Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of

Patient Summary and electronic Prescription

D3.C.1 Appendix-B - Proof of Concept Testing Strategy Details

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ABSTRACT

"D3.C.1 Appendix-B - Proof of Concept Testing Strategy Details" is a revision and major update of **"D3.9.2 - Testing Methodology, Test Plan and Tools"** from epSOS Phase 1. It revises the epSOS testing strategy as defined in D3.9.2, in order to comply with the latest requirements and information in epSOS Phase 2.

In order to test a system, a test strategy has to be defined that describes the strategic approach and goals of the organisation conducting or managing the test. The test strategy forms the normative basis from which all other test activities are dependent on.

This document describes the test approach to be adopted during the construction of the epSOS Architecture and ICT Infrastructure required for the implementation of the epSOS Large Scale Pilot (LSP). It establishes normative standards, a foundation for the test planning, the test techniques and methods, the processes required to support the test effort, the definition of the test environments as well as the test execution and evaluation for the respective tests.

The discussion and content of this document start from some standard test concepts, ideas and recommendations from the members of the epSOS Work Package 3.9.

This document is normative for epSOS and its partners during the development and construction of the ICT Infrastructure. Parts of this document are normative for Participating Nations (PN), as it

defines criteria that are to be adhered to for those entering their systems into Test Phases that are operated and managed by epSOS. Specifically this concerns the test phases:

- Conformance Test (CCT) (pre-Projectathon)
- Service Interoperability Test (SIT) (Projectathon)
- Pre-Pilot Test (PPT)

The following Test Phases are not normative for PN and are only intended to provide PN guidelines:

- Component Unit Test (CUT)
- Component System Test (CST)
- Component Integration Test (CIT)

The Test Plan and Testing tools, developed to verify epSOS systems interoperability are defined and described in this document.

The criteria to define test data are provided in this document as input to WP3.10 (epSOS Phase 1) and to WP3.C (epSOS Phase 2).

Goals, Prerequisites, organisational aspects of Projectathon, the epSOS event to verify system interoperability, are described. Test generation and the implementation of Projectathon was a key task of WP3.10 in epSOS Phase 1, and now a key task of WP3.C in epSOS Phase 2.

The core of the revised epSOS Testing Strategy is presented in the main document D3.C.1; while this appendix provides further details for the testing concepts and assets as they are utilized in epSOS.

Change History

Version	Date	Status Changes	From	Details	Review
V0.0.1	16/11/2009	Draft	S.Sampson	First draft Testing Strategy	WP3.9
V0.0.6	10/08/2010	Draft	S.Sampson+ WP3.9 WG A	Final version of Testing Strategy, the basis for this document	WP3.9
V0.1	10/08/2010	Draft	S.Sampson	First full draft of D3.9.2	
V0.2	18/08/2010	Draft	M.Melgara	Structure of the document reworked	
V0.3	01/09/2010	Draft	S.Sampson	Comments and input from ANDA.	
V0.4	01/09/2010	Draft	M.Šimegh	Add questions and open issues for PAT	
V0.5	02/09/2010	Draft	S.Sampson	Corrections and input from F2F in Paris 24/25 August. Conclusion and further	

				additions in respect to Test Data Generation in #3.8.	
V0.6	06/09/2010	Draft	M.Melgara	Formatting and alignment to D3.9.1	WP3.9
V0.7	23/09/2010	Draft	S.Sampson	Comments from the CRS	WP3.9
V0.8	24/09/2010	Draft	M.Melgara	Version for the External Review	WP3.9
V0.9	06/10/2010	Draft	M.Melgara S.Sampson	Version for the PEB Approval, including external review comments. Additional section 2.6.	WP3.9
V1.0	15/10/2010	Final	J. Artmann	Removed line numbering, updated doc status	WP5.3
V1.1	17/08/2012	Draft	M.Yuksel	Renamed the document title to "D3.C.1 - Proof of Concept Testing Strategy" from "D3.9.2 - Testing Methodology, Test Plan and Tools" and updated the overall content by complying with the latest information from the epSOS Project in 2012.	WP3.C, TPML, PC
V1.2	22/08/2012	Draft	K. Bourquard, M. Yuksel	Karima provided comments and updates from IHE-Europe's perspective. Mustafa went over them to produce the next version.	WP3.C, TPML, PC
V1.3	15/10/2012	Draft	TPML, M.Melgara, M. Yuksel	Marcello and TPML provided comments and some updates. These are applied to the document by Mustafa. Conformance gates are slightly updated with the observations from the latest PPT-slot. Finally, the document is restructured to address reviewer comments.	TPM, NEPCs
V1.4	26/11/2012	Draft	G. Heja, M. Yuksel	Detailed corrections and feedback by Gergely are applied.	TPM, NEPCs
V1.5	10/12/2012	Draft	N. Repas, M. Yuksel	Norbert's input for coverage and quality metrics is integrated.	TPM, NEPCs
V1.6	21/12/2012	Final	G. Heja, J. Thorp, M. Yuksel	Updated according to the final remarks by Gergely and final quality review by Jeremy	All

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1 Introduction

The following is taken from epSOS Annex I, i.e. the Description of Work (DoW). [AnnexI]

Information and communication technologies (ICT) are deployed on a broad scale in healthcare by most epSOS participating nations (PNs). In view of its key priorities of citizen mobility and borderless healthcare, the approach outlined by the European Commission in the eHealth Action Plan is to help ensure the seamless pan-European flow of information between interoperable national systems for the benefit of patients.

In view of the complexity and diversity of national eHealth applications and the tremendous work invested, only little attention has been given so far to international interoperability. The strategic approach of the European Commission is to focus on the core applications of electronic prescription and Patient Summary to serve as “gate-openers” to achieve interoperability on a European scale.

The overarching goal of epSOS (Smart Open Services for European Patients) is to develop a practical epSOS Architecture and ICT infrastructure that will enable secure access to patient health information, particularly with respect to a basic patient summary and ePrescription[1], between European healthcare systems.

The large scale pilots’ main approach is to implement a small set of agreed use cases and an analysis of both existing and foreseeable national solutions. They will be used to design pilot systems that are based on the principle of interconnecting the respective national solutions.

A National Contact Point (NCP) has to be established by each participating country, acting as a bidirectional way of interfacing between the existing different national functions provided by the national IT infrastructures and those provided by the common European infrastructure, created in epSOS. The National Contact Point takes care of external and internal national communication and functions in epSOS and the semantic mapping (if necessary) between information on either side.

The NCP also acts as a kind of mediator as far as the legal and regulatory aspects are concerned. The NCP creates the conditions (by supporting trust, data protection and privacy) for a trusted relationship with other countries’ NCP’s. [AnnexI]

Taking into account the above from Annex I, the goals of WP3.C are:

- To assure PNs that their NCP can integrate and be interoperable with other NCPs from other PNs

[1] Since epSOS Annex I was published the eDispensation service has been identified as a requirement.

- To provide clear testing guidelines for all that wish to participate in the Large Scale Pilot (LSP).
- To ensure that key interoperability issues that would possibly be a problem are eliminated prior to the LSP.
- To provide a safe and secure interoperable epSOS Infrastructure that protects the Health Professionals' (HPs) and Patients' interests.

It is not within the responsibility of epSOS to set the participating nations' goals and success criteria. However, PNs can employ any of the test phases described in this document and the contained success criteria.

epSOS sets the goals and success criteria for the test phases that lie within their responsibility, which are described in this document.

1.1 Background

1.1.1 epSOS Scope

The following is taken from epSOS Annex I.

epSOS scope is to investigate, build and evaluate a service infrastructure to enable cross border interoperability of ePrescription and Patient Summary services, to facilitate patients' mobility, according to the European Commission's recommendation.

The service infrastructure will demonstrate the interoperability between two or more regional/national eHealth infrastructures, allowing the exchange of computer interpretable data and human understandable information.

epSOS will identify means of interoperability which will allow connectivity of services and architectures that are potentially different in every Participating Nation (PN), and to provide Patient Summary (PS), ePrescription (eP) cross-border services.

epSOS will define, develop and test services to allow a patient from country A while being in country B, to exploit eP and PS services available in country A. [AnnexI]

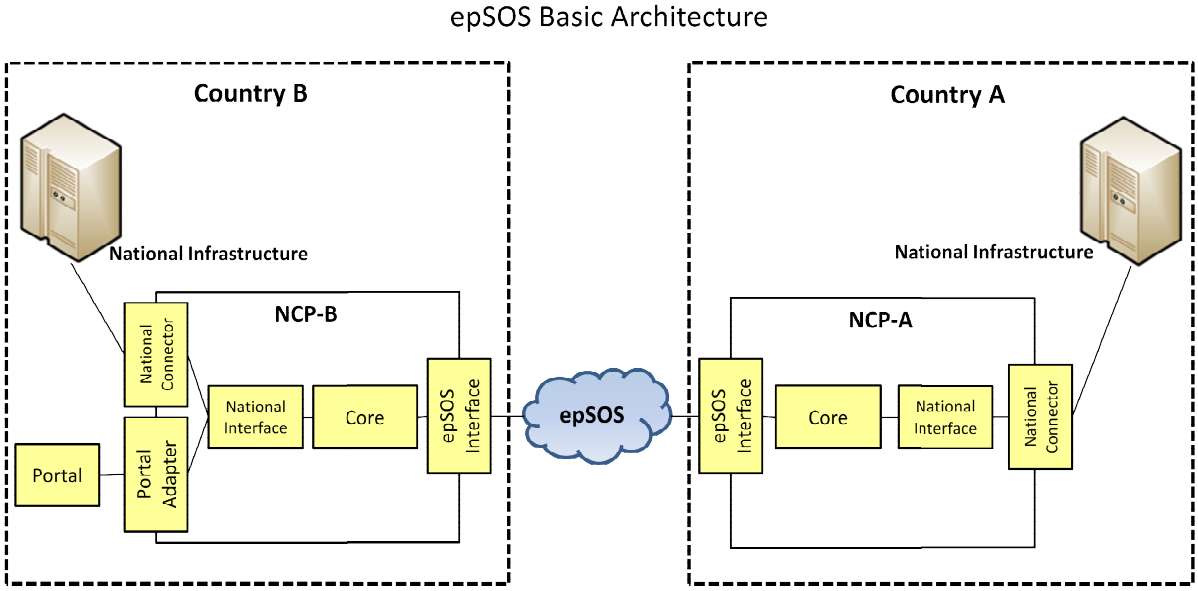


Figure 1 - Basic Architecture

In Phase 1, epSOS has specified precisely the interoperability standards and profiles for communication between NCPs from different PNs. These interoperability specifications have been defined by the output of WP 3.3 Architecture, WP3.4 Common specification components, WP3.5 Semantic Services, WP3.6 Identity Management, WP3.7 Security and Privacy. Together, these specifications along with some refinements specified in **[D3.9.1]**, form the detailed specifications that NCPs have to comply with when sending and receiving information to / from other NCP's. These specifications establish the foundation against which, testing of NCP implementations need to be tested in order to ensure interoperability of NCPs with each other, irrespective of their location and detailed software design.

According to Project Executive Board (PEB) decision on 04/05/2010 in accordance to previous indications of PEB and Project Steering Board (PSB) to define and develop as many common software components as is necessary, epSOS has developed service software modules, conforming to the WP3.8/3.9 High Level Design Document that can be integrated into a PN NCP to facilitate implementation by PN NCPs in the epSOS Infrastructure.

In Phase 1, epSOS has provided Participating Nations with an NCP-in-a-Transparent-Box solution, a set of software components intended to facilitate a seamless integration of their National Infrastructure to the epSOS Infrastructure. The NCP-in-a-Transparent-Box offers a common application interface (National Interface) allowing the PN to develop a bridge to their National Infrastructure. This may require that Participating Nations adapt their own National Infrastructure or the common software components to achieve their integration in the epSOS environment.

In addition epSOS has made a Web Portal (Portal) available to the Participating Nations providing them a simple interface to be used by Country B for retrieving Patient Summaries (PS), ePrescriptions (eP) as well as for issuing eDispensations (eD).

In addition to these efforts, in Phase 2, epSOS has initiated an OpenNCP effort within the scope of WP3.B, which is based on the NCP implementation of SRDC, a beneficiary of epSOS, and the already existing open source common components of epSOS provided by its subcontractors. The aim is to provide, through a collaborative effort by the PNs and the industry, all the common building blocks that are necessary for an NCP software as open source and free software to all PNs. Similarly with NCP-in-a-box, the PNs will again be provided simple Application Programming Interfaces (APIs) to integrate their National Infrastructures. The first version of OpenNCP that is compliant with epSOS Phase 1 specifications was released on November 9, 2012, and then the implementation will be continuously updated.

Through WP3.C, epSOS will try to verify that any NCP solution adapted by a PN (based on NCP-in-a-Transparent-Box, OpenNCP or any other development effort) can be integrated into the epSOS Infrastructure, and that the NCP is interoperable with NCPs of other PNs.

epSOS provides a reference test environment as part of the building of the epSOS Infrastructure, a set of test tools and cases that will enable the PN to verify with a high degree of certainty that their NCP implementation conforms to the epSOS Interoperability Specifications. A number of System Integration Test Phases will be conducted with original anonymous data retrieved from the electronic Prescription and Patient Summary services of Country A.

Within the scope of epSOS Phase 2, in addition to PS and eP services, some new and extended services have been defined as well by WP1.4:

- Health Care Encounter Report (HCER) Service
- Medication Related Overview (MRO) Service
- Emergency 112 Service
- Patient Access Service
- EHIC Service (only definition, no implementation during epSOS lifetime)

When the technical specifications for these services are ready, the test assets of epSOS will be updated by the 3rd party responsible for providing the test environment, tools and cases (namely IHE-Europe) as well.

1.1.2 Out of Scope Elements

epSOS will not integrate the service modules into the PN's NCP. The integration of the service modules into the PN's NCP will be done by PN in the epSOS framework under their own responsibility.

epSOS will not verify that an NCP of a Participating Nation can be integrated or is interoperable with their own National Infrastructure. However, the testing strategy will cover the steps for Participating Nation to perform to verify the integration of their NCPs in the epSOS Infrastructure.

1.1.3 Test strategy definition and test tool development streamline

Test strategy and testing tool development was consolidated in WP3.9 in epSOS Phase 1 and in WP3.C in Phase 2, and is documented in this document.

Test data generation and testing execution were assigned to WP3.10 in epSOS Phase 1 and to WP3.C and PD4 in Phase 2.

A summary of strategy definition, specification and implementation activities in this respect is provided below:

Strategy definition: Definition of the overall Testing Strategy: the goal of the activity is to agree on the global methodology to be applied to perform the interoperability testing of the NCP adapted/implemented by the PNs. Alternatives were submitted to PEB/PSB whereby every PN develops and performs its tests, and test tools and data are generated by the Project. A further proposal was that the epSOS Beneficiaries developed tests, or a specialised expert entity would perform most of the activities. In epSOS Phase 1, the core team defining the overall testing strategy was managed by ELGA, in strict co-operation with IHE Europe:

- PEB/PSB decided in favour of the Project developing the test tools.
- IHE-Europe, an epSOS Beneficiary, was assigned the task to define and develop the testing tools and simulators, given that the majority of profiles to be tested are existing IHE profiles. IHE-Europe testing activities were assigned to WP3.9/3.10 for their technical management. Within the definition of the overall Testing Strategy, it was analysed the way in which interoperability testing has to be performed:
- NCP Interoperability testing is performed in an individual Connectathon, organised and managed by IHE-Europe, and called Projectathon. The Projectathon is not limited to epSOS PNs, but open to vendors and other entities wanting to qualify their products and systems against epSOS specifications. So far, three Projectathons have been organized: the first as an epSOS-only activity in Slovakia in November 2010, and the second (Pisa, April 2011) and third (Bern, May 2012) in conjunction with the European Connectathon. The next Projectathon will be again in conjunction with the European Connectathon, in Istanbul in April 2013. It is the objective of the overall epSOS Testing Strategy to make epSOS testing a part of regular Connectathons, especially European ones. This will allow the gradual inclusion of PNs and services in the epSOS LSP.

