



Healthcare Interoperability Testing and Conformance Harmonisation

WP3:

D3.1 Set of test plans defined to experiment the
overall approaches

QMS for IHE Connectathon



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ABSTRACT
This document is defining a QMS for IHE Connectathon using the Interoperability Testing Quality Management System defined in WP1 in order to evaluate the overall approach. Specific examples of Patient Identification and Sharing of Patient Summary are given in Appendix A and B respectively.
KEYWORDS
Interoperability, quality, management, conformance testing, interoperability testing.

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1 INTRODUCTION

This document proposes a Quality Manual for the IHE Connectathon interoperability testing. The Quality Manual is describing a Quality Management System (QMS) for interoperability testing. The approach to QMS is process oriented and based on ISO 9000 [9]. Being a Quality Manual, the document does not have a chapter with conclusions. Effectively the conclusions of this work will be contained in deliverable D3.3 [25].

Gelöscht: event

The document is one of the deliverables of the FP7 Project HITCH [14]. It is based on two preceding HITCH deliverables, i.e. D1.2 Profile QMS Description [15] and D2.1 Tools selection [16].

Deliverable D1.2 provided a guideline and a checklist for defining an interoperability QMS, which can be implemented in any organisation that has as objective to perform interoperability testing of eHealth products. The guidelines presented in D1.2 were applied in this deliverable in order to be specific for the IHE Connectathon interoperability testing. Generic roles from D1.2 were replaced with corresponding IHE roles. In order to make the IHE Connectathon Quality Manual self-contained, parts of the text from D1.2 were repeated in this document.

Deliverable D2.1 [16] established an inventory of tools available in the field of eHealth interoperability and conformance testing. As testing tools are important element in achieving interoperability, this document takes into account the results of D2.1.

The examples of Profile QMS for Patient Identification and Sharing of Patient Summary that represent parts of the overall IHE Connectathon QMS are given in Appendices A and B respectively.

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- [25] [Feedback to the improvement of overall approaches described in WP1 \(QMS\) and WP2 \(tools strategy\)](#)

3 DEFINITION OF TERMS

Term	Definition
Audit	Audit is an independent, objective assurance and consulting activity designed to add value and improve an organisation's operations. It helps an organisation accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes. [based on 6]
Conformance testing	Testing the extent to which an Implementation Under Test is conforming to specific standards, guidelines or a specific profile.
Connectathon	An IHE Connectathon is an event at which health information technology (HIT) systems are tested for their interoperability and compliance with Actors and Profiles defined in the IHE Technical Frameworks. Such events are overseen by IHE National and Regional Deployment Committees. Testing is conducted under the supervision of a Connectathon Project Manager, project management team and test monitors. Successful results recorded at Connectathons are reported in the common Connectathon results database.
Pre-Connectathon Testing	The pre Connectathon testing is a session of testing realised by each participant at home in order to run specific test cases defined for such testing session. The logs and results of the tests are sent to the Technical Project Manager who will check and validate the tests.
Process	A process is a set of activities that are interrelated or that interact with one another. Processes use resources to transform inputs into outputs. Processes are interconnected because the output from one process becomes the input for another process. In effect, processes are "glued" together by means of such input output relationships.
Profile	In the context of standardization a Profile is a selection of definitions and options from standards or other specifications. Profiling is usually done in order to achieve interoperability between different products and implementations since a profile aims at harmonizing all systems implementing it to use the same messages and contents.

Term	Definition
	IHE's Profiles selects message, content and options from standards like HL7 or DICOM which are then implemented by all IHE-conformant systems. This ensures that IHE systems implementing the same Integration Profile are able to "talk the same language" in practice, thus enforcing interoperability between them. [8]
Profiling	The process of creating a Profile
Quality	The quality of something can be determined by comparing a set of inherent characteristics with a set of requirements. If those inherent characteristics meet all requirements, high or excellent quality is achieved. If those characteristics do not meet all requirements, a low or poor level of quality is achieved. [based on 9]
Quality Management System (QMS)	<p>A Quality Management System is a set of interrelated or interacting elements that organisations use to direct and control how quality policies are implemented and quality objectives are achieved.</p> <p>A process-based QMS uses a process approach to manage and control how its quality policy is implemented and quality objectives are achieved. A process-based QMS describes and manages a network of many interrelated and interconnected processes (elements).</p> <p>Each process uses resources to transform inputs into outputs. Since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input-output relationships. These process interactions create a single process-based QMS. [based on 9]</p>
Quality manual	A Quality Manual documents an organisation's quality management system (QMS). It can be a paper manual or an electronic manual. [based on 9]
Quality Plan	<p>A Quality Plan is a document that is used to specify the procedures and resources to perform the processes required to reach a set of quality objectives set as the final quality goals in the Quality Plan. Quality Plans also assign roles and persons to the corresponding tasks and specifies milestones to be reached within the scope of the quality plan.</p> <p>A Quality Plan is the result of Quality Planning.</p>
Quality Planning	Quality Planning is the process of creating a Quality Plan (see Quality Plan).
Testable assertion	A condition or capability needed by a user to solve a problem or achieve an objective that must be met or possessed by a system or system component to satisfy a standard, specification, or other formally imposed

Term	Definition
	document. [2]
System	A system in which the Implementation Under Test resides.
Test Execution	The process of running a test on the component or system under test, producing actual result(s). [2]
Test Plan	A document describing the scope, approach, resources and schedule of intended test activities. It identifies amongst others test items, the features to be tested, the testing tasks, who will do each task, degree of tester independence, the test environment, the test design techniques and entry and exit criteria to be used, and the rationale for their choice, and any risks requiring contingency planning. It is a record of the test planning process. [2]
Test Report	(Set of) document(s) that summarize(s) test results and other outcome information of a Test Execution. It also contains an evaluation of the corresponding test items against exit criteria. [based on 3]
Test Logs	Record of the test run traces that can be gathered by systems, proxy application, Sniffers or other test tools during test execution. Logs can be gathered at different levels.
Monitor	A skilled professional who is involved in the testing of a component or system. [2]
Validation	Validation is a process. It uses objective evidence to confirm that the requirements which define an intended use or application have been met. Whenever all requirements have been met, a validated status is achieved. The process of validation can be carried out under realistic use conditions or within a simulated use environment. [based on 9]

Table 1: Definition of terms, used in this document

4 ACTOR AND ROLES

This chapter defines IHE [8] actors and roles and their relationship. Figure 1 illustrates the overall organisation of IHE and the text elaborates the details of each role.

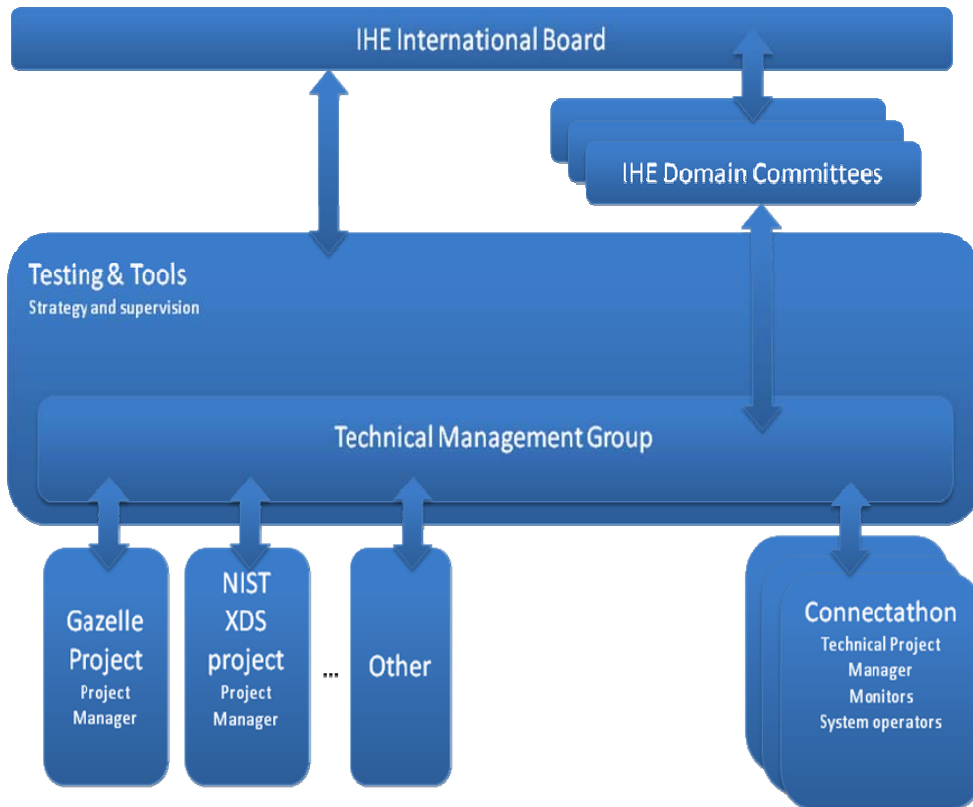


Figure 1: IHE Organisation

IHE International Board: The IHE International Board is the broadest oversight body of IHE and is responsible for overall management, direction, coordination and governance. It performs this by management of IHE international development activities, oversight of the deployment activities conducted by the national partner and regional deployment organizations.

