.2 D_Tec-02   Identify the base standards used by IHE profiles: HL7 V2, HL7 V3/CDA®, HL7 FHIR, DICOM (L2)**

IHE focuses different domains and for each a technical framework defining several integration profiles are defined. These profiles are based on well-known and widely used communication and interoperability standards. It is important to have a basic understanding and to show the

960   capabilities to provide an overview about the most prominent standards used by IHE. Two important sources of standards used in several integration profiles are Health Level 7 (HL7) and Digital Imaging and Communications in Medicine (DICOM):

- HL7 Version 2 (V2): HL7 V2 is a platform independent standard to support healthcare related workflows by defining structured messages to share healthcare related data. The

965   messages are compound of segments (Message Header (MSH), Patient Identification Segment (PID), etc.), which themselves are separated in a sequence of data fields (first name, last name, birthdate…) to provide a high degree of structuring the data. Please read

the overview at:
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=185

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- HL7 Version 3 (V3): HL7 V3 is an interoperability standard aiming to support all healthcare related workflows and related data sharing processes. This specification is based on a formal methodology and object-oriented principles, compared to HL7 V2. It provides the possibility to exchange clinical information based on messages (HL7 V3 Messaging), but furthermore provides a specification to define clinical documents (See
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CDA®). Please read the overview at:
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=186

- HL7 Clinical Document Architecture (CDA®) Release 2: HL7 CDA® is specification for the definition of XML-based clinical documents. CDA® is part of HL7 Version 3 and is based on the HL7 Version 3 Reference Information Model (RIM). Depending on the
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specific needs of application in international or national environments, the specification can be used to define clinical documents like Patient Summary or Laboratory Reports. Please read the overview at:
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

- HL7 Fast Healthcare Interoperability Resources (FHIR): HL7 FHIR is currently a draft
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standard (STU 4.0.0 by the start of 2019) for the exchange of healthcare related information in distributed environments using smartphone, cloud-based systems EHR and others. It is based on modular healthcare related resources, which can be assembled and combined to solve different requirements from clinical and administrative routines. Please read the overview at:
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http://www.hl7.org/implement/standards/product_brief.cfm?product_id=449

- Digital Imaging and Communications in Medicine (DICOM): DICOM is a standard focusing on storing, managing and sharing of medical images as well as integration of imaging devices in the medical context. Picture Archiving and Communication Systems (PACS) uses DICOM as a universal format for this process. Please read chapter 1:
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"Scope and Field of Application for a general overview":
http://dicom.nema.org/medical/dicom/current/output/html/part01.html#chapter_1

- DICOMWeb: DICOMweb™ is the DICOM standard for web-based medical imaging. It is a set of RESTful services, enabling web developers to unlock the power of healthcare images using industry-standard toolsets. DICOMweb can be implemented directly or as
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a proxy to the well-established DIMSE services, to offer modern web-based access to DICOM-enabled systems (Image-producing modalities are not expected to be retrofitted to support DICOMweb): https://www.dicomstandard.org/dicomweb/

2.4.3 D_Tec-03 Understand and explain the basic concepts of terminologies, ontologies, coding systems and value sets used by IHE (LOINC, SNOMED CT, ICD and HL7 code lists). (L2)

In the context of healthcare, it is important to understand basics about terminologies, ontologies, code systems and value sets as well as healthcare related examples of collections of codes:

- Terminology: According to the definition in ISO DTR 12300: "A structured, human and machine-readable representation of clinical concepts required directly or indirectly to describe health conditions and healthcare activities and allow their subsequent retrieval or analysis."