Specification: Definition of testing methodology (also called “epSOS Testing Strategy”), identifying test phases, test targets, responsibilities, in line with the overall Testing Strategy. The testing methodology also includes guidelines to PNs on how to perform integration, testing and post-deployment testing. The test strategy activity was managed by Gematik GmbH (a German beneficiary) in epSOS Phase 1, and by SRDC (a Turkish beneficiary) in Phase 2.

Definition of test tools and simulators: the activity aims to optimise the development of testing tools, by identifying the re-usability of already existing tools developed by IHE. Gap analysis between standard IHE Profiles and epSOS defined profiles in WP3.3, 3.4, 3.5, 3.6, 3.7 was performed in epSOS Phase 1, trying to minimise the delta. The activity was performed by IHE-Europe and the aforementioned WP Leaders.

- The decision to use Gazelle, the testing environment developed by IHE-Europe was taken by epSOS. It will also be used as a remote reference testing environment.
- Definition of Test Plan: Test scenarios and profiles to be tested were described and inserted in the Gazelle system, an overview of which can be found in this document. IHE-Europe and ELGA were responsible for this activity in epSOS Phase 1.

In epSOS Phase 2, WP3.C leader SRDC has revised the requirements of testing in epSOS, by concentrating mostly on the technical capabilities of the testing environment provided by IHE-Europe. These revised requirements are now an appendix to the main D3.C.1 document; D3.C.1 Appendix-A - Revised Requirements of epSOS Testing Environment. In cooperation with IHE-Europe, an improvement path for the existing testing environment has been planned and put into practice.

Implementation: Implementation of the overall testing environment, tools and test cases is an ongoing activity. In epSOS Phase 1, in accordance to a release plan agreed with Fraunhofer ISST and Elga Team (F.E.T.) and in line with the PN development and testing plan, the first versions of all these testing assets were delivered by September 2010, which were then continuously updated before and during 2011 Pisa Projectathon and the first Pre-Pilot Testing (PPT) slot in 2011/2012. The implementation activity is led by IHE Europe, with relevant contributions from epSOS experts, in particular the Semantic Group for the development of the Schematron to test the epSOS documents based on the CDA, and the WP3.C leader as explained in the previous paragraph. In epSOS Phase 2, the improvement of the existing testing assets by IHE-Europe is still progressing.

1.2 Scope of this Document

1.2.1 Goals

The goal of this document is to communicate the test approach that will be followed within epSOS. It defines:

- the standards to be employed and adhered to
- the test levels and phases to be supported
- the test environments to be created
- the test methods and techniques to employ
- the statistics defined to measure progress
- the processes to be implemented to support the test effort
- the Test Plan definition strategy
- the Test Data definition strategy
- the testing activities to be conducted based on the selected implementation activities
- the guidelines for the logistical organisation of the Projectathon[2]
- the testing approaches to be followed at the Pre Projectathon (pre-PAT) and Projectathon (PAT), including criteria to participate
- the testing approaches to be followed at the Pre-Pilot Testing (PPT), including criteria to participate

1.2.2 Targeted Audience

The test strategy is aimed at all those involved in the conception of tests for components directly related to and defined within the scope of the epSOS architecture and ICT infrastructure. Furthermore it clarifies for all involved the epSOS test strategy, including epSOS project members, Participating Nations, suppliers and vendors.

It is expected that the reader has an understanding of testing vocabulary and concepts.

[2] For an overview of the Projectathon see Chapter 7.

1.2.3 Scope

This document provides prerequisites and guidelines for the test planning, test design, test implementation, test execution and test evaluation processes.

It is currently restricted to the testing conducted during the construction of the epSOS architecture and ICT infrastructure. This covers testing activities up to and during the LSP. It does not cover testing beyond the LSP and for migrations to new releases after the LSP, although it should be used as a basis for the continued work.

It is applicable for the development of systems undertaken by epSOS, and to the organisation that assumes the responsibility for its implementation and testing.

It does not provide a test strategy for the Component Unit, Component System and Component Integration Testing phases of components or systems defined by Participating Nation or the Industry.

1.2.4 Document Structure

This document is an appendix to the main deliverable D3.C.1 - Proof of Concept Testing Strategy, which presents the core of the epSOS Testing Strategy and Approach. Taking into account the comments of reviewers, a single document that contains all the information related with the testing strategy is composed into one main document presenting the core, and an appendix (this document) providing further details.

epSOS Testing Strategy and Approach as presented in the main D3.C.1 document first describes the details of the epSOS Testing Strategy, which gathers the criteria to participate to test phases that are under the responsibility of epSOS, namely pre-PAT, PAT and PPT. It also encompasses some concepts defined in the ISO/IEC 9126 for better explaining the epSOS testing approach.

Supporting D3.C.1, this document has six further chapters and an annex:

- **General Conditions** where terminology, standards and the testable services are described.
- **epSOS Testing Methodology** lists the features of the system that are to be tested, and describes the test levels, phases, and environments. In addition, it characterises the test infrastructure, defines the test methods and design techniques, defines approval and signoff and what and to whom status and statistical information is to be sent, and lists the supporting processes.
- **epSOS Test Plan Definition** describes the test plan with respect to the specifications of the WP3.X and the Test Strategy already defined in WP3.9 / WP3.C.
- **Testing Tools** lists the tools that are made available to testers prior to and during epSOS test phases.

- **Testing Plan Structure** presents the actors and the test cases that are defined for epSOS test phases.
- **epSOS Projectathon** provides a brief overview of the Projectathon and the logistical steps that are taken prior to, during and after the Projectathon.
- **Annex** lists References, Glossary and Abbreviations.

2 General Conditions for Test Strategy Definition

2.1 Terminology

All terminology unless otherwise specified here is taken from the “ISTQB Glossary of Software Testing Terms” **[ISTQB]**.

2.2 Standards

The relevant standards that are taken into account for test strategy definition are:

- IEEE Std. 829-2008 Standard for Software and System Test Documentation. Abstract: Test processes determine whether the development products of a given activity conform to the requirements of that activity and whether the system and/or software satisfy its intended use and user needs. Testing process tasks are specified for different integrity levels. These process tasks determine the appropriate breadth and depth of test documentation. The documentation elements for each type of test documentation can then be selected. The scope of testing encompasses software-based systems, computer software, hardware, and their interfaces. This standard applies to software-based systems being developed, maintained, or reused (legacy, commercial off-the-shelf, Non-Developmental Items). The term "software" also includes firmware, microcode, and documentation. Test processes can include inspection, analysis, demonstration, verification, and validation of software and software-based system products.
- IEEE Std. 1012-2004 Standard for Software Verification and Validation Abstract: Software verification and validation (V&V) processes determine whether the development products of a given activity conform to the requirements of that activity and whether the software satisfies its intended use and user needs. Software V&V life cycle process requirements are specified for different software integrity levels. The scope of V&V processes encompasses software-based systems, computer software, hardware, and interfaces. This standard applies to software being developed, maintained, or reused [legacy, commercial off-the-shelf (COTS), non-developmental items]. The term software also includes firmware, microcode, and documentation. Software V&V processes includes analysis, evaluation, review, inspection, assessment, and testing of software products.
- ISTQB Glossary of Software Testing Terms **[ISTQB]** Abstract: Much time and effort is wasted both within and between industry, commerce, government and professional and academic institutions when ambiguities arise as a result of the inability to differentiate adequately between such terms as ‘statement coverage’ and

'decision coverage'; 'test suite', 'test specification' and 'test plan' and similar terms which form an interface between various sectors of society. Moreover, the professional or technical use of these terms is often at variance with different meanings attributed to them.

- An exception here is the use of the term "Test Plan". As this term already has a strong usage within epSOS it will be retained, but is used interchangeably and synonymously with the term "Test Specification". The term "Test Concept" replaces the ISTQB term "Test Plan" but retains its meaning.

2.3 Services

2.3.1 National Contact Point

"A National Contact Point (NCP) acts as a legal entity which creates a secure link between the epSOS trust domain and the national trust domain. It is the only component that has an identity in both domains." **[D3.3.2]**

2.3.2 epSOS Support Services

"There are a number of information sources which are relevant for every NCP and must be in the same state for every NCP. Examples for this are common taxonomies, schemas, and WSE addresses of NCPs. This shared data is centrally managed in order to avoid inconsistencies and version conflicts in the epSOS network.

Services are implemented within an NCP by using a static configuration table. It is the responsibility of each NCP to keep the configuration up to date from centrally managed data storage." **[D3.3.2]**

All of the support services are covered by the Configuration Manager that is described from a high level design perspective in #5.3 of D3.9.1 and the implementation details can be found in Appendix A of the same document.

2.4 Projectathon

epSOS organises and manages Interoperability Testing events, to check the compliance of the PN and vendor implemented systems to the epSOS Interoperability Profiles.

To prevent confusion with the IHE Connectathon, epSOS has renamed it to Projectathon. While the approach is the same, the actors and profiles have been adapted to the requirements of epSOS.

A more detailed description of the epSOS Projectathon is provided in # 7 epSOS Projectathon.

2.5 Pre-Requisites

2.5.1 Reference NCP Implementation

In epSOS Phase 1, epSOS provided a reference NCP-in-a-Transparent-Box implementation for the following reasons:

1. To prove that all defined concepts and requirements as described in the various specifications (WP 3.1 through WP 3.7) can be implemented and tested.
2. To ensure that specification, design, implementation and test issues are identified as early as possible preventing unnecessary delay and extra costs through problems that are identified too late in the implementation or test process.
3. To allow PNs to test their own country specific NCP implementations against an epSOS internally (epSOS / F.E.T. / a Consortium including Vendors) tested[3] reference implementation. This ensures that PN's own interoperability issues are identified and remedied earlier.
4. To allow PNs to integrate their National Infrastructure with an epSOS internally (epSOS / F.E.T.) tested reference implementation. This is in the event that a PN chooses to adopt the NCP-in-a-box solution.

Since epSOS / F.E.T. have developed reusable modules that can be included in a proprietary PN NCP or any other relevant software solution, as expected the reference implementation was also built around these reusable modules.

Reference NCP implementation was only within the scope of epSOS Phase 1, specifically until the activities of the F.E.T. were terminated. In epSOS Phase 2, there is no single reference implementation.

2.5.2 Open Source NCP (OpenNCP)

In epSOS Phase 2, the development of open source and free epSOS components that are compliant with the epSOS interoperability specifications has been initiated based on the legacy open source core components from epSOS Phase 1, and the NCP implementation of one of the epSOS beneficiaries, namely SRDC.

The OpenNCP is a collection of the common components with the aim of constructing an NCP. The responsibility of the development and testing of the components have been divided into several mini-projects, each responsible of a logical collection of components. The first version of OpenNCP that is

[3] The NCP installation will be first approved at the epSOS Projectathon.

compliant with epSOS Phase 1 specifications was released on November 9, 2012, and then the implementation will be continuously updated. The development repository is available at: **http://code.google.com/p/epsos-common-components/**.

2.6 Participating Nation and Industry Responsibility

The following provides the Participating Nations and the Industry an overview of their responsibilities in relation to this document. Each item is followed by a reference within this document where further information can be found.

- It is the Participating Nations and Industry responsibility to test their solutions in order to achieve a suitable robustness before entering the Conformance and System Integration (Projectathon) Test Phases. As a guideline the following testing phases can be utilised:
    - Component Unit Test # 3.1.8.1
    - Component System Test # 3.1.8.2
    - Component Integration Test # 3.1.8.3

    The decision as to which test methods or test design techniques are to be used for these test phases is at the discretion of the Participating Nations and Industry.
- PAT registration # 7.2.3.1
- PAT / Gazelle education # 7.2.3.1
- Familiarisation with the Conformance and System Integration Test Tools and Simulators # 6 (and all sub-chapters).
- Familiarisation with the Conformance and System Integration Test Plan # 5 (and all sub-chapters) that provide an overview of the:
    - Roles
    - Test Cases
    - Workflows
    - Supporting Information
- Familiarisation with the Projectathon # 7.1 and the Participating Nation Activities # 7.2.3 (and all sub-chapters).
- Establish a Laboratory Test Environment # 3.3.1
- Import the Test Data # 3.8.1 (information pertaining to definition) # 3.8.4 (location of data)

- Conduct the Conformance Test # 3.1.8.4 & # 7.2.3.1
- Conduct the System Integration Test # 3.1.8.5
- Conduct the Pre-Pilot Test # 3.1.8.6

3 epSOS Testing Methodology

3.1 Test Levels, Types and Phases

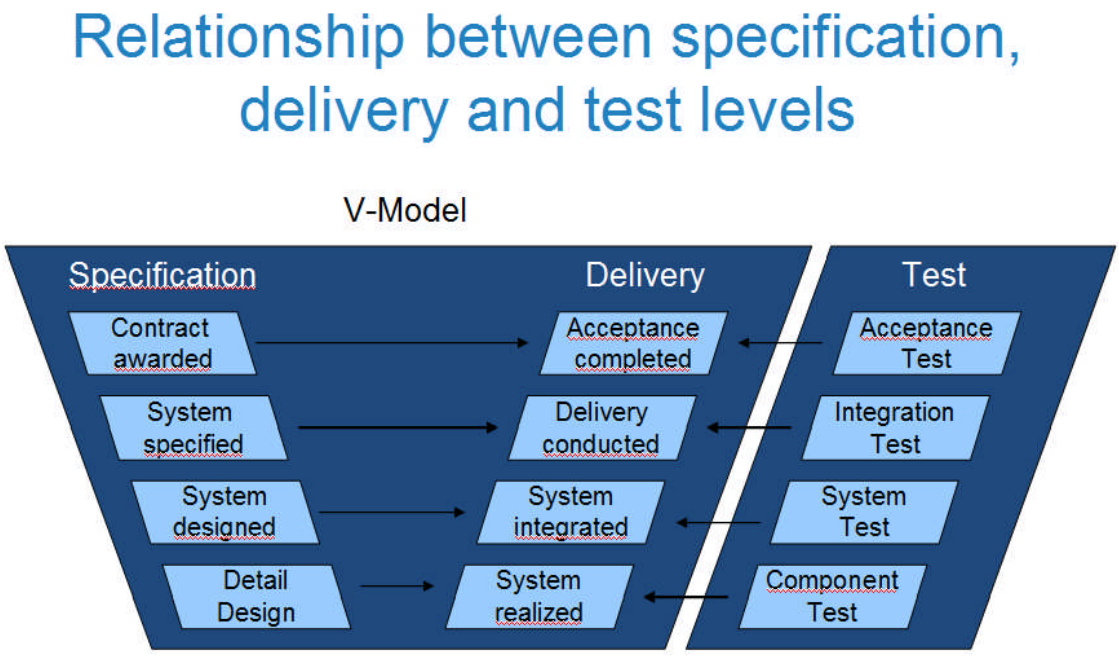
3.1.1 Test Levels

Test Levels are a group of test activities that are organized and managed together. A test level is linked to the responsibilities in a project. Examples of test levels are component test, system test, integration test and acceptance test.

This strategy defines four levels of test:

- Component
- System
- Integration
- Acceptance

The following figure shows the relationship between the levels and their respective specification and delivery levels. The two left hand columns are taken directly from the V Model. The right hand



column is the mapping of the test levels onto the V-Model.

The following sections describe The Test Levels in more detail.

3.1.2 Component Test

Component test is the testing of an individual software component.

The goal of the component test is to assess in a laboratory test environment, whether the test object has implemented accordingly the functions and interfaces and has fulfilled the non functional requirements as specified.

A Component for the purpose of epSOS can be a discrete software module or a sub-system. In relation to the NCP it can be the specific classes defined that make up a component or a complete component (transformation manager, configuration manager, etc.). During this test phase the components that make up a system (e.g. NCP) must be integration tested with each other.

3.1.3 System Test

System test is the process of testing the integrated components as a complete system in a laboratory test environment whose goal is to verify that it meets accordingly the specified requirements of the epSOS project.

Within the scope of epSOS, a system is a complete software system such as an NCP-A or NCP-B.