Testing and Tools Committee : The Testing and Tools Committee is responsible for supervising and coordinating the testing activities conducted by National and Regional Deployment Committees and the development of testing software and other tools used in the testing process. Its responsibilities include:

- Developing and maintaining quality procedures for testing processes and events, including IHE Connectathons

- Coordinating the requirements gathering process for test specifications and test assertions for the IHE Profiles developed in the IHE Domain committees
- Developing, in conjunction with the Domain Coordination Committee, a consistent approach to ensuring testability of Profiles
- Coordinating budget and resources contributed to technical project management of testing activities by National and Regional Deployment Committees
- Securing funding for the development of testing software and related tools
- Managing and coordinating budget and resources, including funding, voluntary manpower and software libraries, contributed to development of testing software and related tools by National and Regional Deployment Committees, and other organizations
- Making recommendations to the Board with respect to intellectual property issues including licensing and use of testing software and related tools
- Providing guidance to the Technical Management Group (TMG) in its oversight of testing activities and development of testing software and related tools
- Coordinating development and maintenance of infrastructure used in testing process, including Websites

Testing and Tools Committee reports to the IHE International Board. It submits to the Board for its approval an annual report, which includes a plan and schedule for testing activities worldwide and a plan and budget for development of testing software and related tools to support these activities.

IHE Domain committees: IHE is organized by clinical and operational domains. In each domain users with clinical and operational experience identify integration and information sharing priorities and vendors of relevant information systems develop consensus, standards-based solutions to address them[14]. Each domain includes a technical committee, whose primary task is developing and documenting these solutions (known as integration profiles), and a planning committee, whose primary tasks are long-term scope planning and organizing deployment activities (such as testing events and educational programs). Each domain develops and maintains its own set of Technical Framework documents. Coordination among domains is the responsibility of the Domain Co-chairs Committee, comprising representatives from each of the domain planning and technical committees.

National/Regional Deployment Committees: IHE National/Regional Deployment Committees are recognised IHE entities responsible for deployment (testing, education, demonstrations and implementation-related projects) in their respective geographical areas. They sponsor and manage Connectathons and communicate about the event to the HIT industry and healthcare community in their region. National/Regional Deployment Committees are not shown in Figure 1.

Technical Management Group: Ensures technical consistency over the various tool development projects. It liaises with the tools development projects managers. It is responsible for the technical liaison towards domain committees and the Connectathon organization.

Tools Development Project Manager: Ensures the development of test cases and tools related to the integration profiles. Generally a tools development Project Manager

is dedicated to some domains or profiles or for some kind of tools (example: the XD* profiles are developed by the NIST team and the Gazelle management tool is supported mainly by the IHE-Europe team).

Technical Project Manager, main task is the technical coordination of the Connectathon. Each region is responsible for the organization of their Connectathon. In the current IHE hierarchy each region (Japan, Europe, North America...) there is a Technical Project Manager. The Technical Project Manager recruits, educates and coordinates monitors.

Monitors are members of the community who serve as independent test result evaluators during the Connectathon. Monitors examine tests in real time or examine evidence after the test. The group of Monitors supervised by the Technical Project Manager compose the **Testing Team** as defined in HITCH.

Systems are tested during the Connectathon. The **System Operator** is the person responsible of configuring and managing the system. In the IHE jargon the system operators are called the "vendors".

Auditor is a person performing the quality audit. IHE sees the need to have such a role in future but at this point in time this role does not exist.

5 QMS PROCESSES

5.1 Introduction

Today, it is a common requirement that eHealth systems support interoperability between health care organisations

Unfortunately, many eHealth systems are not well implemented according to agreed standards and not sufficiently tested for interoperability. This costs a lot of extra resources as many failures are discovered when the system is already in daily operation. The unexpected failure leaves customers and end-users with negative experience and may seriously affect a patient's treatment and in the worst case even patient safety.

To improve the quality of the implementation of the interoperability in eHealth, IHE has launched interoperability testing sessions called Connectathons where systems are tested in a controlled environment.

IHE Connectathon interoperability testing is highly dependent on a systematic approach and reliable documentation. The systematic approach includes development and maintenance of a set of Interoperability Testing Processes (described in chapter 7). The Interoperability Testing Process specifies the activities that need to be done before and during the IHE Connectathon. The activities can be repeated with consistent quality and will lead to the same level of quality independent of the individual person that performs the activities of the given process.

However, in some cases the full documentation or description of interoperability testing processes is not existing or sufficiently developed or maintained. The quality of interoperability testing is therefore dependent on the skills of the person in charge of running the test. Another problem could be that even if the full documentation exists, the actual test of a system is not following the agreed interoperability testing procedure, which leads to a situation where it is difficult to take appropriate, evidence based decisions on how to improve the work.

It is clear that the existence of interoperability Testing Processes is a prerequisite to achieve quality in interoperability testing. But, it is also important to continuously monitor the quality of the Interoperability Testing Processes themselves. This can be done by using a Quality Management System for interoperability testing processes, which is a set of activities aiming at continuously improving the quality.

The main objective of the QMS processes (QMS-P) is to continuously improve the quality of the Interoperability Testing Processes (IT-P).

The main objective for the quality processes is not to develop or specify any of the interoperability testing processes but only to improve the quality of the interoperability testing processes. The quality processes will address a number of questions regarding the interoperability testing processes to check and improve the quality. Below are examples of generic questions:

- Do the interoperability testing processes and activities descriptions exist?
- Are the interoperability testing process descriptions known by relevant actors?
- Are the interoperability testing process and activity descriptions used?
- Are the interoperability testing processes useable?
- Is the testing done by educated and skilled persons?
- Does the interoperability testing process support the achievement of the required interoperability?

The relation between the Interoperability Testing Processes (IT-P) and the Quality Management System Processes (QMS-P) is shown in Figure 2.

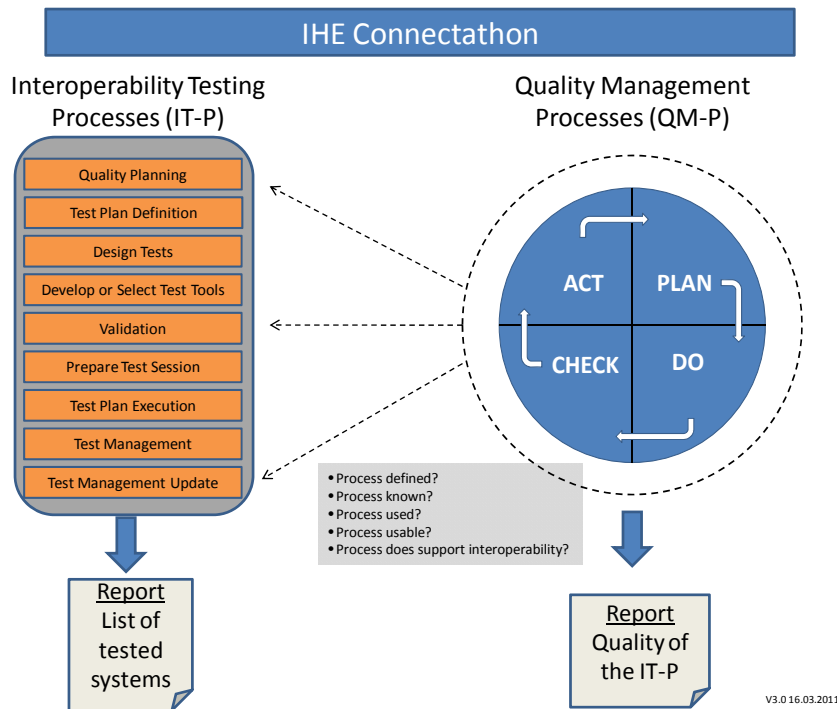


Figure 2 – Relation between interoperability Testing Processes and QMS Processes

Each of the IT-P has a specified output. For example the Design Test Process will deliver a Test specification. Generally, the IT-P will deliver a report with a list of passed systems.

The output from the QMS-P is a report, which describes the actual quality of the IT-P and can point out where the quality can be improved.