- Concept: A semantic unit (entry) in a terminology. It is compound of a descriptor and a code.
  Example: Term: "celebrity" Code: "C" in the code list HL7 Confidentiality Code

- Code System: A mostly flat or hierarchical collection of codes in a computer interpretable format.
  Example: LOINC, ICD, UCUM, HL7 code lists

- Value Set: A Value Set is a versioned excerpt of codes from one or multiple terminologies used to describe health conditions and healthcare activities. A Value Set includes the codes and information about the origin (e.g. source terminology) of the codes.
  Example: Laboratory parameters for the national Austrian eHealth infrastructure, Confidentiality Codes for a national electronic health record

- Ontology: An Ontology is a formally defined system of concepts and relations between these concepts for a specific domain.
  Example: SNOMED-CT

- Logical Observation Identifiers Names and Codes (LOINC): Is an international Code System for the identification of laboratory and clinical studies and tests. (https://loinc.org/)

- Systematized Nomenclature of Medicine – Codes and Terms (SNOMET-CT): Is the most comprehensive, multilingual clinical healthcare terminology in the world and enables consistent representation of clinical content in EHRs. (http://www.snomed.org/)

- International Classification of Diseases (ICD): Is a global standard for health information and published by the WHO. (https://icd.who.int/)

- HL7 Code Lists: HL7 provides several different code systems in their specifications. Some examples are Confidentiality Codes, Address Use, Act Codes, Participation Functions, Specimen Types and others.

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2.4.4 D_Tec-04   Understand and explain the basic concepts of semantic interoperability on the examples of HL7v2.X, HL7v3/CDA, DICOM, HL7 FHIR: where does which content go and how (L2)

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Very often information can be understood and interpreted differently. An example is the term "bow": One can understand "bow" as the front of a ship, whereby another one may interpret it as

1045 weapon e.g. "bow and arrow". By using well defined and commonly agreed codes to describe information objects it can be assured that sender and receiver of the information object have the same understanding about the information object. Semantic interoperability targets to share and interpret information unambiguously, which is an important requirement using automated information interpretation. Therefore, it is a crucial requirement in every communication based

1050 on IHE profiles. IHE provides guidance on which terminologies must, shall or might be used in the specifications of the integration profiles. Examples of use in base standards used in IHE profiles are:

- HL7 V2: This example shows on how to use codes in an abbreviated OBX-Segment of an HL7 V2 observation message transmitting weight scale data. It uses ISO/IEEE 11073-

1055   10101 Nomenclature to describe the weight value:
      OBX|12|NM|…|…|83|263875^MDC_DIM_KILO_G^MDC|||||R|||20180301|…

- HL7 CDA: This example shows an example usage of the HL7 Confidentiality Code System and a related code in a CDA-Header of an example document:
  <confidentialityCode code="N" displayName="normal"

1060   codeSystem="2.16.840.1.113883.5.25" codeSystemName="HL7:Confidentiality"/>

- DICOM: This example shows a snippet of a DICOM Structured Report (SR). The codes are applied as triplets in the brackets starting with the code value, the code system (SRT=SNOMED) and the meaning of the code:
  1.5.1.12: HAS ACQ CONTEXT: CODE: (F-61FDB, SRT, "Radiopharmaceutical agent")

1065   = (C-B1031, SRT, "Fluorodeoxyglucose F^18^")

- HL7 FHIR: This example shows the use of a LOINC code for identifying a Body Weight transmission in a FHIR Observation resource in XML-format:
  <coding>
    <system value="http://loinc.org/">

1070   <code value="29463-7">
    <display value="Body Weight"/>
  </coding>

2.4.5 D_Tec-05   Identify IHE Profiles and White Papers which address the topic of security or privacy (ATNA, BPPC, ITI Access Control Whitepaper) (L2)

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Management of healthcare related data requires to fulfil highest possible security and privacy measures. IHE provides several profiles for the security & privacy domain (see https://wiki.ihe.net/index.php/Category:Security), each contributing to one or more security & privacy controls like identification & authentication, data access control, secrecy, data integrity,

1080 non-repudiation and patients privacy. IHE specifications clearly indicates when security measures are necessary and which profiles might be used.

One of the most common security profiles is Audit Trail and Node Authentication (ATNA) providing guidance on software-component based mutual authentication requirements as well as setting up interoperable Audit storage, management and exchange infrastructure. Taking IHE

1085 XDS Profile as an example, each Transaction used by the Actors defines the structure and set of information necessary to store in a specific Audit log properly.