3.1.4 Integration Test

Integration Testing can be broken down into two categories:

Component integration testing: Testing performed to expose defects in the interfaces and interaction between components. This type of integration test is carried out within the Component or System Test level.

System integration testing: Testing performed to expose defects in the interfaces and interaction between systems; exercising those external interfaces (e.g. Electronic Data Interchange, Internet and OCSP Responder etc.).

With respect to epSOS this test concerns itself with the integration of the NCP-A and NCP-B, the Portal, and the other central services.

3.1.5 Acceptance Test

Acceptance Testing is the formal testing conducted in a production or production type environment with respect to user needs, requirements, and business processes. It is carried out to determine whether or not a system satisfies the acceptance criteria and to enable the epSOS project or any other authorised entity to determine whether or not to accept the system into an operational environment.

3.1.6 Test Types

The building of an epSOS Architecture and ICT infrastructure cannot be regarded as a classical development project where at the end a single component or system is delivered. It requires the development of multiple components and systems from differing Participating Nations and epSOS, with each undertaking their own internal development and test process. Components and systems that are submitted to epSOS will be verified during a Projectathon[4] and then during a Pre-Pilot Testing (PPT) slot as being able to integrate with other components or systems.

The test phases are logically categorised to a Test Type to help distinguish the test focus. For the purpose of this test strategy the following types have been defined:

- Component
- Service
- Pilot

The following sections expand upon the Test Types describing the purpose, responsibility, entry and exit criteria.

3.1.6.1 Component Type

The Component Type concerns the testing of a component or system in the Component and System Test Levels, covering such phases of testing as Component Unit Test, Component System Test, Component Integration Test and Component Conformance Test.

The goal of the Component Type test is a component or system that is verified as fully integrated and ready to be deployed as a service for further interoperability and pilot tests.

3.1.6.2 Service Type

The Service Type concerns the testing of an integrated component or system with other such systems, covering the interoperability testing phase. While the focus of the component type tests is local, the service type tests are global focusing ultimately on verifying interoperability with systems outside of its local infrastructure boundary.

The goal of the Service Type test is a component or system that is verified as interoperable with other integrated components or systems.

[4] For an overview of the Projectathon see chapter 7.

3.1.6.3 Pilot Type

The Pilot Type concerns the testing of an integrated and interoperable component or system covering the Pre-Pilot testing phase.

The goal of the Pre-Pilot Type test is a component or system that is verified as interoperable with other integrated components or systems and is ready to be operationally deployed.

3.1.7 Test Approach

3.1.7.1 Test Steps

The test approach is broken down into five distinct steps.

- **Test Planning** is the activity of establishing or updating a test concept.
- **Test Design** is the process of transforming general testing objectives into tangible test conditions and test cases.
- **Test Implementation** is the process of developing and prioritising test procedures, creating test data and, optionally, preparing test harnesses and writing automated test scripts.
- **Test Execution and Comparison** is the process of running a test on the component or system under test, and producing the actual result(s). Furthermore it involves the identification of the differences between the actual results produced by the component or system under test and the expected results for a test.
- **Test Evaluation** is the process of summarising all test activities and results. It also contains an evaluation of the test process and lessons learned.

3.1.7.2 Test Artefacts

Many test artefacts are created during the test steps, of which some can be file based as well as some tool based. It must be possible for the purpose of communication to generate some or all of the tool based artefacts into file based versions.

The following summarise those artefacts:

- **Test Plan** is the 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, 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.

- **Test Condition** is an item or event of a component or system that could be verified by one or more test cases, e.g. a function, transaction, feature, quality attribute, or structural element.
- **Test Design Specification** is a document specifying the test conditions (coverage items) for a test item, the detailed test approach and identifies the associated high level tests cases. When test conditions are tool based, this document must be generated directly from the tool.
- **Test Case** is a set of input values, execution preconditions, expected results and execution post conditions, developed for a particular objective or test condition, such as to exercise a particular program path or to verify compliance with a specific requirement. Test Cases can be captured in a tool, when not they are captured directly in a Test Specification.
- **Test Case Specification** is a document specifying a set of test cases for a test item. When test cases are tool based, this document must be generated from the tool.
- **Test Data Specification** is a document that describes the test data for test cases. This is an optional document that is created when the test data definition is maintained separately from the test case.
- **Test Script** is the term commonly used to refer to a test procedure specification, especially an automated one.
- **Test Suite** (Workflow Test (IHE Terminology)) is a set of several test cases for a component or system under test, where the post condition of one test is often used as the precondition for the next one.
- **Test Data** is data that exists before a test is executed, and that affects or is affected by the component under test. It refers to the actual test data as defined in the test data specification. Test Data should exist as an external entity in the form of a database or file; definition directly within a test script is not preferred.
- **Test Log** is a chronological record of relevant details about the execution of tests. These can be file or tool based.
- **Defect Report** is a document reporting on any flaw in a component or system that can cause the component or system to fail to perform its required function. These can be file or tool based.
- **Test Summary Report** is a document summarising the testing activities and results. It also contains an evaluation of the corresponding test items against exit criteria. These are file-based, taking some of their data directly from tools.

The figure above places the artefacts within their respective steps.

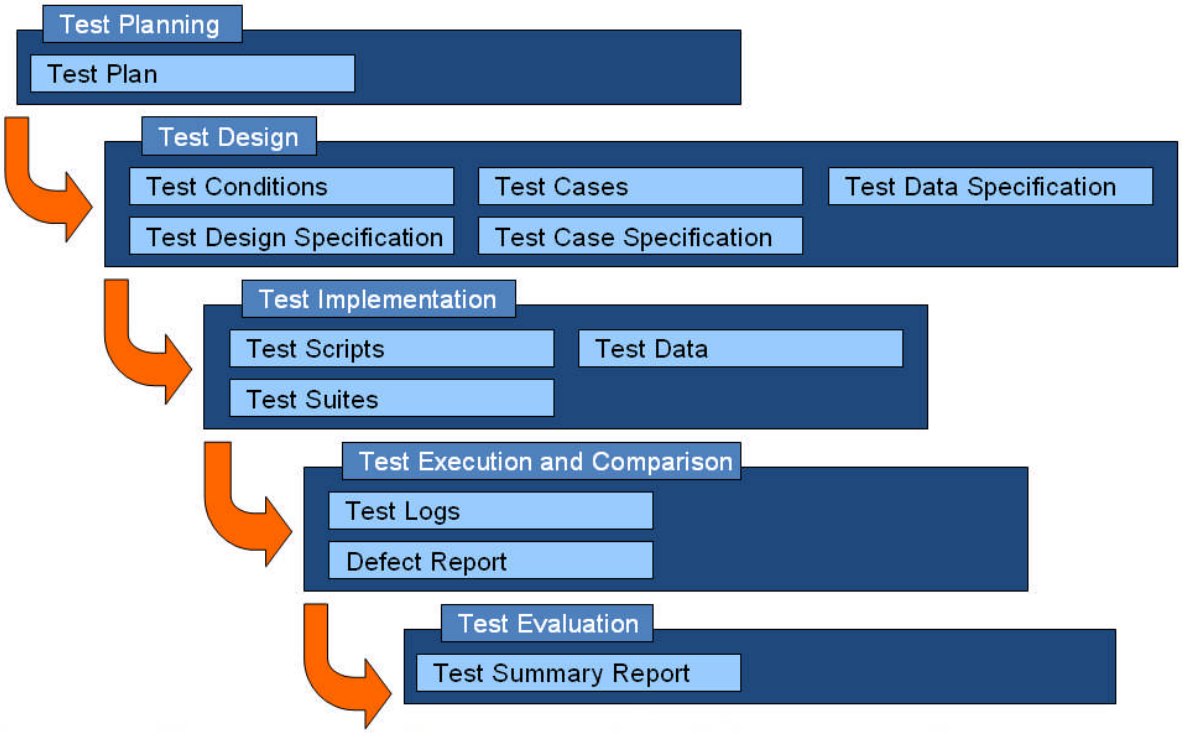


Figure 2 - Actions and Artefacts

3.1.8 Test Phases

Test phases are a distinct set of test activities collected into a manageable group.

The term "phase" may suggest a strict chronological order. However, this is only partly correct, in principle:

- Component level tests precede the System and Integration level tests.
- The Component Test Phases precede the Service Test Phases which themselves precede the pre-Pilot test.

However, tests in a following phase can be conducted so long as the entry criteria for this phase have been met and where applicable dependent tests have been conducted. This requires that a Test Concept defines the Test Phases with their own entry and exit criteria superseding that of this Test Strategy. While this has the advantage of speeding up the test it requires additional effort and analysis in defining the Test Concepts.

This test strategy supports the following Test Phases:

- Component Unit Test (CUT)

- Component System Test (CST)
- Component Integration Test (CIT)
- Conformance Test (CCT) (Pre-Projectathon)
- Service Interoperability Test (SIT) (Projectathon)
- Pre-Pilot Test (PPT)

The following figure shows the relationship between the test levels and phases:

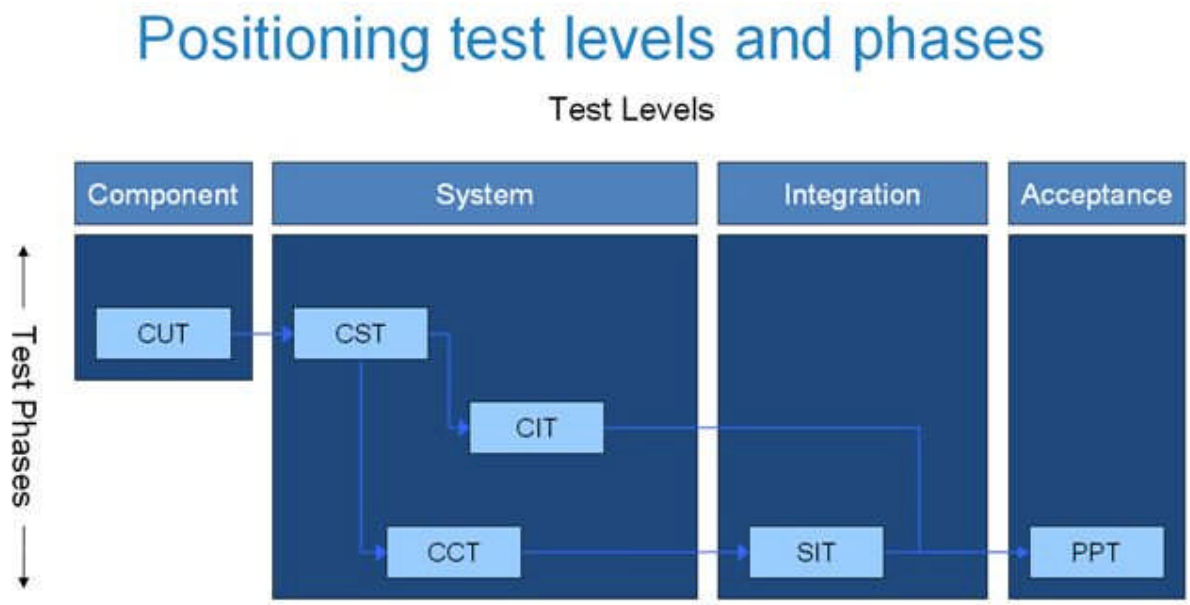


Figure 3 - Levels and Phases

The following sections expand upon the Test Phases describing the purpose, responsibility, entry and exit criteria.

3.1.8.1 Component Unit Test

Purpose

The Component Unit Test is the phase foreseen to test the software components (SWC). Its objective is to expose defects in the internal behaviour of the software component under test. The components are treated as white boxes and as such should be tested using appropriate white box techniques.

During this phase the components that make up the NCP, Portal and any other external service developed by epSOS or its subcontractors are tested. The goal is a fully tested component that is ready for the integration into a complete system.

Responsibility

Task / Organisation	epSOS / IHE-Europe	Participating Nation (Own development)	F.E.T. (NCP-in-a-T-box)	Industry (Components)
Test Planning		X	X	X
Test Design		X	X	X
Test Implementation		X	X	X
Test Execution		X	X	X
Test Evaluation		X	X	X

epSOS and F.E.T.

Where epSOS undertakes the development of a component, the accountability falls ultimately under epSOS but the responsibility for its execution can be assumed by epSOS or its sub-contractors / beneficiaries.

In the case of the NCP-in-a-Transparent-box, the responsibility falls under F.E.T.

In case of OpenNCP, the responsibility falls under the related OpenNCP mini-project team.

Where possible, epSOS[5] will provide Participating Nations with Test Stubs, Drivers, Simulators and Validators to support the testing of the epSOS trust domain interface. See # 6.2 for a list of available simulators and validators.

Participating Nations and Industry

The Participating Nations and the Industry are responsible for their component unit testing. This Test Strategy places no constraints or requirements on their test process.

Entry Criteria

The organisation tasked with the development of the component is to define its entry criteria. Due to the informality of this test phase epSOS places no constraints on its definition.

Exit Criteria

The following must be met and formally documented in order for the component to enter into the next test phase:

- Requirement to modules coverage matrix showing implementation of all requirements with a priority of high and medium.

[5] F.E.T. will not provide any simulators.

- Internal testing coverage of all paths, branches, and conditions showing coverage:

For epSOS LSP	Code Coverage	Use of code-metrics / bug detection software
Gateway / high-priority SW	>80%	Yes / Yes
Support tools	>60%	Yes / Yes
GUI	-	No / Yes

- No open problems of severity 1 and 2 as defined in this document in # 3.6.3.1 Defect Classification.
- No open problems of severity 3 as defined in this document without a functioning workaround.
- Component under Configuration Management, versioned and base-lined.
- Workarounds are documented in the release notes.

When the defined exit criteria have not been met the Test Report must list the deviations and their estimated risk. In this case epSOS must decide if the component can take part in the next test phase.

Deliverables

The following are the expected deliverables:

- A Test Report whose content is defined by the organisation conducting the tests, incorporating the results of the test; including as a minimum the information listed in the exit criteria; as verification that the tests have been completed.

3.1.8.2 Component System Test

Purpose

The Component System Test is the phase foreseen to functionally and non-functionally system test a software component. Its objective is to expose defects in the functional and non-functional behaviour of the software system under test. The systems are treated as black boxes and as such should be tested using appropriate black box techniques.

During this phase the system (NCP, Portal, or external services developed by epSOS) that is made up of the components tested during the component unit test phase will be tested. The goal is a fully tested system that is ready for integration testing.

Responsibility

Task / Organisation	epSOS / IHE-Europe	Participating Nation (Own development)	F.E.T. (NCP-in-a-T-box)	Industry (Components)
Test Planning		X	X	X
Test Design		X	X	X
Test Implementation		X	X	X
Test Execution		X	X	X
Test Evaluation		X	X	X

epSOS and F.E.T.

Where epSOS undertakes the development of a system, the accountability falls ultimately under epSOS but the responsibility for its execution can be assumed by epSOS or its subcontractors.

In the case of the NCP-in-a-Transparent-Box, the responsibility falls under F.E.T.

In case of OpenNCP, the responsibility falls under the related OpenNCP mini-project team(s). In case the system is updated with PN-specific components by the adapting PNs, then it is also the PNs' responsibility to do Component System Tests.

Where applicable, epSOS will provide Participating Nations with Test Stubs, Drivers, Simulators and Validators to support the testing of the epSOS trust domain interface. See # 6.2 for a list of available simulators and validators.

Participating Nations and Industry

The Participating Nations and the Industry are responsible for their component system testing. This strategy places no constraints or requirements on their test process.

Entry Criteria

The following defines the entry criteria for admission to the Component System Test phase:

- The exit criteria for the Component Unit Test phase have been met.
- Availability of all component documentation including but not restricted to release notes, installation and configuration handbook, and user guide.
- Availability of Workarounds

Exit Criteria

The following must be met and formally documented in order for the component to enter into the next test phase:

- Requirement to test case coverage matrix showing 100% coverage of all functional, non-functional and non integrative testing requirements.
- All Test Cases with a priority of 1 or 2 as defined in # 3.6.2.1 Test Case Priority, have the test result Pass.
- 70% of all test cases with a priority of 3 have been executed
- All problems of severity 1 and 2 as defined in # 3.6.3.1 Defect Classification, are closed
- All open problems of severity 3 have a functioning workaround and are described in the Test Report.
- All Test Artefacts are under Configuration Management and base-lined.
- System under Configuration Management, versioned and base-lined.
- System is available as an installable package (Windows Installer [MSI], TAR, ZIP, etc.)