Experience from Quality Management in other sectors shows, that some persons will find Quality Management bureaucratic and narrowing and feel that the intention is to check and control. It is therefore important to emphasise that the use and implementation of the Quality Management System is a supporting tool with the aim to improve the quality of the interoperability testing. To achieve this aim it is necessary to understand both the aim for the Interoperability Testing and the aim for the Quality Management System and to find the right balance in the specification and implementation, so both support the main objective, i.e. to improve the interoperability of the systems, which are tested at IHE Connectathon events.

5.2 QMS principles for interoperability testing

The ISO 9000 family of standards represents an international consensus on good quality management practices. It consists of standards and guidelines relating to quality management systems and related supporting standards.

The ISO 9000 family of standards have defined eight quality management principles, which have been used for defining interoperability quality management principles. The ISO principles were listed in D1.2 [15]. The eight principles are relatively high level to be used in the daily operation of an IHE Connectathon. However this is also not the intention as they serve to a strategic frame and as inspiration to the continuous work by improving the interoperability testing. The principles are elaborated specifically for the IHE Connectathon in section 6.2 of this document.

5.3 The Quality Circle

The implementation of the Quality Management for interoperability testing, is a continuous cycle consisting of four steps of the process *“Plan, Do, Check, Act”* with the execution orders shown in Figure 3.

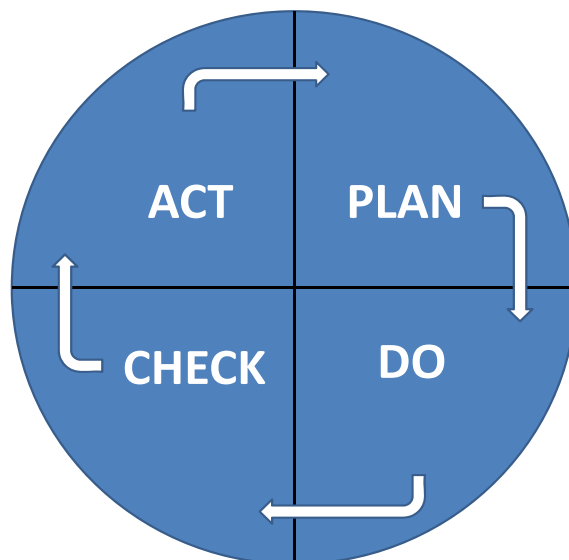


Figure 3 - The PDCA cycle includes four main processes

The PDCA cycle is a dynamic cycle that could be implemented for any process within an organization. It combines planning, implementing, controlling and continuous improvement.

PDCA is a methodology that can be used as a feedback loop so that the IHE Testing and Tools Committee can identify and change the parts of the process that needs improvements.

The PDCA cycle may therefore be used to meet the actual needs of IHE Connectathon and depending of the actual context, eq. interoperability testing of Patient Identification.

5.3.1 QMS Process: Plan

Objective	Establish the needed IT-P to deliver high quality interoperability testing for running an IHE Connectathon.
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Establishing the processes may include:

- Definition of the interoperability testing processes (chapter 7).
- Setting up an organisation chart (chapter 4)
- Preparing actor descriptions (see chapter 4)
- Establishing quality objectives and policies (see section 6.1)
- Communicating the quality objectives and policies to the organisation

The current IHE Connectathon Quality Manual specifies the IT-P to be used (chapter 7). The future work will be to "Plan" further development and maintenance.

5.3.2 QMS Process: Do

Objective	Implement the planned processes. Organize education material and training.
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Implementing the processes may include:

- Ensuring that work is performed by adequately trained and competent people in all aspects of Interoperability Testing for the eHealth domain
- Supervision where necessary
- Performing work in accordance with plans and procedures
- Ensuring that procedures are available where needed
- Access to suitable equipment and infrastructure

5.3.3 QMS Process: Check

Objective	Measure the processes and compare the results against the expected results to ascertain any differences.
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Check could mean any form of monitoring or measurement activity and may include:

- Measure the quality of the interoperability testing processes using visual inspection, complaints and feed-back loops

- An important pro-active check is performing audits to verify that plans and procedures are followed in practice – and are effective. Auditors should be trained and the audit should be designed to focus on verifying things that really matter
- Asking customers about their satisfaction with the IHE Connectathon interoperability testing – for example via a survey

5.3.4 QMS Process: Act

Objective	Analyse the differences and determine their cause. Determine where to apply changes that will include improvement.
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If a check has found discrepancies between the plan and what was done, there is a need to analyse the cause and act to improve the situation. In the Quality Management context, a discrepancy is referred to as a non-conformance. There are three types of improvement actions:

- Action to fix non-conformity. This is an action taken to rectify the immediate problem.
- Corrective action. This is an action to eliminate the cause of the non-conformance
- Preventive action. This is an action to eliminate the cause of a potential non-conformance (something may go wrong if we don't act)

5.4 Continuous improvements

The key to successful implementation of QMS and the PDCA cycle is to be systematic and pragmatic and focus only on areas that really matter.

The continuous improvement of the quality of interoperability testing will be based on a yearly report which describes the quality of the interoperability testing. This report is not substituting the PDCA quality cycles but can serve to capture the most important areas for improving the quality. It can also be produced when an audit process is in place.

A cycle of one year would correspond best with the frequency of Connectathon events. On the global level the Testing and Tools Committee would be the most natural place to control the quality of the overall PDCA cycle. The cycle needs to cover two major aspects, one related to testing and tools and the other to event organisation.

The testing and tools part of the task may be delegated to the Technical Management Group. On this level the main issue is improvement of tools for each of the domains. This level needs to coordinate PDCA quality cycles that every Tools Development Project Manager needs to establish for their respective area of responsibility.

For event organization the global level needs to see that there is consistency in approaches applied in all regions. For each regional Connectathon event a Technical

Project Manager responsible for the event should also establish a quality PDCA cycle. The Regional Deployment Committee should regularly examine the status and agree on corrections that may be required.

The annual cycles in IHE effectively exist already. However, revised cycle synchronisation and the formal documentation of quality cycles may bring improvements. This in particular means raising awareness of all actors on the quality cycle method of monitoring and improving processes, as well as adding or refining the related documentation.

6 QUALITY POLICIES AND OBJECTIVES

Customer satisfaction in eHealth is largely driven by delivering products and services which are interoperable. Today, more than ever, there is a worldwide trend towards meeting the customer expectation regarding quality and the ability to exchange data seamlessly across organisations.

The above trend raises also the awareness that continuous quality improvement is necessary to achieve interoperability.

6.1 Quality Policies for interoperability

This section describes the IHE Connectathon interoperability testing quality.

The quality policies will set the direction of all the activities that need to be performed. The approach to improve the quality of the interoperability testing is to follow a number of defined and agreed processes.

This includes activities for the Connectathon as well as activities before the Connectathon testing session itself.

The IHE Connectathon quality policy is defined through the following 10 statements:

1. IHE and its representatives which lead the Connectathon at the regional level are committed to deliver a high quality of the testing services that will allow verifying conformance and interoperability needs set by end-users, relevant regulatory authorities and national/regional programmes.
2. IHE Connectathons are to be conducted only by IHE National and Regional Deployment Committees recognized by the IHE International Board.
3. These organisations manage communications about the event to the HIT industry as well as healthcare community in their region. Therefore the quality policy needs to be communicated to IHE regional organisation staff, industry and healthcare community.
4. To enable the Connectathon organization to meet the agreed quality all of them need to provide the required input.
5. Any suitable feedback will be reported to relevant parties as IHE are committed to an open reporting culture.
6. Clear relationships between the needs of the end-users are established through the IHE domain committees, responsible to define open technical framework and profile specifications addressing the interoperability in its particular clinical or operational area of healthcare.
7. HIT industry and end-users are members of the IHE domain committees that have the responsibility to involve Technical project Managers.
8. The testing process shall be clearly described and communicated widely. It shall be supported by a test management tool and other testing tools. These tools shall be used as reference in the eHealth domain in order to evaluate

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conformance and interoperability among systems. This process, as a reference, can also be used by national/regional programmes for their own needs.

9. Resources (Technical Project Managers, Monitors and testing development team and experts) shall be well trained and recognized by the eHealth community.
10. IHE shall consistently strive to improve the quality through learning, sharing and participation and shall establish and maintain appropriate controls and conduct periodic reviews of the formulated quality goals.

6.2 Quality Objectives for Interoperability

The quality objectives for the Connectathon interoperability testing must be measurable and facilitate their evaluation for each cycle and therefore allow continuous comparison adjustment. The goal is to improve the overall quality of the interoperability testing year after year.