The following table provides an entry-point to security & privacy profiles. Column "IHE Wiki" shows the links to brief overviews for the top three most tested security & privacy profiles in the IHE Wiki. Column "Technical Framework Vol.1" provides the link to the profiles in the

1090 respective Technical Frameworks:

Rank Global 2010-15	Profile	Global	IHE Wiki	IHE Technical Framework - Vol. 1
1	Consistent Time (CT)	831	https://wiki.ihe.net/index. php/Consistent_Time	IHE IT Infrastructure Technical Framework -Vol.1 – Section 7: http://www.ihe.net/uploadedFiles /Documents/ITI/IHE_ITI_TF_Vol1. pdf#nameddest=7_Consistent_Ti me__CT_
2	Audit Trail and Node Authenticati on (ATNA)	552	https://wiki.ihe.net/index.p hp/Audit_Trail_and_Node_ Authentication	IHE IT Infrastructure Technical Framework - Vol.1 – Section 9: http://www.ihe.net/uploadedFiles /Documents/ITI/IHE_ITI_TF_Vol1. pdf#nameddest=9__Audit_Trail_a nd_Node_Authent
3	Basic Patient Privacy Consent (BPPC)	93	https://wiki.ihe.net/index.p hp/Basic_Patient_Privacy_C onsents	IHE IT Infrastructure Technical Framework – Vol.1 – Section 19: http://www.ihe.net/uploadedFiles /Documents/ITI/IHE_ITI_TF_Vol1. pdf#nameddest=19_Basic_Patient _Privacy_Consen

A lot of effort was done on the topic of access control which is shown by the following White Paper https://wiki.ihe.net/index.php/ITI_Access_Control_White_Paper. IHE offers the Cross-Enterprise User Assertion (XUA) for SOAP based authorization credential distribution. This is

1095 based on using the Security Assertion Markup Language (SAML) and web service (WS)-Trust for issuing, management, distribution and evaluation of authorization credentials in distributed environments like an EHR system.

CISOs may use the "Cookbook for Security Considerations" provided by IHE to select appropriate profiles according the individual system's needs (see

1100 https://wiki.ihe.net/index.php/Cookbook_for_Security_Considerations).

2.4.6 D_Tec-06 Understand and explain the 'top 10' most tested profiles' (as determined by looking at Connectathon statistics) on the level of Volume 1: Use-case covered by the profiles, actors and the transactions between them without options (L2)

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The top-10 profiles shall be understood and explained on the level of Volume 1 as provided by the following table. Column "IHE Wiki" shows the links to brief overviews for each profile in the IHE Wiki. Column "Technical Framework Vol.1" provides the link to the profiles in the respective Technical Frameworks:

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Rank Global 2010-15	Profile	Global	IHE Wiki	IHE Technical Framework - Vol. 1
1	Consistent Time (CT)	831	https://wiki.ihe.net/index.php/Consistent_Time	IHE IT Infrastructure Technical Framework - Vol.1 – Section 7: http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf#nameddest=7_Consistent_Time__CT_
2	Audit Trail and Node Authentication (ATNA)	552	https://wiki.ihe.net/index.php/Audit_Trail_and_Node_Authentication	IHE IT Infrastructure Technical Framework - Vol.1 – Section 9: http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf#nameddest=9__Audit_Trail_and_Node_Authent
3	Cross-Enterprise Clinical Document Sharing (XDS.b)	472	https://wiki.ihe.net/index.php/Cross-Enterprise_Document_Sharing	IHE IT Infrastructure Technical Framework – Vol.1 – Section 10: http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf#nameddest=10_Cross_Enterprise_Document_Sh
4	Patient Identifier Cross-referencing for MPI (PIX for MPI)	269	https://wiki.ihe.net/index.php/Patient_Identifier_Cross-Referencing	IHE IT Infrastructure Technical Framework – Vol.1 – Section 5: http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf#nameddest=5_Patient_Identifier_Cross_refe
5	Patient Demographics Query (PDQ HL7 V2)	267	https://wiki.ihe.net/index.php/Patient_Demographics_Query	IHE IT Infrastructure Technical Framework – Vol.1 – Section 8: http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf#nameddest=8_Patient_Demographics_Query__P