When the defined exit criteria have not been met, the Test Report must list the deviations and their estimated risk. In this case epSOS must decide if the system can take part in the next test phase.

Deliverables

The following are the expected deliverables:

- A Test Report, managed by the organization doing the tests, incorporating the results of the test; including as a minimum the information listed in the exit criteria; as verification that the tests have been completed.
- The system must be provided in the form of an installable CD or downloadable package (MSI, TAR, etc).

3.1.8.3 Component Integration Test

Purpose

The Component Integration Test is the phase foreseen to test the interaction between two systems, which have previously been system tested. Its objective is to expose defects in the interfaces and the interaction with other previously tested systems and to verify that they are interoperable with one another.

This phase can only take place when a software producer develops a system that is required to be integrated with another system (actual or reference).

In the case that a software provider only develops a single system, they will have to wait until the Service Interoperability Test phase (Projectathon) before being able to integration test their systems with those developed by other software producers.

Responsibility

Task / Organisation	epSOS / IHE-Europe	Participating Nation (Own development)	F.E.T. (NCP-in-a-T-box)	Industry (Components)
Test Planning		X	X	X
Test Design		X	X	X
Test Implementation		X	X	X
Test Execution		X	X	X
Test Evaluation		X	X	X

epSOS and F.E.T.

Where epSOS undertakes the development of a system, the accountability falls ultimately under epSOS but the responsibility for its execution can be assumed by epSOS or its subcontractors.

In the case of the NCP-in-a-Transparent-Box, the responsibility falls under F.E.T.

In case of OpenNCP, the responsibility falls under the related OpenNCP mini-project team(s). In case the system is updated with PN-specific components by the adapting PNs, then it is also the PNs responsibility to do Component Integration Tests.

Where applicable, epSOS will provide Test Stubs, Drivers, Simulators and Validators to support the integrative testing of the epSOS trust domain interface. See # 6.2 for a list of available simulators and validators.

Participating Nations and Industry

The Participating Nations and the Industry are responsible for their component integration testing. This Test Strategy places no constraints or requirements on their test process.

Entry Criteria

The following defines the entry criteria for admission to the Component Integration Test phase:

- The exit criteria for the Component System Test phase have been met.
- Availability of updated component documentation including but not restricted to release notes, installation and configuration handbook, and user guide.
- Availability of workarounds.

Exit Criteria

The following must be met and formally documented in order for the component to enter into the next test phase:

- Requirement to test case coverage matrix showing 100% coverage of all integrative testing requirements.
- All Test Cases with a priority of 1 or 2 as defined in # 3.6.2.1 have the test result Pass.
- 70% of all test cases with a priority of 3 have been executed
- All problems of severity 1 and 2 as defined in # 3.6.3.1 Defect Classification are closed
- All open problems of severity 3 have a functioning workaround and are described in the Test Report.
- All Test Artefacts are under Configuration Management and base-lined.
- Component base-lined.

When the defined exit criteria have not been met the Test Report must list the deviations and their estimated risk. In this case epSOS must decide if the system can take part in the next test phase.

Deliverables

The following are the expected deliverables:

- A Test Report, managed by the organization doing the tests, incorporating the results of the test; including as a minimum the information listed in the exit criteria; as verification that the tests have been completed.
- System is available as an installable package (installable CD, MSI, TAR, etc.).

3.1.8.4 Conformance Test (Pre-Projectathon)

Purpose

The Conformance Test is the phase foreseen to test the component or system against the pre-defined epSOS test cases as the pre-requisite for entry into the Service Interoperability Test (Projectathon). Its goal is to verify that all pre-defined test cases pass when executed against the component or system under test. It is also known as Pre-Projectathon Test (pre-PAT). Conformance Testing is also done within the Projectathon and the PPT-slot.

Pre-Projectathon (pre-PAT) is the online (i.e. remote) conformance testing activity that is held prior to a Projectathon. The focus is on checking the compliance of the PN and vendor implemented systems to the epSOS Interoperability Profiles, messages and documents individually. For this purpose, the systems are tested against simulators and validators provided by the epSOS Project in cooperation with IHE-Europe. Completing the Pre-Projectathon is necessary for being allowed to go to the proceeding Projectathon.

Responsibility

Task / Organisation	epSOS / IHE-Europe	Participating Nation (Own development)	F.E.T. (NCP-in-a-T-Box)	Industry (Components)
Test Planning	X	X	X	X
Test Design	X			
Test Implementation	X	X	X	X
Test Execution		X	X	X
Test Evaluation	X			

epSOS, IHE-Europe and F.E.T.

Where epSOS undertakes the development of a system, the accountability falls ultimately under epSOS but the responsibility for its execution can be assumed by epSOS or its sub-contractors / Beneficiaries.

In the case of the NCP-in-a-Transparent-Box, the responsibility falls under F.E.T.

In case of OpenNCP, this time the responsibility falls under the adapting PNs and vendors, as OpenNCP itself is not a complete reference implementation, but a set of integrated components that have to be further completed by the adapting PNs / vendors.

As certain decisions pertaining to the division of work have already been taken these are reflected here.

- Test Design is assumed by the beneficiary IHE-Europe and epSOS.
- Test Implementation is assumed by the beneficiary IHE-Europe.
- Test evaluation is assumed by the beneficiary IHE-Europe (third party).

Where applicable, epSOS will provide Participating Nations all necessary Test Stubs, Drivers, Simulators and Validators to support the conformance testing. See # 6.2 for a list of available simulators and validators.

A pre-PAT slot is announced prior to a Projectathon (PAT) by epSOS testing team and IHE-Europe, and is kept open for several weeks until the PAT itself. In the last 2-3 weeks before PAT, IHE-Europe validates the tests that are completed by the PNs / vendors against the conformance validators and simulators.

Participating Nations and Industry

- Test Planning will be assumed by Participating Nations, F.E.T. or the Industry.
- It is not ruled out that the Participating Nations, F.E.T. or the Industry have anything to implement.

- Test Execution will be assumed by the Participating Nations, F.E.T. or the Industry.

Entry Criteria

Only the PNs and vendors that are registered for a Projectathon are allowed (actually, "have to") complete the corresponding Conformance Test session (i.e. pre-Projectathon Test). The registration is again managed by IHE-Europe and epSOS through the Gazelle tool.

The other conformance testing activities within the Projectathon and PPT-slot are part of the corresponding testing sessions.

Exit Criteria

As the entry into the Service Interoperability Test (SIT) (Projectathon) is dependent on the results of the Conformance Test, and the responsibility for SIT lies within epSOS, the following exit criterion applies to all software producers' epSOS, PN, vendors and software producers alike:

- All Test Cases registered in Gazelle according to the implemented profiles are executed and have the test result Pass.

Deliverables

All who are to participate in the Service Interoperability Test (Projectathon) are to provide epSOS with their Conformance Test (pre-Projectathon) Results. The participants register their test logs through the Gazelle Management Tool as in the case of PAT, and the results are validated by IHE-Europe.

Following the audit of test results by IHE-Europe, epSOS provides the submitter with a confirmation of participation to proceed with the proceeding Projectathon.

3.1.8.5 Service Interoperability Test (Projectathon)

Purpose

The Service Interoperability Test is the phase to test the pre-defined test cases as defined by epSOS. The SIT has a Workshop characteristic and is conducted in a pre-determined location, within a pre-defined duration in which the test cases are executed. Participants register their interest and providing they meet the entry criteria can take part.

Its objective is to verify that all pre-defined functional, non-functional and integrative test cases pass when executed by:

- A standalone component or system
- A component that is integrated with other standalone components or systems

The goal is to verify the interaction of integrated components during the execution of end to end business processes.

The Service Interoperability Test is also known as Projectathon within the scope of epSOS. Projectathon is an interoperability testing event similar to Connectathon, organised and managed by the epSOS Project in cooperation with IHE-Europe, to assure the interoperability of the PN and vendor implemented systems according to the epSOS Interoperability Profiles. It is usually held together with European Connectathons. In addition to (some) conformance and (mostly) interoperability testing, Projectathon includes end-to-end functional testing with the involvement of HPs. PNs need not to participate with their actual national infrastructures to a Projectathon; a simulation of the national environment is accepted as well. Only the PNs who successfully pass a Projectathon are allowed to go to Pre-Pilot Testing.

Responsibility

Task / Organisation	epSOS / IHE-Europe	Participating Nation (Own development)	F.E.T. (NCP-in-a-T-Box)	Industry (Components)
Test Planning	X			
Test Design	X			
Test Implementation	X	X	X	X
Test Execution		X	X	X
Test Evaluation	X			

epSOS and IHE-Europe

Where epSOS undertakes the development of a system, the accountability falls ultimately under epSOS but the responsibility for its execution can be assumed by epSOS or its sub-contractors / beneficiaries.

In the case of the NCP-in-a-Transparent-Box, the responsibility falls under F.E.T.

In case of OpenNCP, this time the responsibility falls under the adapting PNs and vendors, as OpenNCP itself is not a complete reference implementation, but a set of integrated components that have to be further completed by the adapting PNs / vendors.

As certain decisions pertaining to the division of work have already been taken, these are reflected here.

- Test Planning is assumed by epSOS and the beneficiary IHE-Europe.
- Test Design is assumed by the beneficiary IHE and epSOS.
- Test Implementation is assumed by the beneficiary IHE-Europe.

- Test evaluation is assumed by the beneficiary IHE-Europe.

epSOS will provide Participating Nations all necessary Test Stubs, Drivers, Simulators and Validators to realize interoperability testing. See # 6 for some details about the testing tools.

Participating Nations, F.E.T., and Industry

- It is not ruled out that the Participating Nations, F.E.T. or the Industry have anything to implement.
- Test Execution will be assumed by the Participating Nations, F.E.T. or the Industry.

In addition, Participating Nations, F.E.T. and the industry are responsible for the delivery, installation, configuration and management of their systems during the Projectathon. Additionally, they will be responsible for the execution of test cases and the delivery of all results to the officiating monitors. Furthermore they are responsible for the analysis of problems arising due to testing of their systems against simulators/validators or other systems.

The PN should ensure that Health Professionals are part of the team responsible for executing end-to-end functional tests and for evaluating the test results.

Entry Criteria

The following entry criterion applies to all participants of the SIT:

- The exit criteria for the Conformance Test phase (pre-Projectathon) have been met.

Exit Criteria

The purpose of the exit criterion is to determine when testing can be halted, but as the duration defines the end of the test there is no need to define a formal exit criterion. At the end of the tests, the results are collected and a final summary report is created and communicated to all participants. This test report indicates whether or not the participants have passed the Projectathon. If a participants passes, they can proceed with Pre-Pilot tests; otherwise, they have to participate to a Projectathon again.

Deliverables

- Test Results entered by the Participating Nation / vendor into the Gazelle system (requirement for the Test Evaluation)
- A Test Report to be provided by IHE-Europe (through the testing leader in epSOS) for each participating PN or organisation indicating whether or not they have passed the Projectathon and can proceed with the Pre-Pilot tests.

3.1.8.6 Pre-Pilot Test

Purpose

The Pre-Pilot Test (also called LSP-Testing) is the phase to regression test the installed components in their target pilot environment firstly as a standalone component and secondly with other standalone components or systems. Finally services are tested in the complete Large Scale Pilot testing infrastructure, separated from the LSP-Operational Infrastructure for safety and security reasons.

Its goal is to ensure that there are no problems or issues with the setup and configuration of the epSOS Infrastructure and the components connected to it. Tests are executed using dummy data, or real patient data that has been anonymized (decision is up to the Participating Nation). A Participating Nation may decide to use real Patient data or real Patients, who require to be informed that they are participating in a pre-pilot trial. Extensive and possibly exhaustive end-to-end testing is performed, involving HPs from Country B, to ensure the level of safety in the document semantic transformation to achieve functional interoperability and get statistically significant data for the Evaluation performed by WP1.2.

Additionally a clinical risk assessment is to be conducted against the original data sent from Country A and the data received by Country B to ensure that during the transformation of data, the unity of the patient data is preserved.

Once a PN has passed this phase and their Pilot fulfils the entry criteria for the LSP Operation, it is able to enter the Trust Domain of epSOS and will be interoperable with all other Pilots that have the same status.

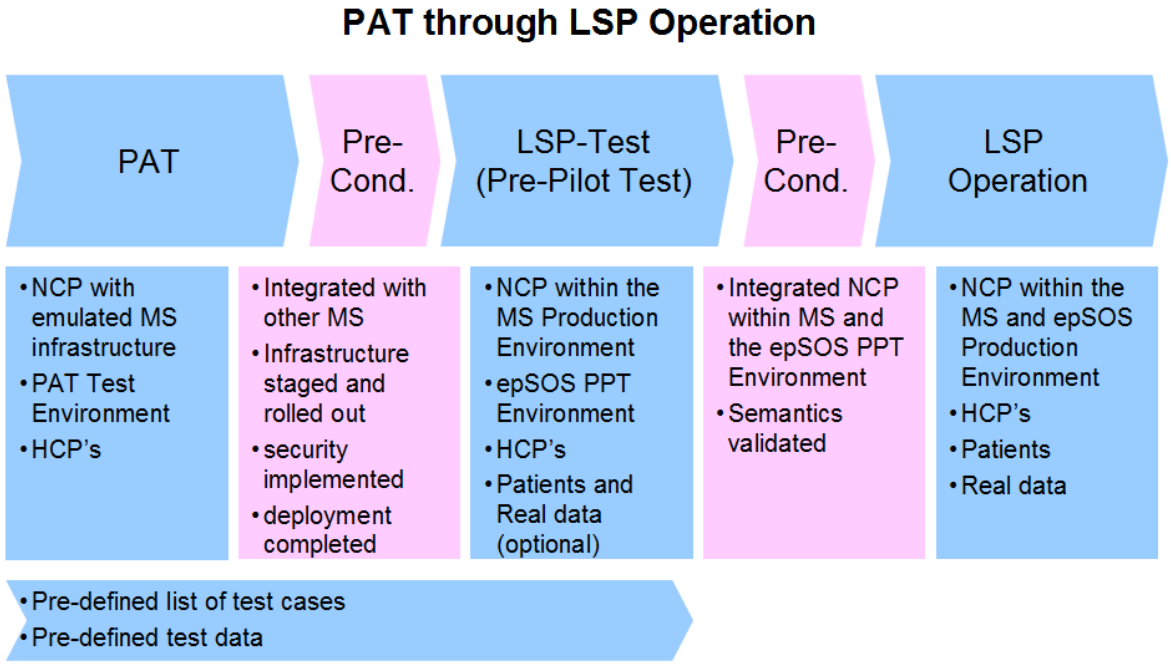


Figure 4 - PAT through LSP Operation

Pre-Pilot Testing is similar to a combination of pre-Projectathon and Projectathon considering the scope of testing activities; i.e. it includes conformance, interoperability and end-to-end functional testing. The main difference is that, the NCP has to be connected to the real national infrastructure, but with virtual data. Its goal is to ensure that there are no problems or issues with the setup and configuration of the pilot environment of a PN. PPT is a “conformance gate” to go into real operation. According to the needs of the PNs, two weeks long PPT slots are organized a few times in a year for completing these tests. However, PPT is a continuous process and the PNs need to operate their testing environments even after starting real operation.

Responsibility

Task / Organisation	epSOS / IHE-Europe	Participating Nation (own Development)	F.E.T. (NCP-in-a-T-Box)	Industry (Components)
Test Planning	X	X		
Test Design	X	X		
Test Implementation	X	X		
Test Execution		X		
Test Evaluation	X	X		

epSOS

The responsibility for the preparation, organisation, evaluation of results, and reporting of this test phase with respect to the NCP lies wholly within epSOS, through IHE-Europe. The end to end tests from the Portal or Participating Nation B National Infrastructure through to the Participating Nation A National Infrastructure will indirectly test all components in the process chain.