The IHE Connectathon quality objectives derived from the quality policy are:

1. IHE will continuously improve the quality of interoperability testing services;
 - a. Increase the number of key-vendors that are participating in the annual Connectathon
 - b. Increase the coverage and depth of testing
 - c. Increase the number of tested profiles
 - d. Increase the number of products that have successfully passed the tests at the annual Connectathon
 - e. Increase the number of experts and monitors
2. IHE will strive to maintain its position as the leading global interoperability testing organisation in its domains;
 - a. Increase the number of Connectathon events over the world
 - b. Increase the usage of the Connectathon events by national/regional programs
3. IHE will maintain an up-to-date interoperability testing environment that includes documentation and testing services;
4. IHE will provide a reference platform for eHealth interoperability testing. This includes the test management tool, other required test tools and a test case database that can be reused and adapted to different purposes;
5. IHE will communicate widely the quality policy and all information needed for Connectathon users;
6. IHE shall consistently strive to improve the quality through learning, sharing and participation and shall establish and maintain appropriate controls and conduct periodic reviews of the formulated quality goals.
7. Maintain the know-how related to the interoperability and conformance testing processes and disseminate that knowledge.

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For each of these objectives measures are listed in Table 2.

7 INTEROPERABILITY TESTING PROCESSES

Figure 4 introduces the interoperability testing processes under the IHE interoperability testing QMS.

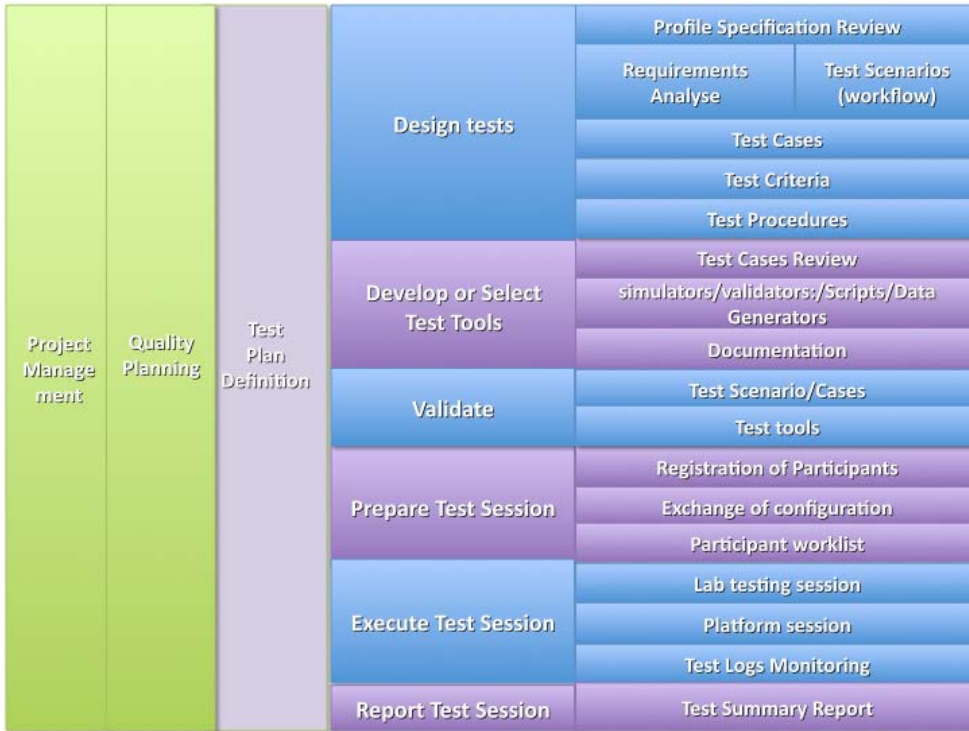


Figure 4: Testing Process and Activities

7.1 Quality planning

Objective	Quality planning defines the quality objectives and selects documents and tools where the quality shall be improved. Quality planning will also specify milestones and the resources for the work.
Input	Quality policies and objectives
Output	Quality Plan
Responsible	Testing and Tools Committee

7.1.1 The needs for Quality planning

IHE provides a detailed profile specification and a testing process to promote the adoption of standards-based interoperability by vendors and users of healthcare information systems. The process culminates in the Connectathon, a weeklong interoperability testing event.

The IHE Connectathon is the healthcare IT industry's only large-scale interoperability testing event.

The annual IHE Connectathons have during the years grown in size and thousands of vendor-to-vendor connections have been tested overall, and tens of thousands of transactions passed between the systems involved in testing.

The IHE Connectathon is well known and accepted as a considerable success, regarding the use of health informatics standards and to gain interoperability.

A continuation of the success is important, but as the IHE community and the annual Connectathons grow every year, it is important to continuously monitor and improve the quality of all steps in the interoperability testing.

A Quality Plan will specify the most important areas for improving the quality and thus ensure a focused used of resources.

7.1.2 Quality Plan for interoperability testing

To improve the quality of the Connectathon interoperability testing, the Quality Plan must be sufficient to achieve the required quality goals (quality policy and objectives) expected of the organization.

Quality Plan development is a team effort where exchange of information between team members during development is just as important as the resulting plans. The key objective is to create a cohesive dialog and subsequently develop awareness of potential or already known quality issues. Based on this awareness, project managers can prepare plans and actions to counter any weaknesses or deficiencies in the planning and execution, thus ensuring that all quality goals are met effectively.

The IHE quality policy and objectives are described in chapter 5 and can be translated into the following measurable requirements regarding the quality of the interoperability testing. The Connectathon Quality requirements are listed in Table 2 below.

IHE Connectathon Policy or objective	Quality requirement for Interoperability test	Measurable goal (indicators)
IHE will continuously improve the quality of interoperability services.	Increase the number of vendors and systems which are tested	List with numbers

	Increase the number of test performed. Make use of better tools for improved testing in terms of quality and quantity	List with numbers
	Increase test coverage	Number of assertions tested
IHE will maintain an updated work environment for interoperability documentation and testing services.	New profiles developing by the domains will be tested in the year N+1 after their publication Information is available in the website	Review the availability of the supporting tools for new profiles Review the updated website
Gazelle Management Tool becomes the reference for test management in eHealth	The number of unresolved bugs should be minimised The test cases database contains a large amount of test cases and is accessed by several user groups	Number of fixed bugs/Number of reported bugs Number of test cases per profile List of user groups
IHE will communicate its quality policy with its staff, members, vendors and partners and solicit their inputs to enable the organisation to meet their expectations.	The quality policy will be put on the web-site, including a form to receive inputs.	Available before the registration opens. The feedback to quality documents shall be encouraged and emailed to TPM.
IHE will have and maintain a clear policy with respect to access to testing results.	The NDA document will be available before the Connectathon event.	Available before the registration opens.
IHE shall consistently strive to improve the quality through learning, sharing and participation and shall establish and maintain appropriate controls and conduct periodic reviews of the formulated quality goals.	A quality review of the IHE Connectathon process will be held	Max. 2 weeks after the Connectathon
Increase awareness on achievements in improving the	IHE will organise presentations and education sessions	List of presentations done during the one year period.

interoperability and conformance testing process.		
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Table 2 - Connectathon Quality requirements and measures

7.2 Test Plan Definition

Objective	The test plan definition will describe the test strategy and its implementation: all activities are carefully defined and planned in order to test profile specification in the IHE Connectathon
Input	Quality Plan
Output	Test Plan definition
Responsible	Technical Project Manager

7.2.1 Scope

The scope of the test plan for one specific Connectathon, including the pre Connectathon testing, depends on the following items:

- The profiles selected by the participating systems i.e. for which domains/actors they have applied for testing [13];
- The test cases already available or to be implemented in the time frame;
- The number of new profiles for which a sufficient number of systems are registered;
- New requirements as they were expressed by the users or coming in through regulation.

Two types of tests are conducted during the Connectathon:

- Conformance testing:
 - the behaviour of the Domain/actors implemented by the system are tested against testing tools or other systems following test cases registered in the Gazelle Management tool;
 - In the case of the content profiles, the documents are tested against schematrons or the content is audited by a Monitor when the data are displayed;
- Interoperability testing: medical workflows where several systems are playing roles are tested and validated by Monitors, following test cases already described in the Gazelle Management Tool.

The Technical Project Manager (TPM) will select and build the testing corpus for each pre Connectathon testing and Connectathon:

- Profiles: they are all described in the Gazelle database. When they are new, the TPM will add and describe them in the database. The TPM generally selects

roughly about 45 profiles per Connectathon from the choice of 150 existing profiles;

- Test cases: After the selection of the profiles, the TPM selects the test cases related to the profiles and actors already registered in the Gazelle database. The number of test cases is 471. For new profiles, the test cases are defined by the TPM.
- Testing tools: the TPM selects the testing tools and Data samples already existing. In the case of new profiles, the TPM will plan with the tools development Managers the development of new tools and the creation of new data samples if needed.
- Training materials: the TPM prepares training materials and gives training for System operators on one hand and Monitors on the other hand. The already existing training materials are updated each year or for each Connectathon related to the new panel of profiles and selected tools; all the lectures are today given using webinar facilities.