6	Scheduled Workflow (SWF)	241	https://wiki.ihe.net/index.php/Scheduled_Workflow	IHE Radiology Technical Framework – Vol.1 – Section 3: https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_TF_Vol1.pdf
7	Patient Identifier Cross-Reference HL7 V3 (PIX HL7 V3)	196	https://wiki.ihe.net/index.php/Patient_Identifier_Cross-Reference_HL7_v3	IHE IT Infrastructure Technical Framework – Vol.1 – Section 23: http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf#nameddest=23_Patient_Identifier_Cross_ref
8	Patient Demographic c Query HL7 V3 (PDQ HL7 V3)	190	https://wiki.ihe.net/index.php/Patient_Demographics_Query_HL7_v3	IHE IT Infrastructure Technical Framework – Vol.1 – Section 24: http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf#nameddest=24_Patient_Demographics_Query_H
9	Cross-enterprise Document Sharing for Imaging (XDS-I.b)	183	https://wiki.ihe.net/index.php/Cross-enterprise_Document_Sharing_for_Imaging	IHE Radiology Technical Framework – Vol.1 – Section 18: https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_TF_Vol1.pdf
10	Cross-Enterprise Document Sharing of Scanned Documents (XDS-SD)	148	https://wiki.ihe.net/index.php/Cross-enterprise_Sharing_of_Scanned_Documents	IHE IT Infrastructure Technical Framework – Vol.1 – Section 20: https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf

2.5 E_Depl: Accelerate Health Information Exchange deployment

Duration: 2 hours

Acceleration of health information exchange deployments is important to foster the integration of interoperable IT solutions. On a European level, substantial efforts have been undertaken in the EU Antilope project to define interoperability use cases based on profiles and standards. Due to the definition of common requirements, manufacturers can align their products to these common requirements, which reduces efforts in customization. Additionally, IHE supports testing of project-specific deployment specifications, based on IHE Profiles. This can be done in terms of so called Projectathons. The aim of this section is to understand and raise awareness of processes and tools which support efficient project deployments.

Learning Outcomes

- E_Depl-01 Understanding and explaining the layers of Interoperability: IHE Interoperability
1125   Use Case Deployment Methodology

- E_Depl-02 Using IHE profiles in procurement as described in the COMMISSION DECISION (EU) 2015/1302

- E_Depl-03 Understand large-scale deployment testing strategies with Projectathons and deployed systems on-boarding

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- E_ Depl-04 Understand the role of Gazelle, IHE interoperability testing platform and its deployment (IHE-Services)

2.5.1 E_Depl-01 Understanding and explaining the layers of Interoperability: IHE Interoperability Use Case Deployment Methodology (L1)

1135   IHE has substantially contributed to numerous projects on interoperability worldwide, with a focus on a Use Case Deployment Methodology. One result of this work is the **refined eHealth Interoperability Framework (eEIF)** developed in Antilope project (http://www.Antilope-project.eu) and its extension developed in eStandards project (http://www.estandards-project.eu).

The eEIF describes the layers of interoperability (see https://www.antilope-project.eu/wp-
1140   content/uploads/2013/05/D1.1-Refinement_of_Antilope_Use_Cases_v1.2.pdf) :

- Legal

- Organisational

- Semantic

- Technical

1145   The framework also describes an initial set of interoperability use cases that can be used as the basis for national/regional deployment on eHealth. Wherever applicable and useful, several variants of these use cases are given, to support the different deployment scales. Also, concrete realization scenarios, based on available profiles and standards, are specified for each of these use cases. The linking to standards and profiles in these realization scenarios provides guidance
1150   upon which to build localization and interoperable implementations. For further information on use cases see: https://usecase-repository.ihe-europe.net/

The eEIF framework increases consistency where possible, across eHealth projectsreducing project risks, giving higher quality with reused test tools, and offering a broader choice of compatible solutions. Although initially created in the USA (HITSP) and further operationalized
1155   in Europe, it has now been adopted and used across the world.