The Participating Nations have to maintain a test environment to participate to the Pre-Pilot Testing. The only difference of this test environment from the operational environment should be that the test environment should provide virtual data, not real patient data. This test environment should always be available, even after passing a Pre-Pilot Testing (PPT) slot. PPT is a living process, for example, when there is a change need to be done during operation, it has to be done first on the testing environment, and then transferred to the operational environment.

Together with IHE-Europe, epSOS organizes PPT slots that are formal Pre-Pilot Test execution and verification slots that should normally take 2 weeks. With the exception of the first PPT-slot that took much longer (i.e. six months), epSOS will strictly conform to this 2 weeks deadline for the next PPT-slots. During a PPT-slot, the scope of testing activities to be completed by the PNs are almost identical to the test cases that are executed during Pre-Projectathon and Projectathon phases.

Hence, a PPT-slot covers conformance, interoperability and end-to-end functional testing. Also, a PPT-slot is again managed (registration, providing test logs, validating tests, etc.) via the Gazelle Management Tool.

Participating Nations

Participating Nations are responsible for the delivery, installation, configuration and management of their systems during the Pre-Pilot Test phase. Additionally they are responsible for the execution of test cases and the delivery of all results to epSOS through the Gazelle Management tool. Furthermore they are responsible for the analysis of problems arising due to testing of their systems against simulators/validators or other systems.

The PN should ensure that Health Professionals are part of the team responsible for executing end-to-end functional tests and for evaluating the test results.

Entry Criteria

- Test Report from the Service Interoperability Test indicating that the Projectathon has been passed.
- The PNs have to provide evidence to KT3.C.4 leader and WP3.C leader that they are ready for the PPT-slot through links to validation results in the test simulators provided by Gazelle. These tests will be identical to the pre-Projectathon tests, whose steps are explained here: http://gazelle.ihe.net/epSOS-doc/. The PNs are also encouraged to do peer-2-peer tests among themselves, and inform again KT3.C.4 leader and WP3.C leader about the results. Note that this pre-PPT phase is not a formal process managed through Gazelle Management tool and verified by IHE-Europe, but it is still mandatory for making sure that the PNs are actually capable of achieving a PPT-slot.

Exit Criteria

- All Test Cases related to standalone (i.e. conformance) tests have been executed and have the test result Pass.
- All Test Cases related to interoperability tests have been executed and have the test result Pass.
- All Test Cases related to end-to-end functional tests have been executed and have the test result Pass.
- The Clinical Risk Assessment presents no adverse risk to patients.

When the defined exit criteria have not been met the Test Report must list the deviations and their estimated risk.

Deliverables

- Clinical Risk Assessment.
- Test Results entered by the Participating Nation into the Gazelle Management tool (requirement for the Test Evaluation)
- A Test Report to be provided by epSOS via IHE-Europe for each participating PN indicating whether or not they have passed the Pre-Pilot Test and are able to switch to live operation and enter the Trust Domain of epSOS. The raw results, i.e. a part of this Test Report, is provided automatically by the Gazelle Management tool. The Test Report is to be produced by WP3.10 in epSOS Phase 1 and WP3.C in Phase 2.

3.2 Test Items

The following lists those features found in input specifications that need to be tested, as well as those that cannot be tested. In the case that requirements cannot be tested the justification is described.

The features to be tested are restricted to the NCP and Portal. Requirements relating to the national Infrastructures cannot be tested by epSOS, but such testing is a pre-requisite for each PN.

Functional (FR) and Non-Functional (NFR) requirements will be analysed.

3.2.1 Features to be tested

The following features are to be tested and can be located in the functional service requirements of **[D3.1.2]** and **[D3.2.2]** accordingly. Please refer to these documents for detailed information pertaining to individual requirements.

The features to be tested are divided into two categories:

1. Covers the features to be tested during the development of the NCP and Portal.
2. Covers the features to be tested during the Projectathon.

3.2.1.1 Features to be tested during the development of NCP and Portal

Those PNs / vendors who are developing NCP and/or Portal are responsible for the corresponding Component, System and Integration Tests of the NCP in both their A and B flavours, along with the Portal.

FR02 – Trust between countries – restricted to the interface NCP-B to NCP-A. Trust establishment between two different PNs depends on their decision from the legal/organizational perspective. Trust can be established mutually between the two countries NCPs, with the technical implementation proposed by epSOS. The HP does not play a role in the establishment of the trust relationship, but is

affected by its outcome, for example a patient from a country whereby no trust relationship exists. The NCP-B in this case must be prepared for such a scenario.

FR03 – Patient Identification – NCP-B will send a Patient identification request to the NCP-A, which in turn will forward the request to the National Infrastructure of PN A. The NCP-A will receive the Patient Identification data from the PN A National Infrastructure and forward it to the NCP-B. Testing is restricted to validating according to epSOS requirements, that a patient can be identified through the Portal or the National Connector of the NCP-B, and the epSOS interface of the NCP-A.

FR04 – Patient consent to access data – NCP-B will send a Patient Consent request to the NCP-A, which in turn will forward the request to the National Infrastructure of PN A. The NCP-A will receive the Patient Consent answer provided / not provided from the PN A National Infrastructure and forward it to the NCP-B. Testing is restricted to validating according to epSOS requirements, that consent to access patient data can be granted through the Portal or the National Connector of the NCP-B, and the epSOS interface of the NCP-A. It will be possible to conduct the test from the connector side of the NCP-B via the NCP and the Portal.

FR05 – Structured Information – Verify that the information passed between two NCPs is structured / converted according to the requirements of epSOS. This has to be verified between the NCPs and further verified on the Portal.

FR09 – Prescription presentation – see FR05.

FR10 – ‘Available’ (and thus, valid) prescription – Verify that only prescriptions that are valid are displayed.

FR12 – Original Prescription – see FR05.

FR15 – Dispensed medicine information sent to country A – Verify that information passed between two NCPs is structured / converted according to the requirements of epSOS. This has to be verified between the NCPs and further verified on the Portal.

FR19 - Patient summary of Country A available – see FR05.

FR20 – Information Traceability – the requirement does not provide enough information about which systems are responsible for auditing data. Therefore it is assumed that all systems are responsible for auditing data (NCP-A, NCP-B, and Portal). However, only the NCPs will be verified by epSOS according to epSOS requirements.

NFR02 – Communication – secure communication between NCP’s will be verified during interoperability testing.

NFR03 – Response Time – the response time of an NCP and the response time between NCPs will be verified to be within the defined parameters. This will be restricted to proving that the roundtrip

time between the Portal, NCP-B and NCP-A is not excessively slow. The response time of the PN National Infrastructure will not be measured.

NFR04 – It is assumed that an unauthorised party is anyone other than the HCP. It will be verified that patient data cannot be obtained through malicious or non-malicious methods within the NCP.

NFR05 – epSOS will verify that the NCP is not accessible via any of its interfaces to anyone other than authorised persons.

NFR06 – epSOS will verify that all access or attempted access to medical data via the NCP is audited. This is restricted to the NCP-A and NCP-B.

NFR07 – Integrity – epSOS will verify that the NCP A and B have not damaged, reduced or altered the data in anyway.

NFR08 – non repudiation – Can only be tested between the NCPs.

There are no specific Patient Summary / Electronic Prescription / Electronic Dispensation features to be tested as all requirements are covered by the general requirements above.

3.2.1.2 epSOS NCP features to be tested at Projectathon

Although there will be no Test Cases created with the intention of specifically testing the Portal during the Projectathon, it will be used to initiate certain workflows and to view subsequent results. Therefore the Portal will be implicitly tested.

FR01 – HP Identification and Authentication – despite being a national implementation it belongs to the processes Electronic Prescribing, Electronic Dispensing and Patient Summary and can be visually validated by the HP-B.

FR02 – Trust between countries – restricted to the interface NCP-B to NCP-A. Trust establishment between two different PNs depends on their decision from the legal/organizational perspective. Trust will be established mutually between two countries, with the technical implementation proposed by epSOS. The HP does not play a role in the establishment of the trust relationship, but is affected by its outcome, for example a patient from a country whereby no trust relationship exists. The NCP-B in this case must be prepared for such a scenario.

FR03 – Patient Identification – this can be tested along the entire process path ending with a visual validation by the HP-B.

FR04 – Patient consent to access data – this can be tested along the entire process path ending with a visual validation by the HP-B.

FR05 – Structured Information – this can be tested along the entire process path ending with a visual validation by the HP-B.

FR06 – Equivalent Information – It has to be tested that the initial information in Country A and the received information in Country B are equivalent along the entire process. The final step is a visual validation by the HP-B. This test and the following one are performed by HPs, during end-to-end functional testing held within Projectathon and Pre-Pilot Testing (see 3.8.2.4.2 for more details).

FR07 – Information understandable – this can be tested along the entire process path ending with a visual validation by the HP-B.

FR08 – Information selection – deals with the display and selection of prescriptions to the Dispenser and although it cannot be verified by epSOS, it must be verified by a PN Health Professional.

FR09 – Prescription presentation – this can be visually validated by the HP-B.

FR10 – 'Available' (and thus, valid) prescription – Verify that only prescriptions that are valid are displayed.

FR12 – Original prescription – this can be visually validated by the HP-B.

FR13 – Identification of the medicinal product – this can be visually validated by the HP-B.

FR15 – Dispensed medicine information sent to country A.

FR16 – Identification of original prescription and medicinal product dispensed – Verify that the data returned to PN A in the eD contains the Prescription Id from the original eP.

FR17 – Original dispensed medicine – Verify that the data returned to PN A in the eD contains the brand name of the Medicinal Product dispensed plus the active ingredient and quantity.

FR19 – Patient summary of Country A available – this can be tested along the entire process path ending with a visual validation by the HP-B.

FR20 – Information Traceability – restricted to the NCP's.

NFR07 – Integrity – epSOS will verify that the NCP A and B have not damaged, reduced or altered the data in anyway.

NFR08 – non repudiation – Can only be tested between the NCPs.

3.2.2 Features not to be tested

The following features have a functional aspect that do not relate to the functionality between two NCPs, but between an NCP and its respective national infrastructure or its HP. As epSOS does not test the interfaces within the national infrastructures, it is regarded as outside of the scope of this test strategy.

FR11 – Access to Medication Summary by dispenser - No centralised test tool will be provided by epSOS, since this is a requirement that is implemented on a voluntary basis. Responsibility to test it is left to the PN piloting it (see D3.1.2).

FR14 – Substitution – this cannot be tested as it relates solely to a process related to the Dispenser. If a medicine is subsequently substituted, this information must be sent back to Country-A, which is covered in FR15.

FR20 – Information Traceability – epSOS will not verify the traceability of information stored on systems other than the NCP.

NFR01 – Service Availability – The description relates to operational requirements, the result of which would be the definition of SLA's, and the setting up of a Command Centre responsible for monitoring all systems that are connected directly to the epSOS Infrastructure. It is assumed that epSOS will not create a command centre but allow the PN to regulate themselves.

NFR03 – Response Time – does not cover the response time of any Country B system other than the NCP, or any other Country A system other than the NCP. However, end-to-end response time will be measured for service evaluation purposes.

NFR04 – Confidentiality – epSOS will not verify that patient data in systems other than the NCP can be obtained through malicious or non-malicious methods.

NFR05 – the description does not refer specifically to the NCP but generally as Systems. This requirement therefore encompasses all systems in the end to end process. It is not possible for epSOS to verify systems other than the NCP.

NFR06 – No other epSOS LSP Services other than an NCP are defined that will receive or have access to medical data.

NFR09 – Trust - This requirement concerns itself with the non-functional aspect of trust between countries, specifically those policies defined by epSOS and to be implemented by the Participating Nations. The implementation of those policies will be verified through Audits during and post rollout. As the rollout is not scope of this test strategy it should be addressed by WP4.3.

NFR10 – Guaranteed delivery – epSOS cannot verify that the HP-B confirms that the data is properly received.

NFR11 – This is a requirement of a PN. This type of functionality must be restricted to the PN national infrastructure and not the NCP. It must already be standard within a PN national infrastructure as this problem could already occur within their borders.

NFR12 – Supervision services – are operational services and as such are out of scope of epSOS. These services cover the creation of SLAs and probes, the monitoring of real time performance and

services. It is the responsibility of the operational organisations to verify these requirements. This is also coupled with NFR01 – Service Availability.

3.2.3 Testing Coverage

epSOS testing coverage should be based on the software's complexity and safety risk. The selection of epSOS testing activities, tasks, and work items should be commensurate with the complexity of the software design and the risk associated with the use of the software for the specified intended use.

The level of structural testing can be evaluated using metrics that are designed to show what percentage of the software structure has been evaluated during structural testing. These metrics are typically referred to as “coverage” and are a measure of completeness with respect to test selection criteria. The amount of structural coverage should be commensurate with the level of risk posed by the software.

Common structural coverage metrics include:

Statement Coverage	This criteria requires sufficient test cases for each program statement to be executed at least once; however, its achievement is insufficient to provide confidence in a software product's behaviour.
Decision (Branch) Coverage	This criteria requires sufficient test cases for each program decision or branch to be executed so that each possible outcome occurs at least once. It is considered to be a minimum level of coverage for most software products, but decision coverage alone is insufficient for high-integrity applications.
Condition Coverage	This criteria requires sufficient test cases for each condition in a program decision to take on all possible outcomes at least once. It differs from branch coverage only when multiple conditions must be evaluated to reach a decision.
Multi-Condition Coverage	This criteria requires sufficient test cases to exercise all possible combinations of conditions in a program decision.
Loop Coverage	This criteria requires sufficient test cases for all program loops to be executed for zero, one, two, and many iterations covering initialization, typical running and termination (boundary) conditions.

Path Coverage	This criteria requires sufficient test cases for each feasible path, basis path, etc., from start to exit of a defined program segment, to be executed at least once. Because of the very large number of possible paths through a software program, path coverage is generally not achievable. The amount of path coverage is normally established based on the risk or criticality of the software under test.
Data Flow Coverage	This criteria requires sufficient test cases for each feasible data flow to be executed at least once. A number of data flow testing strategies are available.

3.3 Test Environments and Infrastructure

3.3.1 Test Environments

This test strategy defines the following test environments:

- Unit Test Environment (UTE)
- Laboratory Test Environment (LTE)
- Reference Test Environment (RTE)
- Projectathon Test Environment (CTE)
- Pre-Pilot Test Environment (PTE)

The Unit Test Environment (UTE) is a test environment where the developers from epSOS, Participating Nations, suppliers or vendors unit test their components and each of whom is responsible for its creation and management. The test environment is typically made up of developers' machines with supporting testing software. It is not possible to describe the architecture of such a test environment as it can vary from organisation to organisation. The test phase Component Unit Test would use such a test environment.

The Laboratory Test Environment (LTE) is a test environment where testers from epSOS, Participating Nations, suppliers or vendors perform functional, integration and conformance tests of their components or systems, each of whom is responsible for its creation and management. The test environment is typically made up of virtual or actual test systems, with supporting test software. It is not possible to describe the architecture of such a test environment as it can vary from organisation to organisation.

The Reference Test Environment (RTE) is a test environment where developers and testers of Participating Nations, suppliers or vendors have the possibility to connect and integrate their components and systems by applying well-defined test plans, tools and processes. The epSOS project was responsible for the establishment of the RTE and its management during epSOS Phase 1; however in epSOS Phase 2, there is no unique RTE (i.e. reference implementation). It is assumed that the experienced PNs that are already in operation will act as reference implementation when necessary.

The Projectathon Test Environment (CTE) is a test environment where Participating Nations, suppliers and vendors can interoperability test their components and systems against other Participating Nations, suppliers and vendors components and systems. The epSOS project is responsible for the definition of the CTE; epSOS setups and manages systems and services required to connect PN solutions with one another; the PNs are responsible for the setup and management of their systems within this environment. This environment is used during both Conformance Test (Pre-Projectathon) and Service Interoperability Test (Projectathon). CTE is configured through the central configuration mechanisms provided by epSOS, hence the system becomes locatable by all other PNs.