7.2.2 Activity planning

Every year, the overall planning is as shown in Figure 5 (to be customised and detailed for every Connectathon)

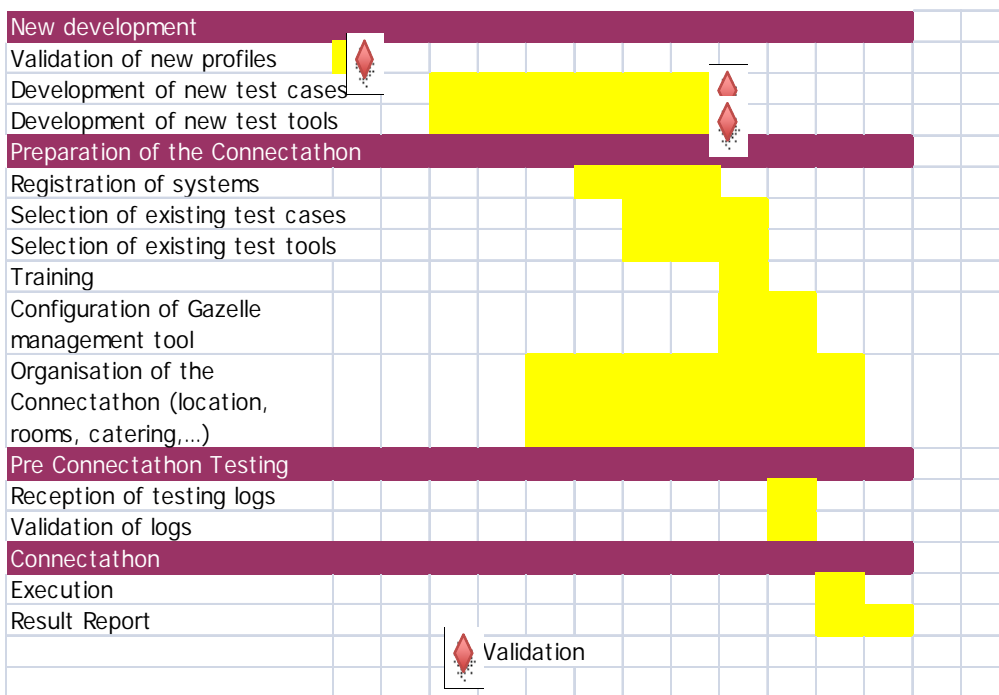


Figure 5: Planning over the year (in month units)

The Technical Project Manager (TPM) defines carefully the scope, taking into account the risk assessment that he has to establish. The Test plan definition is validated by the Test and Tools committee.

7.3 Design tests

Objective	The objective of the Test Design is to produce test cases that will test the requirements and define acceptance criteria which will be used during the test execution session
Input	Test Plan definition
Output	Test design specifications
Responsible	Technical Project Manager

When new profiles are written or existing profiles modified, the Technical Project Manager reads the profile and lists the assertions out of the profile in order to transform them in testable assertions.

In the next step, the Technical Project Manager uses the testable assertions as input and writes pre Connectathon test design specifications that assume each IHE actor in the profile will be tested with test software that does not require a second or third partner to be present.

For the Connectathon tests the Technical Project Manager reads the Technical Framework and writes two types of Connectathon tests:

- a. Unit tests are designed to involve two actors and test one or a small number of transactions in a profile. The target is to involve two systems if at all possible, allowing that sometimes a third system from a participant could also be required.
- b. Workflow tests are designed to include all or most of the actors in one or possibly multiple profiles (for example XDS + ATNA + PIX/PDQ + PCC content). These tests by definition involve multiple participating systems and test workflow from end to end.

The tests design shall include instructions for the testers to run the test and instructions to the monitors for verifying it. The difficulty of the exercise consists in defining the precondition for the test to be run, the scenario of the test and the list of acceptance criteria.

The tests are published to participants in advance of the Connectathon.

This activity is directly supported by the Gazelle tool Management that allows to describe actors and transactions, conformance and workflow test cases, normal conditions and default conditions for each profile.

For each test case, the following information is needed:

- Test case summary: keyword, name and type of test (pre Connectathon testing or Connectathon), peer, type, version;
- Test description: the description is the guideline for the Monitor and provides the purpose, description, and how to evaluate the test
- Test roles: gives information on the actors, transactions, number of tests to be realised, and the optionality;
- Test steps: for each step, given the actor roles, short description, type of message, optionality and the status with respect of the security.

Following the scope of the test plan definition, the TPM will select the existing test cases already available in the database and add the additional tests needed for the pre Connectathon testing or Connectathon.

The list of test cases is used for preparing the system work list.

7.4 Develop or Select Test Tools

Objective	The objective of this activity is to select, extend or develop new test tools needed to run the tests that were specified in the previous activity.
Input	Test design specifications
Output	A set of test tools (either developed or selected), specification of the tool requirements, developer and user documentation
Responsible	Technical Project Manager

Once the test design specifications are available, the TPM examines whether tools that can automate such tests are available or they need to be developed. The tools that are likely to always be required and used are test management tools. They will see continuous improvements in terms of functionality, stability speed, user friendliness and others. Other testing needs may be addressed by conformance testing tools and/or interoperability testing tools.

The TPM will also examine if additional configurations of the test management tool are needed and developed.

Where existing tools that could be used, are identified, the TPM needs to examine in detail whether the tools correspond 100% to the needs and selects one or more tools to be used. The examination needs to take into account many tool aspects starting from capability to perform specific tests but looking also at other aspects, for example documentation availability and quality, licensing regime etc. (see Deliverable D2.1[16]). If an existing tool has a promising potential but does not satisfy all the needs, the TMP should try to arrange that the tool is improved before being included in the selection of tools. The information on tools that are selected need to be communicated to the community, together with information on relevant discussion mailing lists or issue reporting mechanisms.

Where no suitable tools can be identified, the TPM needs to explore the possibility to have them developed in time for the upcoming events and defines a realistic development planning. The TPM may engage himself in the development or find external partners that are capable and ready to develop the tools. Irrespective of where the development takes place, the resulting tools need to satisfy the criteria set in D2.1 [16]. For newly developed test tools the users need to receive the same information as for selected tools. As new tools may be less stable than existing tools, the discussion list and issue tracking systems may prove to be even more important to have.

7.5 Validation

Objective	The objective of validation is to ensure and, to the extent needed, enhance the quality of test cases and test tools to a level that is found appropriate for using them for testing eHealth systems.
Input	Specification of the tool requirements, test design specifications
Output	Validation report
Responsible	Technical Project Manager

Current IHE guidelines make several statements related to validation. The main ones are:

- a. Each Technical Project Manager is responsible for the test definitions and validity of the tests
- b. Technical Project Managers will be asked to review results of a test written by someone else and will perform reviews by using the list of the profile assertions.
- c. Test review also happens before and during the Connectathon events when participants read the test definitions and then have the opportunity to ask how these are linked to requirements in the IHE Technical Profiles or other domain standards.
- d. Organizations developing test tools at times propose issue tracking mechanisms and mailing lists that could be used to discuss the way test cases and test tools are implemented

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While the above points are important for validation, the overall treatment of validation issues in the context of PDCA cycles could profit from being strengthened.

The following improvements are in progress:

- a. The review of test specifications should be subject to a formal peer review process. The list of items that need to be checked during peer review should be part of the quality documentation
- b. Whenever possible dedicated validation test runs should be arranged in order to remove the large chunk of initial errors in test implementation

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and verify that profile requirements are consistently understood. Traces from such early runs need to be thoroughly examined, checking all aspects that may be relevant (messages, message content (presence/absence, values), timing, and other conditions. It may be very useful to keep such traces for later use if new problems get reported.

- c. Problems found at any stage (early validation, pre-Connectathon and Connectathon) need to be reported through an issue tracking system
- d. Both the reported problem and the way the problem was resolved should be maintained and should be visible to all interested parties – systems, test managers, tool development managers, monitors and others
- e. It is good that the issue tracking system provides useful statistical information, for example the time required to fix the problem.
- f. A validation status of each test case could be maintained. The example statuses that could be used: a) validated b) in development c) suppressed d) suspended until revalidated.

The tool used to follow all reported bugs, traces and other validation information is the Jira tool [22]. The management of the test tools is divided by projects, one per test tool. For each project, the activity, planning, validation process, problems, etc. are reported and the access is opened to all members who want to consult information and the state of development.