Benefit for international, national, regional and local projects:

- Education on use cases for their adoption

- Multicriteria database for an easy access to a specific use case or scenario

- Selection of set of profiles and standards related to the use cases

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- Specific attention to the 27 profiles recognized by the European Commission. and the 32 IHE Profiles identified by the HHS-Office of the National Coordinator in the USA See E_Depl-02

2.5.2 E_Depl-02 Using IHE profiles in procurement as described in the
1165 ###   COMMISSION DECISION (EU) 2015/1302 (L1)

Whenever a local authority, a hospital association, or a department in charge of procurement processes is going to call for tenders for health IT-systems, the detailed requirements for interfaces capabilities of the future system needs to be considered in order to ease the integration of the new system into existing IT landscapes. Fur such public procurement processes the

1170 European Union has claimed and identified in a commission decision that 27 IHE profiles can be used for this purpose (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D1302&from=GA). Hence, by referencing to an IHE profile in procurement processes a vendor can clearly state the requirements in terms of needed interfaces. These 27 profiles include the most prominent profiles from the IHE ITI TF, like

1175 XDS.b and ATNA.

2.5.2.1 Using IHE profiles in the USA national Interoperability Standards Advisory

The Interoperability Standards Advisory (ISA) process represents the model by which the US Office of the National Coordinator for Health Information Technology (ONC) will coordinate

1180 the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the healthcare industry to address specific interoperability needs including, but not limited to, interoperability for clinical, public health, research and administrative purposes. ONC encourages all stakeholders to implement and use the standards and implementation specifications identified in the ISA as applicable to the specific

1185 interoperability needs, they seek to address. Furthermore, ONC encourages further pilot testing and industry experience to be sought with respect to standards and implementation specifications identified as "emerging" in the ISA.

The 32 IHE Profiles identified in the 2019 Reference Edition ISA can be accessed at: https://www.healthit.gov/isa/sites/isa/files/inline-files/2019ISAReferenceEdition.pdf

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2.5.3 E_Depl-03 Understand large-scale deployment testing strategies with
Projectathons and deployed systems on-boarding (L1)

The Projectathon is a testing session dedicated to a specific deployment project using a set of IHE Profiles and extension to them, in their interoperability specifications (See 2.2.13).

1195 Participants test conformity and interoperability of their systems or solutions against the deployment project's interoperability specifications based on IHE Profiles. In this case the test

plans and testing tools are customized to the projects requirements and additional end to end testing on specific workflow (sequence diagrams) can be provided (group testing orchestration). Consequently, the Gazelle testing management platform can be also effective in order to perform this set of tests and to verify that the systems have correctly implemented the interoperability specifications of the deployment projects.

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The organization which has the leadership of the project has the responsibility to define the testing criteria for the project requirements and publishes the successful results at the end of the Projectathon following their own rules. The testing session can be delegated to the IHE team where IHE is experienced and can provide the necessary skills for managing such a testing event. The Projectathon can leverage as input criteria, IHE Profile Conformity Assessment and also be the preliminary event before any project specific conformity assessment, quality label or certification process.

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Below are examples of past Projectathons:

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- epSOS Projectathons- The epSOS European Projectathon used the Projectathon facilities for testing cross-border exchanges of medical documents. Several IHE Profiles such as XDR, ATNA, CT, XCA, XCPD and BPPC were selected and embedded in the specifications. Five Projectathons have been set up since 2010.

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- eHDSI Projectathons- Under the CEF programme (Connecting Europe Facility), the eHDSI operations (eHealth Digital Service Infrastructure) is now under the supervision of DG Santé which organises the Projectathons at the European Commission facilities with the support of the IHE team.

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- EPD (PHR) Projectathon- The EPD (PHR) Projectathon in Switzerland was organised in Berne for the second time in September 2018 where 800 tests were verified for 23 companies. The Projectathon in Switzerland is the test preparation event for companies before the Suisse certification process.The Suisse specifications include several IHE Profiles and their national extensions.