The Pre-Pilot Test Environment (PTE) is a conglomeration of Pilot Systems from Participating Nations. When a PN achieves a PPT-slot and completes all the requirements (i.e. legal, technical, organizational) for operation, a copy of the PTE is created in the operation environment, using real patient data, and handed over to the respective operations management groups to be run as a Pilot System. In parallel, the PTE is still maintained; it is never shut down during the project since the PPT is a continuous process. PTE is also configured through the central configuration mechanisms provided by epSOS, hence the system becomes locatable by all other PNs.

3.3.2 Test Infrastructure

3.3.2.1 Document Management

Projectplace is the chosen application for document management. All documents when not managed under Projectplace must be uploaded to Projectplace when they are finalised.

An exception is the Test Plan (Test Cases) which is maintained in the Gazelle® test management tool. See #6.1 Gazelle® Management Tool for more Information.

3.3.2.2 Test management

Due to the structure of the project a Test Management Process / Tool is only required for the Component Conformance Test (pre-Projectathon), System Integration Test (Projectathon) and Pre-

Pilot Test (PPT) phases. It is agreed that the Test Process and Tools of IHE are employed for these phases.

Gazelle® management tool from IHE-Europe will be used to manage Test Cases. See #6.1 Gazelle® Management Tool for more Information.

3.3.2.3 Problem Management

Due to the structure of the project a Problem Management Process / Tool is only required for the Component Conformance Test (pre-Projectathon), System Integration Test (Projectathon) and Pre-Pilot Test (PPT) phases. It is agreed that the both epSOS Central Service Desk[6] and the Problem Management Process and Tools of IHE-Europe[7] are employed for these phases.

3.4 Test Methods and Design Techniques

3.4.1 Test Methods

A Test method is a test process that can be employed to test a component or system in a particular way. The methods can be used in isolation or together, or in some cases they are implicitly related i.e. black box testing encompasses functional and non functional testing.

It is the decision of the Industry Partners, beneficiaries, Participating Nations, their suppliers or vendors as to which testing methods they employ during the testing of their components or systems that make up the epSOS Architecture and ICT infrastructure. The following is not an exhaustive list of test methods but a guideline to what could be employed:

Method	Description
Black Box Testing	Testing, either functional or non-functional, without reference to the internal structure of the component or system.
Component Integration Testing	Testing performed to expose defects in the interfaces and interaction between integrated components.
Dynamic Testing	Testing that involves the execution of the software of a component or system.
Functional Testing	Testing based on an analysis of the specification of the functionality of a component or system.

[6] epSOS Central Service Desk, https://support.epsos.cz/

[7] Gazelle JIRA, http://gazelle.ihe.net/jira/

Installation Testing	The process of testing the installability of a software product.
Integration Testing	Testing performed to expose defects in the interfaces and in the interactions between integrated components or systems.
Interoperability Testing	Testing performed to determine the capability of the software product to interact with one or more specific components or systems.
Non Functional Testing	Testing the attributes of a component or system that do not relate to functionality, e.g. reliability, efficiency, usability, maintainability and portability.
Operational Testing	Testing conducted to evaluate a component or system in its operational environment.
Performance Testing	The process of testing to determine the performance of a software product. Performance Testing can be distinguished further by three techniques: • Stress testing: A type of performance testing conducted to evaluate a system or component at or beyond the limits of its anticipated or specified work loads, or with reduced availability of resources such as access to memory or servers. • Load Testing: A type of performance testing conducted to evaluate the behaviour of a component or system with increasing load, e.g. numbers of parallel users and/or numbers of transactions, to determine what load can be handled by the component or system. • Volume testing: Testing where the system is subjected to large volumes of data.
Regression Testing	Testing of a previously tested program following modification to ensure that defects have not been introduced or uncovered in unchanged areas of the software, as a result of the changes made. It is performed when the software or the environment is changed.
Reviews	An evaluation of a product or project status to ascertain discrepancies from planned results and to recommend improvements. Examples include technical, formal and informal reviews.
Risk Based Testing	An approach to testing to reduce the level of product risks and inform stakeholders on their status, starting in the initial stages of a project. It involves the identification of product risks and their use in guiding the

	test process.
Security Testing	Testing to determine the security of the software product.
Smoke Testing	A subset of all defined/planned test cases that cover the main functionality of a component or system, to ascertain that the most crucial functions of a program work, but not bothering with finer details. A daily build and smoke test is among industrial best practices.
Static Testing	Testing of a component or system at specification or implementation level without execution of that software, e.g. reviews.
System Integration Testing	Testing the integration of systems and packages; testing interfaces to external systems.

This test strategy assumes that the components / systems will be developed by Industry Partners, beneficiaries, Participating Nations, their suppliers or vendors as defined in **[D3.3.2]** #6.3.

3.4.2 Test Design Techniques

A test design technique is a procedure used to derive and/or select test cases.

During the preparation of the test concept and following the analysis of the input requirements, the test design techniques must be identified that will be used later during the test design process. This section defines and describes the test design techniques[8] that can be defined in the test concept to support the identification and justification of test cases.

The following Test Design Techniques must be considered:

Technique	Description
Boundary Value Analysis	A black box test design technique in which test cases are designed based on boundary values.
Cause Effect Graphing	A black box test design technique in which test cases are designed from cause effect graphs.

[8] If further test design techniques are identified during the test planning process they must be added to this test strategy.

Technique	Description
Classification Tree Method	A black box test design technique in which test cases, described by means of a classification tree, are designed to execute combinations of representatives of input and/or output domains.
Decision Table Testing	A black box technique in which test cases are designed to execute the combinations of inputs and/or stimuli (causes) shown in a decision table.
Equivalence Partitioning	A black box test design technique in which test cases are designed to execute representatives from equivalence partitions. Principally the test cases are designed to cover each partition at least once.
Pair wise Testing	A black box test design technique in which test cases are designed to execute all possible discrete combinations of each pair of input parameters.
State Transition Testing	A black box testing technique in which test cases are designed to execute valid and invalid state transitions.
Use Case Testing	A black box test design technique in which test cases are designed to execute user scenarios.

3.5 Controlling and Reporting

3.5.1 Reporting

There is a requirement from TPM and PD4 to receive status information from WP3.C (previously it was WP 3.9 / 3.10) pertaining to testing at varying stages of the test process. The following lists their requirements:

- Post the Conformance Test and prior to the System Integration Test (Projectathon) to receive status information as to which Participating Nations are participating in the Projectathon and for which Profiles / Actors.
- Post Projectathon to receive status information as to which Participating Nations have passed / failed which Profiles and Actors.

When the test process is managed by IHE-Europe (i.e. pre-Projectathon, Projectathon and PPT slots), IHE-Europe has to generate reports on test results for the related test activity. This test report should contain both raw results, and also analysis of the results together with feedback on detected

issues. IHE-Europe will be supported by the WP3.C leader, KT3.C.4 PPT leader and semantic experts who acted as monitors during the preparation of these reports.

In the case of individual tests that have to be done prior to a PPT-slot (i.e. pre-PPT-slot), the PNs have to provide evidence of test executions to WP3.C leader and KT3.C.4 PPT leader. This process is not managed by IHE-Europe.

WP3.C and KT3.C.4 will collect these reports and provide them to TPM and WP1.2.

3.5.2 Statistics

- When the test process is managed by IHE-Europe (i.e. pre-Projectathon, Projectathon and PPT slots), test statistics will be managed according to the normal procedures defined and operated by IHE-Europe for Connectathon.

3.5.3 Approval and Signoff

The Participating Nations receive only a notification that they have passed the Projectathon, which does not constitute an approval of their solution but only a confirmation that they are able to integrate with other NCPs.

Further testing during the Pre Pilot Test slot will confirm that the Participating Nation solution has passed the required tests prior to being allowed to enter the Large Scale Pilot, but again is not a formal Approval and Signoff.

In epSOS Phase 1, WP3.10 defined technical quality gates whereas WP4.3 defined organisational ones. These quality gates form, in addition to the test cases to be executed, the criteria that allows a Participating Nation to pass from the Pre-Pilot Test to the Large Scale Pilot.

3.6 Supporting Processes

The following describes the processes that are required to support the test effort. These processes are also required to support the Specification and Development effort as they provide and guarantee the traceability between the requirements, test artefacts and the components or systems to be tested.

As the systems to be implemented have very strong legal implications in terms of data protection laws of the participating nations, it is necessary to ensure a high level of traceability between what is to be tested, the given requirements and test specifications. epSOS must be able to verify in the case of a dispute that the NCP component or system in terms of its interface to the epSOS trust domain is implemented according to the specification.

epSOS cannot verify or guarantee that a participating nation has implemented their NCP component or system in terms of its national facing interface according to epSOS specifications. However, it is possible for epSOS to define test specifications based on epSOS specifications and enforce the participating nation to implement these and provide epSOS with the results. The results must be audited by epSOS and would become part of the entry criteria into later test phases.

epSOS cannot specify, verify or guarantee how a participating nation manages or treats the patient data from another participating nation within their own national infrastructure. This should be regulated through agreements between participating nations, which is actually founded on the epSOS Framework Agreement (FWA).

3.6.1 Requirements Management

A requirement is a capability to which a project outcome (product or service) should conform.

Requirements management is the process of eliciting, documenting, analyzing, tracing, categorising and agreeing on these capabilities, controlling their change and communicating them to relevant stakeholders.

Requirements Management Process is defined and operated by the TPM Discipline “Requirement Management”. TPM has defined and is applying formal procedures. The Jama Contour tool is being used for epSOS common requirements management.

In epSOS Phase 2, upon the request of TPM, WP3.C has revised the requirements of testing. This study is available both in the main deliverable of this WP3.C, namely D3.C.1 - Proof of Concept Testing Strategy, and as an appendix to this deliverable: D3.C.1 Appendix A - Revised Requirements of epSOS Testing Environment. Starting from 2012, the test assets that are provided by IHE-Europe are being updated according to these revised requirements.

3.6.2 Test Management

Test Management is the activity of managing the test process. A large number of test artefacts are created or generated during a test process, from a single Test Strategy to possibly hundreds of Test Cases and Test Scripts, to furthermore thousands of Test Logs. Without a suitable test management tool the process of managing these artefacts will become too overwhelming.

A professional Test Management tool enables the Tester to:

- Structure their tests accordingly
- Trace test artefacts with one another
- Report on the progress of test
- Integrate with a Requirements Management tool to ensure traceability.

Due to the structure of the project a Test Management Process / Tool is only required for the Component Conformance Test (pre-Projectathon), System Integration Test (Projectathon) and Pre-Pilot Test phases.

Gazelle® Management tool from IHE-Europe is used to manage Test Cases. See #6.1 Gazelle® Management Tool for more Information.

3.6.2.1 Test Case Priority

Testing is the process of reducing risk. To enable the tester to focus on the highest risks they need to know which tests to execute first. The assignment of a test case priority enables them to identify which tests have to be executed first.

The process of determining test case priority can be simplified or obtained through analysis of differing factors and the use of complicated formulas. The following table attempts to provide a simplified approach using the implication a resulting defect might have on the system to determine the priority.

The Test Case Priority can be classified into three categories:

Classification	Test	Implication[9]
1.	A Test Case that must be executed. The non execution must be justified and approved by the Project Manager.	The non execution could: – impair the system in such a way that it becomes unavailable, – result in human injury or loss of life – lead to the corruption or loss of critical data – constitute a severe security breach – lead to a severe usability / performance issue
2.	A Test Case that should be executed. The non-execution must be justified and approved by the Project Manager.	The non execution could: – result in a defect that impairs the system in such a way that a key feature becomes unavailable

[9] This does not constitute an exhaustive list of implications for the purpose of assigning test case priority, but is only meant to provide some guidelines.

Classification	Test	Implication[9]
		– lead to the corruption or loss of non critical data – constitute a security breach – lead to a usability / performance issue
3.	A Test Case that could be executed. The non-execution does not have to be justified and approved by the Project Manager.	The non execution could: – result in a defect that impairs a system in such a way that a feature does not function without some kind of manual intervention or workaround – results in a cosmetic defect – lead to a minor usability / performance issue

3.6.3 Problem Management

A problem or defect is a product anomaly or flaw, which is a deviation from the specification.

Problem management is the process of identifying, analyzing, recording, categorising and agreeing on problems, controlling them and communicating them to the relevant parties.

Due to the structure of the project a Problem Management Process / Tool is only required for the Component Conformance Test (pre-Projectathon), System Integration Test (Projectathon) and Pre-Pilot Test phases. It is agreed that the both epSOS Central Service Desk[10] and the Problem Management Process and Tools of IHE-Europe[11] are employed for these phases.

3.6.3.1 Defect Classification

Defect Severity is the operational impact a defect has on the system. Defect Classification is a sub process of the Problem Management process and describes how identified software defects are to be classified and a formal defect severity is to be assigned to them. It is suggested that the following Defect Classification is implemented for all test phases.

[10] epSOS Central Service Desk, https://support.epsos.cz/

[11] Gazelle JIRA, http://gazelle.ihe.net/jira/

The impact of Defect Severity can be classified into four categories:

Classification	Test	Implication
1. Fatal	Functional A defect resulting in the failure of the complete software system, of an essential subsystem or subsystem functionality whereby a workaround is not available. Non-Functional A defect resulting in a security breach with restricted or unrestricted access to sensitive data; severely restricted system or essential function performance[12]; corruption of system or application critical/sensitive data; or risk to human life.	The test object cannot be released.
2. Major	Functional A defect resulting in the failure of a complete software system or of essential subsystem functionality whereby a workaround is available. Non Functional A defect resulting in a security breach with restricted / unrestricted access to non critical or non sensitive data, restricted system or essential performance, corruption of system or application non critical data.	The test object should not be released.
3. Moderate	A defect resulting in the failure of non essential subsystem functionality whereby a workaround is or is not available.	The test object may be released with restricted usability.
4. Minor	A defect not resulting in the failure of the system or subsystem that has no effect on its functionality or usability. It concerns itself mainly with spelling mistakes and cosmetic failures.	The test object can be released.

[12] Performance Testing is directly related to the performance requirements. Severely restricted would be outside of the given requirements, whereby restricted would be far from the mean but still within the upper limit.

During the SIT (Projectathon) problems are recorded but are not classified by IHE as to their severity. Problems must be classified by the Projectathon participants, who are responsible for the solution, followed by re-execution of the corresponding tests.

3.6.4 Software Configuration Management

The traditional software configuration management (SCM) process is the process of handling changes in a software project. It identifies the functional and physical attributes of software at various points in time, and performs systematic control of changes to the identified attributes for the purpose of maintaining software integrity and traceability throughout the software development life cycle.

The SCM process further defines the need to trace changes, and the ability to verify that the final delivered software has all of the planned requirements that are supposed to be included in the release. It identifies four procedures that must be defined for each software project to ensure that an SCM process is implemented. They are:

- Configuration identification
- Configuration control
- Configuration status accounting
- Configuration audits

It is suggested that all PNs comply with these common principles of the SCM process in their development and maintenance activities. The same applies to the OpenNCP effort as well.

3.7 Test Specification and Test Data Definition Methodology

This section defines the approach for identifying, recording and distributing the Test Cases and the Associated Test Data.

3.7.1 Test Specification Definition Methodology

A Test Specification describes the test cases that have been identified through an informal direct analysis of the requirements, or the result of a formal test design process. It describes the case to test from a functional or non functional perspective without describing the technical implementation, which follows in the Test Procedure or Test Script.

A Test Specification can be created for a Product (NCP / Portal) or a specific phase (System Integration Test). As the development and testing within epSOS occurs mostly through third parties it is expected that these organisations create their Test Specifications:

- NCP / Portal development – the Software Producer (F.E.T., Participating Nations, Vendors, etc.) need to create Test Specifications for the test phases CUT, CST, and CIT.