7.6 Prepare test session

Objective	The objective of preparing a test session with all participants is mainly to reduce the risks associated with test sessions failing or not being able to start at all, thus putting unnecessary workload and time on the participants.
Input	Test design specifications , test tools
Output	Test session planning report
Responsible	Technical project Manager

The session will take the form of a 5 days face-to-face event, preceded by a 2-month period of in-house testing. During the in-house testing period system operators will have the ability to test their systems against simulators. They will have a test plan to follow and test traces to submit to the test manager as a proof of the good preparation of the system.

The test manager evaluates the test traces provided by each of the registered systems and accepts or refuses their participations to the face-to-face event.

System operators are trained during a 2-hour webinar that guides them through the testing process. The webinar is recorded and made available to the participants on the event web page.

Training material consists of:

- Reference material: It is composed of the IHE Technical Frameworks [13] corresponding to the tested profiles as well as the standards they are referencing.
- Test Plan: Participants to the Connectathon can access the Test Plan relevant to the systems they are testing through the Gazelle Test Management web application. Only the tests relevant to the system will be available to the participants. The test plan can be downloaded as a pdf document.
- Policies and Guideline documentation: Policies and Guidelines for the Connectathon are each time distributed through a web page dedicated to the particular event. Some documents are reused from a Connectathon to the other [10]. Some documents are adapted every year, as for example for the upcoming 2011 event in Pisa [18].

Monitors are trained during a 2-hour webinar that guides them through the face-to-face testing process. The webinar is recorded and made available to the auditors on the event web page. Monitors have access to all material available to the system operators. During the first day of the Connectathon new monitors are paired with an experienced monitor.

Monitors are recruited by the Technical Project Manager. Monitors recruitment is based on the neutrality and experience of the individuals. National IHE organisations are helping in recruiting monitors and are providing guidance on the neutrality and experience of the candidates.

In order to participate to the test session an SUT needs to support one or more of the domains tested during the session. During the two months that precede the Connectathon the SUT needs to pass pre-Connectathon tests in order to show evidence of their readiness to attend the event.

For every event there are logistics requirements that need to be addressed by the local organiser. These requirements are provided in a dedicated RFP [17].

Communication with system operators is performed through a mailing list. A detailed planning of expected actions is exchanged with the participants through the mailing list. Gazelle allows the participants to share the configuration parameters of their systems. They can provide configuration information about their systems and gather relevant configuration information from the test partners. Test plans are also shared with the participants to ensure a better preparation.

The test session planning report is written by TPM. It needs to verify that all the items listed above have been well covered for the event in question.

7.7 Test Plan Execution

Objective	Test plan execution includes pre Connectathon testing and Connectathon testing. The objective of the lab testing is to gather enough evidence that a system is well-prepared for the Connectathon, i.e. has chances to pass many tests in the Connectathon testing session.
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Input	Test design specifications, test tools, other systems, Connectathon platform
Output	Test execution planning report (including performance indicators, satisfaction questionnaires, ...)
Responsible	Technical Project Manager

Test plan execution during the Connectathon requires a set of performance indicators that facilitate monitoring of the test execution progress: number of test performed, systems not testing, systems currently testing with a set of other systems, configuration of the systems, etc. Performance Indicators from different viewpoints provide the Project manager with a synthetic measure that reflects the way testing is progressing at any point during the Connectathon event. Figure 6 presents different types of performance indicators used by the TPM.

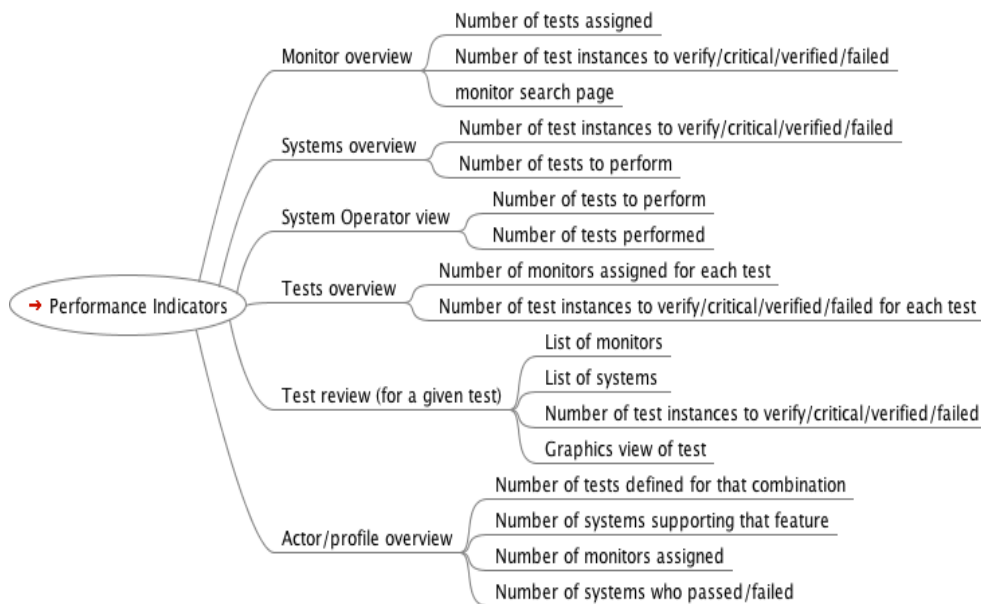


Figure 6: Connectathon performance indicators

In order to receive feedback from both participants as well as monitors, questionnaires are prepared in advance and distributed at the end of the Connectathon session. Three questionnaires are distributed related to the following topics:

- Logistics
- Technical, including feedback on the test tools
- Suggestions for test improvements giving precise feedback on particular test cases.

The TPM will analyse the questionnaires and prepare statistics and an action plan for the improvement of the testing process.

7.8 Test Management

Objective	The objective of the test management is to lead the testing process according to the test plan definitions and by respecting schedule, resources and budget.
Input	Quality Planning, Test Plan
Output	Project Management Documentation
Responsible	Technical Project Manager

The yearly activity of interoperability testing in IHE is a project itself and thus needs to be led and managed accordingly as a project. To do that, the Technical Project Manager has the responsibility to define:

- The planning and roadmap for all the tasks of the process, eq. by using for example Gantt charts;
- The budget for performing all project activities;
- The organisation of the project (roles and responsibility of each member of the team);
- Risk assessment
- Accounting and management report to follow the progress of the project.
- Reporting to the top level management

The overall planning for a one year period as shown in Figure 5 has to be further refined for each of the activities. Some of those activities will have rather simple plans where most important elements are start and end dates, resources required and related costs. Perhaps the task of development of new test cases could be considered as an example for a relatively straightforward activity in terms of project management.

The opposite example of a potentially complex project could be the development of a new test tool. Such a project could require teams with specific knowledge and skills, several phases in the development and consequent validation of test tools. In IHE such a task could be delegated to Tools Development Project Managers. They need to establish and maintain project management documents that for the tool development work they will be lead. Tools Development Project Managers need to align their plans with the overall plans under the responsibility of the TPM.

The preparation of the Connectathon requires that the TPM sets the objectives that are ambitious enough but also achievable within the time available. To do that the TPM needs to use past experience data as well as estimates of minimal, average and maximal duration for performing a set of tests and for evaluating the validity of the tests. This needs to take into account the fact that some tests will fail and that system operators may require time to fix their problems and rerun the tests. The stability of a given profile is affecting greatly the number of expected correction cycles and therefore the expected throughput of the event. As a result of such analysis, the TMP needs to plan which is the optimal number of monitors as well as which is the realistic number of test profiles that could be targeted for an event.

The organisation of the Connectathon event as such (location, rooms, catering, etc.) requires a different set of project management plans. The main responsibility for such project plans is with local organisers who need to coordinate this with TPM.

The testing during the pre Connectathon phase as well as during Connectathon is to a large extent a self organising activity.

For pre Connectathon testing, TPM task is to make all information on tools, tests and registration available to candidate companies in a timely manner. Once the TPM announces the start of pre Connectathon testing, systems do their testing independently and report their results to the TPM who in turn has to confirm that they are ready for participation in the Connectathon. The timing of pre Connectathon testing with respect to other activities is as shown in Figure 5. The window for pre Connectathon testing is as a rule large enough that every system should have enough time to perform their tests.

During the Connectathon, system operators see the list of potential partners for their test, establish the contact and agree to do their test. The test instance is registered in Gazelle and once the test is completed the results of a test instance are fed into Gazelle by one of the system operators. Monitors see the list of test instance results that need to be examined and register in Gazelle the test instance they will examine. After examination the result is registered in Gazelle.

System operators are trying to maximise the number of successful tests of their systems until they reach a desired status of 3 successful runs. Monitors are trying to clear the backlog of finished tests that have not been examined.