The Projectathon is one step of the complete testing process from prototype, pre-pilot environment to the real world. The same testing environment will support each step of the testing process, organised as a face-to-face or a virtual testing event.

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	Connectathon	**Projectathon**
Governance	Under the supervision of IHE regional/national deployment.	Under the supervision of the project (the lead organization).
Rules for passing	IHE test methods are used. Criteria are developed in the IHE Test Plan.	Test methods are customized to fit the project specifications. Criteria are developed by the

		project.
Publication of the results	IHE Connectathon Results web repository.	Published by the project (the lead organization).

2.5.4 E_ Depl-04 Understand the role of Gazelle, IHE interoperability testing platform and its deployment (IHE-Services) (L1)

The Gazelle Test Bed for software testing, especially for interoperability and conformance
1230 testing. Development of Gazelle started in 2006 by INRIA (https://www.inria.fr/) and is now
continued by Kereval (https://www.kereval.com/). Gazelle comprises, among other features, a
test management tool, simulators, and validators.

The test management tool is used to manage the participating software/systems under test, the
users, the monitors, and the orchestration of these for conducted test cases. Hence this system is
1235 used during a Connectathon by the participants in order to identify suitable systems a vendor can
run test against.

The messages exchanged during an interoperability test can be recorded using Gazelle's proxy
(https://gazelle.ihe.net/content/proxy-user-guide). The recorded messages can then be validated
using one of the available validation services included in Gazelle. This step is considered as a
1240 conformance test, proving conformance of the implementation according to the specifications
found in the IHE technical frameworks. Whenever data is needed to be exchanged following
these specification Data Generation Tools can be used (e.g. for the generation of CDA
documents).

Beside the software systems available by vendors taking part at the Connectathon, Gazelle
1245 provides simulators (https://gazelle.ihe.net/content/simulators) that mimic the functionality of
specified IHE actors in order to test interfaces. This is especially of interest during the timespan
between Connectathons and therefore enables vendors to prepare their system's interfaces for
peer-to-peer tests at Connectathons.

IHE-Services provides the maintenance of Gazelle during a Connectathon but also offers other,
1250 mainly on Gazelle based, services. These services include customization for special-purpose
interoperability testing, adaptation of validation and simulators, as well as, hosting a cloud-based
instance of Gazelle or an in-house installation of Gazelle at different premises. Information on
IHE-service can be found at https://www.ihe-europe.net/deployment/IHE-Services. More
information on Gazelle can be found on the Gazelle web page (https://gazelle.ihe.net/)

1255 IHE Services maintains and operates the enterprise edition of Gazelle providing a minimum of
two upgrades per year to users of Gazelle, a full helpdesk support as well as a validated
configuration of the tools scaled and fitted for each case separately. In addition IHE services can

provide additional added value services to promote IHE profiles and the use of Gazelle as a testing platform. Those are:

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1. Consultancy and training on Interoperability Architecture, IHE profiles and underlying standards;
2. Interoperability Conformity assessment to IHE profiles of health IT products;
3. Preparation and organization of face-to-face interoperability test sessions as a managed service;

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4. Preparation and organization of on-line virtual interoperability test sessions ;
5. Development of tool extensions tailored to project-specific interoperability requirements ;
6. Specification of tailored test plans and test cases for projects building on IHE profiles;
7. Support for installation and maintenance of project-dedicated testing infrastructures;
8. Independent and impartial monitoring and reporting of interoperability testing results;

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9. Support the production of interoperability demonstration showcases.

3   IHE Glossaries

"Appendix D: Glossary" is part of the general introduction to the content of IHE profiles, see the IHE Homepage on the [Technical Frameworks page](https://www.ihe.net/resources/technical_frameworks/#GenIntro) under "General Introduction and Shared Appendices" (https://www.ihe.net/resources/technical_frameworks/#GenIntro). This glossary is updated regularly as part of the IHE Development activities.

IHE Europe also provides a glossary at https://www.ihe-europe.net/sites/default/files/2016-03/IHE%20GEN%20%20Glossary.pdf