- CCT (pre-PAT) and Projectathon (SIT / PAT) – IHE-Europe is responsible for creating the Test Specification with the support of WP3.C (previously WP3.9) and communicating it to all Participating Nations who have registered their interest to take part.
- Pre-Pilot Test (PPT) – IHE-Europe is responsible for creating the Test Specification with the support of WP3.C (previously WP3.9), specifically KT3.C.4, and communicating it to all Participating Nations that are taking part in the LSP.

As a guideline the Test Specification according to IEEE 829 should contain the following information:

- Test items (references to requirements, or other documents)
- Input specifications (non technical; the actual content has to be specified but not the data type, unless it is absolutely necessary for the test procedure)
- Output specifications (expected intermediate and end results)
- Environmental needs (special non-standard Hardware, Software, or other needs)
- Special procedural requirements (special constraints)
- Inter-case dependencies (test cases that must be executed prior to the current one)

The following sections describe the steps necessary to create a Test Specification.

3.7.1.1 Identify Test Cases

Identify input material

- Provides the basis for test (Specifications, Test Strategy, and Test Concept etc.)

Analyse input material

- Formally identify all requirements (if they are not already identified)
- Analyse requirements ensuring they are understandable, unambiguous, and Testable

Identify Cases

- Formal Test Design process
- Establish and Design Test Cases

3.7.1.2 Describe Test Cases

- Input and Output Specifications
- Environmental needs
- Dependencies
- Describe test data (structure and not content, see Test Data Definition Strategy)

3.7.1.3 Review Test Specification

- Formal review to verify scope and correctness.

3.8 Test Data Definition Methodology

For successful and efficient testing it is necessary to have test data produced by an independent entity. In the best case by the authority that will validate the tests performed during the testing sessions, namely the Projectathon. In epSOS Phase 1, WP3.9 WG A was responsible for providing the test strategy and testing tools in order to validate, approve, or reject the software under test. In epSOS Phase 2, WP3.C has these responsibilities. In epSOS Phase 1, WP3.10 was responsible for providing clean and correct test data to be used during testing phases. In epSOS Phase 2, WP3.B (supported with Clinical Semantic Expert Group and WP3.C) has these responsibilities. In addition, all the PNs that participate to the testing events are responsible for providing the test data in their systems, e.g. by complying with the Critical Test Data (CTD) and Representative Test Data (RTD) guidelines provided by epSOS for clinical documents.

3.8.1 Defining Test Data

The Test Data Definition is derived from specifications. During the analysis of specifications test data types are identified. The test data for epSOS can be divided into several sub groups:

1. Patient identification data
2. Document data
3. Technical data

3.8.1.1 Patient identification data

It is necessary to provide identification information for a number of patients for PNs acting as Country-A and participating in epSOS, or at least participating in the Projectathon and PPT. These patient identification data must be present in the testing environment of the Participating Nation, and the necessary credentials (e.g. unique patient identifier, name/surname/birth date, depending on the nation) have to be shared with the rest of the testing partners, through the mechanism proposed by the WP3.C / KT3.C.4 leader (e.g. an excel file in the Projectplace). IHE also has to provide patient identification credentials for the virtual patients that are available in its simulators.

During specific workflow tests, these data sets might be updated or new data sets created which can be used by all participants.

3.8.1.2 Document data

In epSOS Phase 1, there are 7 different document types used, namely the Patient Summary in the CDA Level 3 (fully structured) and CDA Level 1 (*.pdf embedded in the CDA envelope), the ePrescription document in CDA Level 3 and CDA Level 1, the eDispensation document in CDA Level 3 and CDA Level 1, and the Patient Consent document in CDA Level 1 (*.pdf embedded in the CDA envelope).

Several versions of each document type must be generated by epSOS as defined in the epSOS Pivot Format, as specified by WP 3.5 – Semantic Services. Each Participating Nation will need to import these documents, translate them to their native language and store them according to their structure and format. The participants of the Projectathon use the different types of documents, depending on which role they adopt, either as information creator in Country A or as a developer / implementer of a specific NCP solution or as an information consumer in Country B.

During special workflow tests (specific test scenarios) the participants will create new documents of each particular type, which following validation and approval of the epSOS evaluation team can be used in the same way as other documents.

3.8.1.3 Technical data

The technical data are for example the MVC, MTC and Local Terminology Repository (LTR), the XML Schema and Schematron of the epSOS documents, certain security tokens and / or certificates, or any other non patient / document data that are necessary for testing.

3.8.2 Generating Test Data

The test data used in the pre-Projectathon, Projectathon and PPT can be either “dummy data” (artificial data, generated by members of the epSOS testing team or from i.e. national authorities) or it can be real data, which is made anonymous by the epSOS testing team or a national representative.

All the necessary test data have to be provided by the participants before a testing event, according to a deadline that is set by the WP3.C / KT3.C.4 leader for that specific event.

If real data is used, it must be verified that the data cannot be linked to any living or dead persons (metadata of the documents, header entries, local and global Patient Ids, etc. must be anonymized prior to its usage or loading into the National Infrastructure).

The epSOS testing team does not have any preferences. Either solution or a mixture of both is possible.

3.8.2.1 Patient identification data

The data sets shall contain all the relevant patient information that is required to be used within each epSOS Pilot Participating Nation. The structure of the information, the character sets, the syntax of the information (i.e. patient address: AT: Musterstrasse 1, 1234 Demostadt vs. FR: 23, Rue de Test, 12345 La Testing) has to be the same as in the "real world scenario".

3.8.2.2 Document data

Medical documents, used within the epSOS pilots are stored for testing purposes within the test environment. For sufficient testing, epSOS needs several different documents of each type (structured [Level 3] and pdf-embedded [Level 1]), as they are used in the different Participating Nations, as well as several pivot documents. The epSOS team will produce the pivot documents, whereas the national documents are provided by the different Participating Nations.

The following approach shall be followed for the generation of document data:

- Test Data for End-to-End Validation
    - Critical Test Data (CTD): epSOS has to create through a team of physicians and semantic experts appointed by the PNs, a set of well-formed and not well-formed[13] PS, eP and eD documents in the English language based upon the epSOS Schema and MVC. PNs have to transform them to their own CDA document format and language
    - Representative Test Data (RTD): In addition, PNs have to provide sample documents representative of typical data generated by the underlying national infrastructure. RTD is PN specific, while CTD tries to remain unique among all PNs.

The advantages of this approach are pre-defined data sets that are common to all PNs and results that are predictable and easier to analyse in the event of failure. In addition to common data (CTD), there are also PN specific data (RTD).

3.8.2.3 Technical data

As the scope of the technical data varies, they are supplied from several places. For example, the schematrons for document validation are implemented by IHE-Europe and available in Gazelle® Management tool. The latest version of MVC / MTC is always available at Central Services, HealthTerm installation (eCRTS). MVC is maintained by epSOS, through the Semantic Experts

[13] Not well-formed documents are medical documents containing values that are not specified in the MVC or cannot be translated.

Team, and MTC is under the responsibility of the PNs. The central configuration area[14] is run by epSOS, and the configuration parameters of individual PNs are stored in this area through the tools provided by epSOS, by each PN.

3.8.2.4 Data Sets

Two data sets have been identified:

- Critical Test Data – is created manually to cover the widest extent of the underlying standard / profile. While a system may create such data, much of the data serves the purpose of ensuring the robustness of the system under test and supporting the development and validation of test tools.
- Representative Test Data – occurs in actual implementations and attempts to be representative of typical data generated by such systems. It can be generated by a HP, or derived from existing documents anonymising the patient sensitive data.

The following characterises these test data sets.

3.8.2.4.1 Critical Test Data

Within the context of epSOS, Critical Test Data is to be developed in parallel with the test case and tool development. Critical Test Data can be developed by a team independent of the PNs but requires a solid knowledge of the underlying specifications and standards. Only one set of Critical Test Data is required to be created.

Critical Test Data cannot be used to test the Country A National Connector directly. To test the National Connector A, the test data must be designed according to Country A formats.

Critical Test Data can be used to test NCP-B and Country B Front-end, but there might be constraints related to Terminology and Coding system translation/transcoding. Country A coding systems shall be applied: a Critical Test Data per PN has to be generated.

3.8.2.4.2 Representative Test Data

Within the context of epSOS, the Representative Test Data will be used as reference data for documents generated by a specific PN. They form the basic test data for the functional end-to-end testing at the Projectathon.

The test data has to be produced by the PN in the course of their NCP implementation and integration and serves three purposes:

[14] epSOS Central Config Area, https://econfig.nczisk.sk:8445/

- Support the testing of systems receiving the test data
- Support the senders of test data in the detection of data errors leading to improved quality of the data.
- Help identify gaps in the testing tools. There is a need for as many sets as there are sources of data. Each PN alone is a data source.

In the case of Documents (eP / eD, PS) Representative Test Data has to be provided in three formats:

- epSOS CDA 2 L3 document
- PDF of the Original Country A, embedded in a CDA L1 document
- Human readable version of the original document in English, to be used by the HP from Country B during validation of the content

The following lists the constraints that apply to the use of the representative test data sets:

- NCP, Country A National Connector, MTC-A, Country B Front-End must be able to handle these tests.
- Representative Test Data must be transformed (i.e. transcoding and translation) at every interface.
- PN Support, specifically the HPs of PN A are required during testing phases such as PAT and PPT to verify the data received by PN B.

Combining the Critical and Reference Test Data concepts, with the types of test data, the following tables are derived, to express the applicability and the test generation approach, which is later followed by WP3.10: Proof of Concept Testing.

Data Type / Set	Critical Test Data	Representative Test Data
Personal Data	Lower priority	Required
Document Data	Required	Required
Technical Data	Lower priority	Required

The following table depicts requirements on the generation of test data:

Data Type / Set	Critical Test Data	Representative Test Data
Personal Data	No stringent needs other than adherence to requirements and standards.	PN specific name and ID formats.

Document Data	The correctness of this test data must be strictly controlled to assure test data quality	The correctness of this test data must be strictly controlled to assure test data quality
Technical Data	No stringent requirements.	Must represent real configuration data.

Following the guidelines that are presented in this document regarding CTD and RTD, WP3.10 has generated CTD for clinical document types in epSOS. The folder that contains all the information about CTD and RTD in Projectplace is available at https://service.projectplace.com/pp/pp.cgi/r554036564. The content of CTD is defined in https://service.projectplace.com/pp/pp.cgi/r577042375. In addition to the 3 CTDs defined in this document, the PNs have to provide 1 completely null flavoured (NF) and 1 totally filled in document. The clinical validity of these 2 additional documents is not questioned. FAQ about CTD are available at https://service.projectplace.com/pp/pp.cgi/r571738012. The credentials for CTD need to be stored on https://service.projectplace.com/pp/pp.cgi/r574972429. Finally, the PNs need to provide the actual content of their RTDs and CTDs to a file manager hosted by Gazelle: http://gazelle.ihe.net/elfinder.

3.8.3 Storing Test Data

The patient identification data are stored as CTD and RTD credentials in an Excel file hosted in Projectplace: https://service.projectplace.com/pp/pp.cgi/r574972429.

For CTD and RTD instances, a file manager provided by the Gazelle tool is used: http://gazelle.ihe.net/elfinder.

The technical data is hosted in several places as explained above; e.g. eCRTS, epSOS central config area.

The test logs that correspond to test executions are hosted in Gazelle® Management tool by all the testing event participants.

3.8.4 Distributing Test Data

The Gazelle® Management tool will be used as the testing platform during the Projectathon as well as during the pre-PAT or PPT-slots, in order to qualify a software component / solution.

The test data is distributed through the same mechanisms where they are stored, as explained in the previous section.

3.9 Quality Metrics

The following list of potential metrics might give an overview of epSOS service quality metrics to be considered. No single metric is able to unambiguously measure a particular attribute. Different metrics may give different rank orderings of the same attribute, making comparisons across categories difficult and uncertain.

This section lists the quality metrics and describes the qualities of a good metric, the difficulty of measuring certain attributes, and criteria for selecting among metrics. epSOS should consider the presented quality metrics.

3.9.1 What Makes a Good Metric?

- **Simple and computable:** Learning the metric and applying the metric must be straightforward and easy tasks.
- **Persuasive:** The metrics should be measuring the correct attribute. In other words, they display face validity.
- **Consistent and objective:** The results must be reproducible.
- **Consistent in units or dimensions:** Units should be interpretable and obvious.
- **Programming language independent:** The metrics should not be based on specific tasks and should be based on the type of service being tested.
- **Gives feedback:** Results from the metrics must give useful information back to the person performing the test

3.9.2 List of Applicable Metrics

- Fault density
- Defect density
- Defect indices
- Estimated number of faults remaining (by seeding)
- Fault-days number
- Residual fault count
- Cumulative failure profile
- Software purity level
- Requirements compliance
- Test coverage
- Data or information flow complexity
- Reliability growth function
- Requirements traceability

- Failure analysis elapsed time
- Error distribution(s)
- Testing sufficiently
- Software maturity index
- Mean time to failure
- Person-hours per major defect detected
- Failure rate
- Number of conflicting requirements
- Software documentation and source listing
- Number of entries and exits per module
- Rely-required software reliability
- Software science measures
- Software release readiness
- Graph-theoretic complexity for architecture
- Completeness
- Cyclomatic complexity
- Test accuracy
- Minimal unit test case determination
- System performance reliability
- Run reliability
- Independent process reliability
- Design structure
- Combined hardware and software (system) availability
- Mean time to discover the next k-faults / k-fault tolerance

3.9.3 Choosing Metrics

Determining which metric to choose from the family of available metrics is a difficult process. No unique measure exists that a developer can use or a user can apply to perfectly capture the concept of quality.

Determining which metric to use is further complicated because different stakeholders have different preferences for software attributes. Some stakeholders care about the complexity of the software; others may not.

For a metric should be considered reliable, it needs to have a strong association with the underlying quality construct that it is trying to measure. IEEE provides five validity measures[15] that epSOS service testers & developers can apply to decide which metrics are most effective at capturing the latent quality measure:

Linear correlation coefficients	Tests how well the variation in the metrics explains the variations in the underlying quality factors. This validity test can be used to determine whether the metric should be used when measuring or observing a particular quality factor is difficult
Rank correlation coefficients	Provides a second test for determining whether a particular metric can be used as a proxy for a quality factor. The advantage of using a rank order correlation is that it is able to track changes during the development of a software product and see if those changes affect software quality. Additionally, rank correlations can be used to test for consistency across products or processes.
Prediction error	Is used to determine the degree of accuracy that a metric has when it is assessing the quality of a particular piece of software.
Discriminative power	Tests to see how well a particular metric is able to separate low quality software components from high quality software components.
Reliability	If a metric is able to meet each of the four previous validity measures in a predetermined percentage of tests then the metric is considered reliable.

[15] IEEE Standard for a Software Quality Metrics Methodology, IEEE Std 1061™-1998 (R2009)(Revision of IEEE Std 1061-1992)

4 epSOS Test Plan Definition

This section describes the test plan with respect to the specifications of the WP3.X and the Test Strategy already defined in WP3.9 / WP3.C. The test plan guide describes:

- the concepts used
- the assumptions and open issues
- the tests cases
- the workflow tests

4.1 Definition of the concepts used to define the epSOS test plan/cases

4.1.1 Profiles:

IHE Integration Profiles describe the solution to a specific integration problem, and document the system roles (Actors), standards and design details for implementers to develop systems that cooperate to address that problem. For example, the eDispensation service is based on the IHE-XDR profile, ITI-41 transaction. IHE actors and transactions that are profiled by epSOS are presented in the following figure. It should be noted that yet (as of December 2012) the XCF profile is not used in practice.