TPM is required to resolve any problem that may arise. The most critical problems are network problems or problems with the Gazelle tool as such problems block or delay the activity of all participants. Smaller problems are that individual systems are having problems setting things up, using Gazelle or scheduling their testing sessions.

The TPM is using Gazelle to have at his disposition performance indicators that show him how the overall testing process is progressing. Where a problem is identified, the TPM may need to take a corrective action. Such action could mean some reallocation of monitor tasks, additional technical assistance to some system operators, assistance in scheduling among critical partners and others as required.

Following a completion of a Connectathon event the TPM prepares a report that will be used for improving all aspects of future IHE interoperability testing, starting from management, test cases and test tools and finally including process description improvements.

7.9 Test Management Update

Objective	Two objectives are to be met: <ol style="list-style-type: none"> 1. Quality improvement of the testing process; 2. To maintain a stable and efficient test environment by updating the test plan definition in order to follow the life cycle of the interoperability specifications
Input	Project Management, Quality planning, test plan definition
Output	Action plan with proposed updates of Project Management, Quality planning, test plan definition and other relevant documents
Responsible	Technical Project Manager

Test Management Update is the process of controlling the deployment and maintenance of all testing processes. It starts with an audit of the previous cycle that has to be planned on a regular basis.

To maintain the stability of the environment, for each activity a regular report is delivered by the TPM in terms of the evolution of the tasks, workload, resources and problems.

Particular attention in IHE is given to the report and action plan after the yearly Connectathon event. At that point the TPM needs to report on all experiences that could be derived from that event. The report needs to specifically address findings from testing during pre Connectathon and during the Connectathon event. Such a report needs to indicate anything that is worth noting in relation to relevant test cases, test tools, test execution as well as in relevant quality documents.

The preparation of the report and the action plan will be based on data collected through Gazelle and on data from questionnaires filled by various types of participants. The TPM will analyse the sources and prepare statistics as well as the action plan for the improvement of the testing processes.

The report should be examined by the Testing & Tools Committee and should help improve Connectathon events in other regions and future Connectathon events.

In relation to the test cases it is important to report on:

- Test coverage (sufficient or needs to be increased)
- Test and related profile stability (profile stable but tests need improvements, both profile documentation and tests need improvement)

In relation to test tools the report needs to identify tools that are stable and performing well and tools that could be improved. Such improvements may mean improving the stability and/or reliability of the tool in question, need for additional functionality that would facilitate/accelerate testing or need to extend the number of test cases implemented in a tool.

The report needs to assess the extent to which planning for an event was accurate or there are lessons to be taken from the execution phase. For this analysis the initial plans, the achieved results and various performance indicators need to be processed in order to identify where improvements are required.

Last but not least, the report needs to address the experience of using the quality documentation. In the context of the PDCA cycle the report would belong to the "Check" phase. The Testing & Tools Committee as well as Regional Deployment Committees would make decisions and/or recommendations that should initiate the "Act" phase where the relevant quality documentation would be updated.

After the audit and the report, all the reported actions are used to update the management of the project in order to prepare the next cycle.

8 APPENDIX A: QUALITY MANAGEMENT FOR PATIENT IDENTIFICATION TESTING

8.1 Quality Planning

8.1.1 Objectives and Indicators

When testing the interoperability and conformance of one of several profiles IHE Connectathon quality objectives shall be applied. In the case of Patient identification and Patient Summary Document where the tools were selected in the deliverable D2.1 [16], few objectives shall be added:

1. Testing tools are adapted to the profiles (PIX and PDQ and XDS_MS profiles);
2. Testing tools give reliable results.

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The measurable goals are

1. The test results are, to the extent possible, evaluated directly by the tools;
2. The results are the same when the same test is repeated.

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8.1.2 Quality plan

In order to meet the objectives the following activities will be analysed and supported by specific actions:

1. Identify the list of the documents that are needed for designing tests: the documents are profiles specifications, list of the testing tools, guidelines for formalising the test cases and verify the missed documents
2. Identify the tools and their suitability: already described in the document D2.1 [16]. the evaluation will be based on the following item:
 - o Actors: existing simulators which simulate an actor (analyse if all functionalities are simulated)
 - o Messages: existing validators who validate the messages used in these two profiles
 - o Security: check if the simulators support TLS.
3. Validation of the tools and the execution of the tests: process of validation is described, bug report, development and maintenance planning available, development team is clearly identified for each test tool:
4. Identify if the training materials for the Monitors and implementers are sufficient and well documented: analyse the training materials (the training must describe the profiles, the test cases, the test tools and their usage, the test management tool used for checking the tests,...) , monitor guidelines available, training planning available and accessible for the Monitors,

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5. Identify the coverage of the test cases: check if the test cases are in line with the assertions defined in the specifications.
6. After execution, check the number of test cases made by each system.
7. Provide a questionnaire to the operators and monitors to provide their feedback

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Actions	To be done	Priority
List of documents	Template "list of document report"	3
List of tools	Template of "list of tools" indicating the gap	1
Validation of the tools	Template "Validation of the tools report";	2
Training	Monitor guidelines	1
	Template for Analysing the training material	3
	Training planning and evaluation of the training session	3
Coverage of the tests	Template for analysing the test cases	2
	Report of the tests by SUTs	1
Questionnaire	Participant and monitor feedback	1

8.1.3 List of the deliverables

- List of documents
- List of tools document
- Monitor guidelines
- Report of the evaluation of the training process
- Report of the evaluation of the test coverage
- Participant feedback

All the deliverables are based on generic templates but refined specifically for the Patient identification and Patient Summary areas. The templates must be available before each activity of the testing plan.

8.1.4 Risk assessments

Identified risk	level	Reasons	Action
Templates not ready on time	high	Too many templates to define The definition is too complex	Reduce the number of actions to be done Reduce the complexity
Information is not available	Medium	The information is available but is dispersed in many places	List information sources where the information is available
The quality plan is too detailed and not consistent with the objectives	high	Define clear quality indicators which can be easily met with the right actions	Review very often that the quality plan meets the objectives

8.2 Patient Identification Test Plan Definition

8.2.1 Scope

The scope of the test plan is to define all the activities needed for testing the systems implementing the two profiles:

- Patient Identifier Cross Referencing (PIX)
- Patient demographics Query (PDQ)

The specifications of the two profiles are described in the ITI technical framework [21]:

- http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Rev7-0_Vol1_FT_2010-08-10.pdf
- http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Rev7-0_Vol2a_FT_2010-08-10.pdf
- http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Rev7-0_Vol2b_FT_2010-08-10.pdf
- http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Rev7-0_Vol2x_FT_2010-08-10.pdf
- http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Rev7-0_Vol3_FT_2010-08-10.pdf

The tests of the national extensions are out of the scope of the next Connectathon.

8.2.2 Test plan

For Patient Identifier Cross Referencing (PIX) the Actors which will be tested are summarised in the Table 3.

Actors	Transactions	Optionality	Section
Patient Identity Source	Patient Identity Feed [ITI-8]	R	ITI TF-2a: 3.8
Patient Identifier Cross-reference Consumer	PIX Query [ITI-9]	R	ITI TF-2a: 3.9
PIX Update Notification [ITI-10]		O	ITI TF-2a: 3.10
Patient Identifier Cross-reference Manager	Patient Identity Feed [ITI-8]	R	ITI TF-2a: 3.8
PIX Query [ITI-9]		R	ITI TF-2a: 3.9
PIX Update Notification [ITI-10]		R	ITI TF-2a: 3.10

Table 3: PIX actors

For Patient demographics Query (PDQ) the Actors which will be tested are summarised in the Table 4.

Actors	Transaction	Optionality	Section
Patient Demographics Consumer	Patient Demographics Query [ITI-21]	R	ITI TF-2a: 3.21
	Patient Demographics and Visit Query [ITI-22]	O	ITI TF-2a: 3.22
Patient Demographics Supplier	Patient Demographics Query [ITI-21]	R	ITI TF-2a: 3.21
	Patient Demographics and Visit Query [ITI-22]	O	ITI TF-2a: 3.22

Table 4: PDQ actors

When the Patient Demographics Supplier Actor is in interaction with actors in other IHE profiles that perform patient information reconciliation activities (e.g., Radiology PIR), the PDQ Supplier Actor may use the updated information to respond to PDQ Queries. In addition, the Patient Demographics Query Profile may play an integral workflow role in conjunction with other IHE Profiles.

8.3 Design Tests

The test cases are already defined and available in Gazelle management Tools [19]. 31 test cases are available for PIX profile and 26 test cases for PDQ profiles (including test cases for PDQ-v3). The tests cases covered conformance and interoperability testing.

The test cases for the PIX profile selected to be tested at the Connectathon are:

- PIX_FEED: The **Patient Identity Source** actor must demonstrate 3 functionalities :
 - admit/register a patient
 - update a patient
 - patient identity merge
- PIX_CLIENT: the purpose of these tests is for the Patient Identity Cross Reference Consumer to query the Patient Identity Cross Reference Manager for a patient IDs in one domain, given the patient ID in another domain.
- PIX_SEED_MANAGER: the purpose of this test is to place well-known patients in each PIX Manager. These records have all a global patient ID with the master Assigning Authority used at the Connectathon.

The test cases for the PDQ profile selected to be tested at the Connectathon are:

- PDQ_EXACT_NAME : Query: by ID, names for the patient and other fields
- PDQ_MULTIPLE_QUERY : Multiple type of queries
- PDQ_CONTINUATION_TEST : Continuation in query response

8.4 Develop or Select Test Tools

No new tools will be developed for the Connectathon.

The tools that are available are listed in Table 5. The tools in grey will be used during the Connectathon in Pisa.

	Test Cases	Message Content Validation	Workflow	Test Management
TTCN-3	Yes	Yes	Yes	Yes
Open eHealth	No	Yes (some Schematron available for HL7v3 messages)	Yes	No
OHT	Yes	No	No	No
Gazelle	Yes	Partly (only through calls to external tools)	Yes	Yes
Mesa Tools	Yes	Yes but limited to some fields	Yes	No
HL7v2 Validation NIST	No	Yes	No	No
HL7v2 Validation INRIA	No	Yes	No	No

Table 5: Patient identification tools

8.5 Validation

The following test tools are validated and the bugs are reported in [22].

The report in January 2011 gives the following status of bug resolution:

- HL7 V2 validation INRIA Tools : 6 bugs reported : 4 solved and 2 created
- Gazelle management tool: 50 created and 42 resolved

For the Connectathon 2011, PIX/PDQ profile testing, the relevant input document is the Technical Framework - Revision 7.0. The transactions are specified in Volume 2a. The actual test cases are made available made known in Gazelle and pre-Connectathon tools.

Test cases are validated together with the tool that implements them. Tests are run during pre-Connectathon testing and possible problems are reported. Any deficiencies found in the pre-Connectathon tools are fixed by the developers of the tool in question. Any problems found in test case description in Gazelle are to be fixed by the TPM.

For reporting problems and related discussions a dedicated mailing list is set up. For PIX/PDQ profile ihe_pix_pdq_testing@googlegroups.com is used.

8.6 Prepare Test Session

Training: the training is common to all the profiles that will be tested during the Connectathon. The training material is available at the following URL: <http://gazelle.ihe.net/?q=node/58> [23].

Test cases: the test cases are distributed to all registered systems and the systems must be configured for the Connectathon.

Pre Connectathon testing: the test logs are to be uploaded in the specific area opened for each system registered in the Gazelle Management tool.

The Connectathon 2011 information web page is <http://gazelle.ihe.net/?q=node/58>. All information is available, including Policies and Guidelines at <http://gazelle.ihe.net/?q=node/128>.

A blog is also opened which gives specific information on the Connectathon process.

8.7 Test Plan Execution

The test plan execution for the current year applies and there are no specific actions for the Patient identification.

As for the other profiles, the TPM will monitor performance indicators for PIX/PDQ profile and relevant actors and take action to maximise the outcome of the event, will prepare statistics and action plan for future improvements.

HITCH deliverable D3.2 [20] is preparing a questionnaire that will specifically collect information relevant for assessing the quality of IHE IP-T processes from the perspective of Patient identification testing participants.

8.8 Test Management

Project plans for patient identification follow the overall yearly planning. Test cases have been stable and there is no new test case or test tool development.

For the testing in the Connectathon it should be noted that Patient identification testing can follow version 2.3 or version 3.0 of HL7 standard.

Version 2.3 of patient identification was present during several preceding Connectathon events. The number and complexity of tests are such that there should be no problem that all actors finish all foreseen tests during the event.

The patient identification implementation of v3.0 of HL7 in the systems coming to Connectathon could potentially be less stable. Therefore, it is to be expected that a larger number of correction cycles may be required before a successful test instance is eventually achieved. Monitors are likely to need a bit more time to examine such test traces and confirm their correctness. Therefore the TPM should pay a bit more attention to v3.0 patient identification test instance indicators.

8.9 Quality management review for 2011 Patient Identification

The questions about the availability of relevant descriptions, tools etc. for Patient identification are to be answered by a focus group.

The audit process will also focus on

- The availability of the documentation according the answers from the focus group ;
- The report of the TPM at the end of the Connectathon.

9 APPENDIX B: QUALITY MANAGEMENT FOR SHARING OF PATIENT SUMMARY TESTING

In the case of the Sharing of patient summary, the quality objectives will focus on testing the semantic interoperability:

1. The tests will evaluate if the presentation of the shared data to the end-user (HCP) is semantically correct and match with the sending data.

The measurable goals could be the number of test cases which take into account the semantic aspects and the organisation of the data when displayed.

9.1 Quality Planning

See section 8.1: the quality planning is merged with the quality planning for the Patient identification profile.

9.2 Test Plan Definition

9.2.1 Scope

The scope of the test plan is to define all the activities needed for testing the systems implementing the profile:

- Cross-Enterprise Sharing of Medical Summary (XDS-MS)

The specifications of the profile are described in the PCC technical framework [24]:

- http://www.ihe.net/Technical_Framework/upload/IHE_PCC_TF_Rev6-0_Vol_1_2010-08-30.pdf
- http://www.ihe.net/Technical_Framework/upload/IHE_PCC_TF_Rev6-0_Vol_2_2010-08-30.pdf

The tests of the national extensions are out of the scope of the next Connectathon in Pisa.

9.2.2 Test plan definition

There are two actors in the XDS-MS profile, the **Content Creator** and the **Content Consumer**. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles and is out of scope of this profile.

9.3 Design Tests

The test cases are already defined and available in Gazelle management Tools:
<http://gazelle.ihe.net/GMM>

Two test cases are defined for the Connectathon in Europe

1. **XDS-MS Document Scrutiny:** The purpose of the test is to look for proper document structure, proper use of coded values and any other CDA or IHE specific requirements defined in PCC TF 3. The Document Source should use the same documents produced in the XDSMSDocumentLoad test (or similar documents if those cannot easily be exported). The Monitor will take the files offline and perform evaluation. The monitor will document any deficiencies and ask the Document Source system operators to correct them during the Connectathon.
2. **XDS-MS Embedded process:** A XDS-MS Document Consumer is required to support Discharge Summary and Referral documents. There are four processing options defined for the Document Consumer: View, Document Import, Section Import and Discrete Data Import. In this test, the Document Consumer locates two documents produced by a single Document Source. The Document Consumer demonstrates which of the 4 processing options are supported for each document.

No new test cases are planned to be designed.

9.4 Develop or Select Test Tools

No new tools will be developed for the Connectathon.

The tools that are available are listed in Table 6. The tools in grey will be used during the Connectathon in Pisa.

	Test Cases	Message Validation	Content	Workflow	Test Management
Gazelle	Yes	Yes, through call to external tools		Yes	Yes
NIST CDA Validation	No	Yes, Schematron based validation of exchanged the document		No	No
INRIA CDA Validation	No	Yes, Schematron based validation of exchanged the document		No	No
iheos	Yes	Yes, validation of the		Yes	No

		transport message		
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Table 6: Patient summary tools

9.5 Validation

The following test tools are validated and the bugs are reported in [22].

At this point in time, no bug is reported for the schematron tool.

9.6 Prepare Test Session

See section 8.6. No specific information for this profile.

9.7 Test Plan Execution

The test plan execution for the current year applies and there are no specific actions for the Cross-Enterprise Sharing of Medical Summary (XDS-MS).

As for the other profiles, the TPM will monitor performance indicators for XDS-MS profile and relevant actors and take action to maximise the outcome of the event, will prepare statistics and action plan for future improvements.

HITCH deliverable D3.2 [20] is preparing a questionnaire that will specifically collect information relevant for assessing the quality of IHE IP-T processes from the perspective of Patient identification testing participants.

9.8 Test Management

Project plans for patient identification follow the overall yearly planning. Test cases have been stable and there is no new test case or test tool development.

There is nothing specific required in term of management for XDS-MS testing.

9.9 Quality management review for 2011 Sharing of Patient Summary

The questions about the availability of relevant descriptions, tools etc. for Sharing of Patient Summary are to be answered by focus group.

The audit process will also focus on:

- The availability of the documentation according the answers from the focus group ;

- The report of the TPM at the end of the Connectathon.