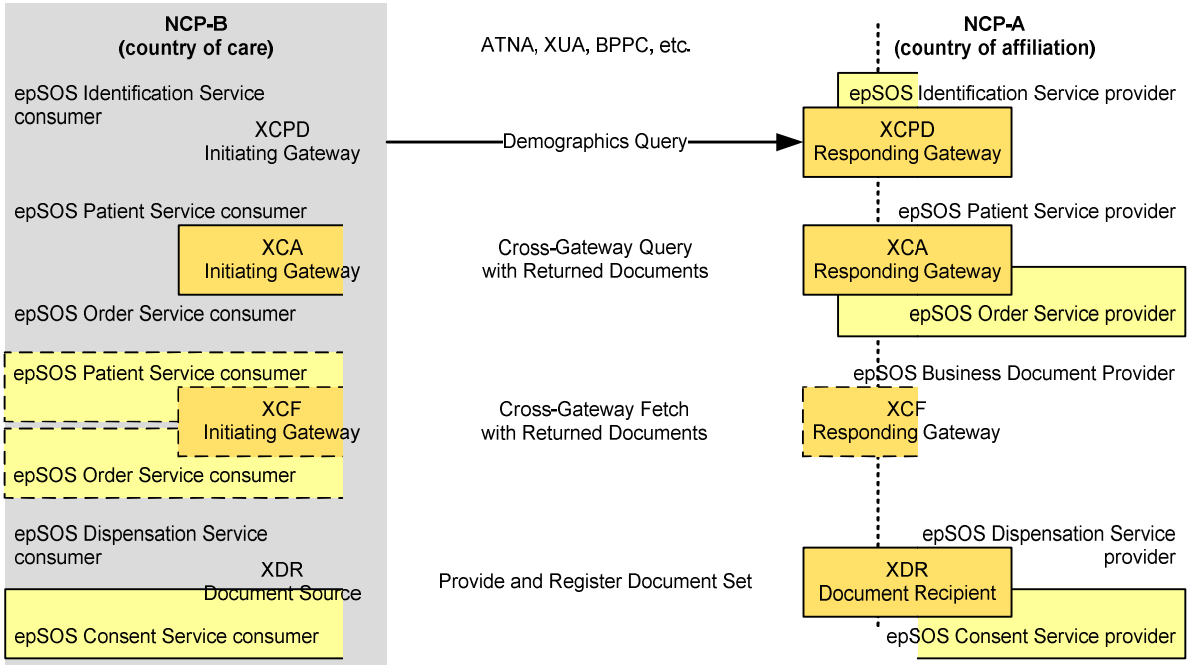


Figure 5 IHE actors and transactions that are profiled by epSOS

4.1.2 Roles/actors:

IHE Actors are responsible for producing, managing and/or acting on information in the context of an IHE Profile. For each test case, the roles played by the system are described in order to test their conformance to the corresponding actor(s). An example actor is CONTENT_CONSUMER, which is utilized in many test cases.

4.1.3 epSOS test case:

A test case describes in the detail the actors, their interactions, and the intended results (conformance tests). Several types of test cases are defined:

- Peer to peer test - where two actors exchange messages (request/ respond)
- No peer test - where a content of a document is checked. Example: the ePrescription document in CDA format is analyzed and validated.
- Display test - where a monitor directly checks the display result on the screen. For example, a Patient Summary is displayed by the application and the GP can read directly the document.

4.1.4 Test steps

A test case is described with one or more steps, where each corresponds to one functional test. For example, a test to obtain one particular fault condition is considered as a step.

4.1.5 Workflow test

The workflow test (interoperability test) tests a complete use case and combines several epSOS services. For the epSOS Projectathon, generic workflows are defined and cover the most common use cases and take into account the different roles played by the HP's (Doctor, Nurse and Pharmacist) as well as the patient as his/her own healthcare manager, as the patient can give/revoke consent and therefore allows/denies access to his/her own medical data.

4.2 Test Plan Assumptions

The definition of the test cases is based on the following assumptions. The following list of documents was used to specify the test cases and workflow tests:

[D3.1.2]	Final definition of functional service requirements – ePrescription
[D3.2.2]	Final definition of functional service requirements – Patient Summary
[D3.3.2]	Final epSOS System technical specification
[D3.4.2]	Common Components Specifications
[D3.5.2]	Final semantic services definition (In particular Appendix C, Pivot document specifications)
[D3.6.2]	Final Identity Management Specification Definition
[D3.7.2]	Final Security Services Specification Definition
[D3.9.1]	epSOS Pilot System Components Specifications

4.2.1 Security aspects

- Audit Trail: only the content of the audit log message is tested. Transport is not tested, since it is in the responsibility of each Participating Nation and was not specified within the epSOS LSP.
- Two assertions are covered by the epSOS LSP: the HP identity assertion and the TRC (Treatment Relationship Confirmation) assertion. Identity assertion relates to the principle that HP is already identified at the NCP. When a patient seeks a treatment, a new, optional, assertion is requested, the TRC. This assertion contains the patient id, the purpose of use and a reference to the identity assertion used for the communication. Before issuing this

assertion, the patient id is discovered, by sending a message to the patient identification service containing the identity assertion. When the patient identifier is resolved, the TRC assertion is issued. All subsequent messages will contain the identity assertion and (optionally) the TRC assertion. On the receiving side, SAML assertions will be scrutinised and the relation between the TRC and the identity assertion will be verified.

- Establishing the VPN connection is independent from the system conformance and as such we have not taken the VPN aspects into consideration in the provided test plans. Establishing VPN communications is part of conformance gates though.
- In the first two PATs, certificates provided by IHE-Europe were used by the participants. However, in epSOS Phase 2, epSOS compliant certificates are used by participants, as explained in conformance gates.

5 Test Plan Structure

5.1 Actors

The following actors are defined for the epSOS tests cases:

epSOS Actors
NCP-A - National Contact Point Country A
NCP-B - National Contact Point Country B
CONTENT_CREATOR - Content Creator
CONTENT_CONSUMER - Content Consumer
ARR - Audit Record Repository
SN - Secure Node
TIME_CLIENT - Time Client
TS - Time Server

5.2 epSOS Test Cases

The Test Cases are registered directly in the Gazelle® test management tool in the Gazelle Master Model. See #6.1 Gazelle® Management Tool for more information.

5.2.1 pre-Projectathon and PPT-slot Test Cases (Conformance Tests)

The following are the list of test cases that are used in pre-Projectathons and PPT-slots as of December 2012; i.e. they are the test cases for conformance testing, and need to be completed by individuals against the IHE simulators and validators. The types of epSOS test cases are defined in # 4.1.3.

They are available through **http://gazelle.ihe.net/epSOS-doc/** as well.

Table 1 pre-Projectathon and PPT-slot Test Cases

Code	DisplayName	Description	NCP
epSOS-1	CDA Content Creator	The purpose of this test is to gather sample CDA documents from participating systems	NCP-A and NCP-B
epSOS-2	NCP-A Identification Service	The purpose of this test is to evaluate the capability of the NCP-A to respond to an identification service request	NCP-A
epSOS-3	NCP-A Patient Service	The purpose of this test is to evaluate the capability of the NCP-A to respond to a patient service request. We test here the XCA query	NCP-A
epSOS-4	NCP-A Order Service	The purpose of this test is to evaluate the capability of the NCP-A to respond to an order service request. We test here the XCA query	NCP-A
epSOS-5	NCP-A Dispensation Service	The purpose of this test is evaluate the ability of the NCP-A to receive an eDispensation document from the NCP-B	NCP-A
epSOS-6	NCP-A Consent Service	The purpose of this test is evaluate the ability of the NCP-A to receive an eConsent document from the NCP-B	NCP-A
epSOS-7	NCP-B Identification Service	The purpose of this test is to evaluate the capability of the NCP-B to initiate valid identification service request	NCP-B
epSOS-8	NCP-B Patient Service	The purpose of this test is to evaluate the capability of the NCP-B to send a patient service request to the NCP-A. We test here the XCA responses	NCP-B
epSOS-9	NCP-B Order Service	The purpose of this test is to evaluate the capability of the NCP-B to send an order service request to the NCP-A. We test here the XCA responses.	NCP-B
epSOS-10	NCP-B Dispensation Service	The purpose of this test is to evaluate the capability of the NCP-B to send a Dispensation Service Initialize() request to the NCP-A. We test here the XDR document submission	NCP-B
epSOS-11	NCP-B Consent Service	The purpose of this test is to evaluate the capability of the NCP-B to send a consent service request to the NCP-A. We test here the XDR responses	NCP-B

Depending on the services that are implemented by a participant, the following tables show different configurations of conformance test cases:

PN-A Patient Summary PN-B Patient Summary

epSOS-1	epSOS-1
epSOS-2	epSOS-7
epSOS-3	epSOS-8
epSOS-6	epSOS-11

PN-A ePrescription PN-B ePrescription

epSOS-1	epSOS-1
epSOS-2	epSOS-7
epSOS-4	epSOS-9
epSOS-6	epSOS-11

PN-A eDispensation PN-B eDispensation

epSOS-1	epSOS-1
epSOS-2	epSOS-7
epSOS-5	epSOS-10
epSOS-6	epSOS-11

5.2.2 Projectathon and PPT-slot Test Cases (Interoperability and Conformance Tests)

The following are the list of test cases that are used in Projectathons and PPT-slots as of August 2012; i.e. they are the test cases for mostly interoperability (workflow tests) and partially conformance testing (scrutiny tests), and need to be completed peer-2-peer and by individuals against the IHE validators:

Table 2 Projectathon and PPT-slot Test Cases

Test-Id	Keyword	Keyword	Version	Status	Peer type
11458	epSOS_Authorization	This test shows the role based access to epSOS documents, according the role description in epSOS Specification	PPT2011	ready	P2P_TEST
11490	epSOS_Scrutiny_Audit_Messa	In this test the structure of the Audit Message is verified	PAT2010	ready	NO_PEER_TEST
11562	epSOS_Scrutiny_Certificates	The purpose of this test is to verify the conformity of the certificates with the epSOS requirements.	PPT2011	ready	NO_PEER_TEST
11468	epSOS_Scrutiny_eDispensatio	In this test the structure of the CDA L3 document epSOS eDispensation is verified.	PAT2010	ready	NO_PEER_TEST
11479	epSOS_Scrutiny_ePrescription	In this test the structure of the CDA L3 document epSOS ePrescription is verified.	PAT2010	ready	NO_PEER_TEST
11462	epSOS_Scrutiny_PS	In this test the structure of the CDA L3 document epSOS Patient Summary is verified.	PAT2010	ready	NO_PEER_TEST
11563	epSOS_Scrutiny_SAML	The purpose of this test is to verify the conformity of the SAML assertions used in the context of the epSOS project.	PPT2011	ready	NO_PEER_TEST
11472	epSOS_WF_ePresc_eDispens	This test shows the complete workflow in the epSOS ePrescription Service context.	PAT2010	ready	P2P_TEST
11561	epSOS_WF_PS	This test shows the complete workflow in the epSOS Patient Summary Service context.	PPT2011	ready	P2P_TEST

5.2.3 Test Cases for end-to-end Functional Testing

End-to-end functional testing is part of both Projectathons and PPT-slots. However, it is not directly managed through the Gazelle® Management Tool, as in the case of the test cases presented in the previous sections. The HPs and/or semantic experts of the participants acting as Country B do several patient data exchanges for both Patient Summary and ePrescription / eDispensation documents, just like the epSOS_WF_PS and epSOS_WF_ePresc_eDispens workflow tests. But instead of technical details, the HPs and/or semantic experts are asked to fill in electronic questionnaires regarding the clinical validity and quality of the exchanged information.

These questionnaires are prepared by epSOS semantic experts, and hosted by IHE-Europe at **http://gazelle.ihe.net/content/epsos-cda-evaluation-form**. The filled in questionnaires are evaluated by epSOS semantic experts. The details of end-to-end functional testing is presented in D3.10.1 Appendix 8 - epSOS end-to-end Functional Testing for Projectathon and Pre Pilot Testing: Guidelines for HPs and PNs.

5.3 Test Methodology

In this section, the reader will find some examples of how the test plan was built according to the assumptions made during the meeting which was held in Rennes, France from July, 26th – 30th, 2010 and where the specifications of the test cases were defined and registered in the Gazelle tool for the first time. Later, almost all test cases have been updated according to feedback from the testing team and test event participants.

5.3.1 epSOS document assumptions

- The original documents are XDS-SD CDA documents embedding a PDF of the original print-out document.
- Projectathon participants have to initialise their databases with provided set of patients and HPs (minimum 5 per role). They need to create sample Level 3 CDA documents for eP, eD, ePS and consent documents for those patients (*epSOS Friendly documents*). The original documents for these samples need also to be available as XDS-SD documents (PDF embedded in a CDA; or Level 1). The participants should comply with the Critical Test Data and Representative Test Data guidelines. Participants need to have configured roles (GPs, nurses and pharmacists).
- Pivot documents will be created by NCPs during the Projectathon or during the pre-Projectathon phase for testing purposes.
- Only transactions between NCP-A and NCP-B are tested. Transactions from the National Infrastructure to the NCPs are not tested, since they are out of scope of epSOS. Only the

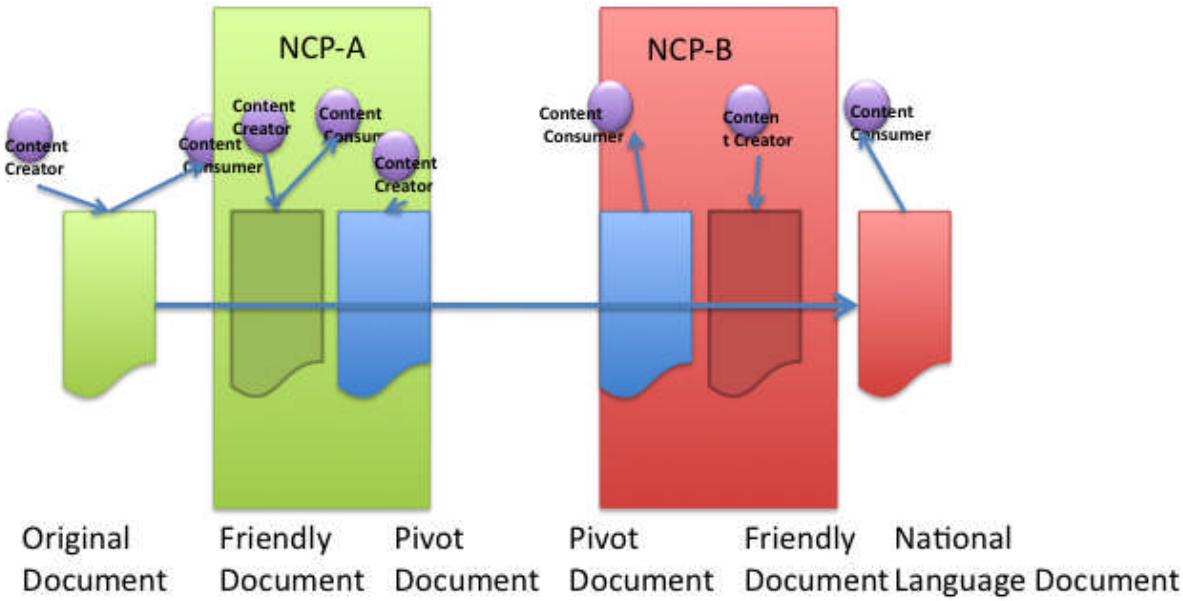
content of documents is tested (eP, eD, ePS, Audit Messages, embedded documents) for exchanges that take place between the National Infrastructure and the NCP (Content testing).

- Three generic workflow tests have been defined that covers several use cases defined in D3.1.2 and D3.2.2.

5.3.2 epSOS Document testing

The lifetime of the epSOS documents is the following:

- V1: the National Infrastructure (NI) sends an original document into NCP-A via an interface. This document has to be an “epSOS Friendly document”. This version is provided by the CONTENT_CREATOR actor.
- V2: NCP-A transforms the “epSOS Friendly document” into the pivot document. As such it acts as a CONTENT_CREATOR. NCP-A also acts as a CONTENT_CONSUMER of epSOS “Friendly documents”.
- V3: NCP-B consumes the Pivot document and therefore acts as a CONTENT_CONSUMER. It translates epSOS Pivot document into the national language. As such it acts as a CONTENT_CREATOR.



The Test Cases are defined as the following:

- Roles:
  - NCP is a consumer of the CONTENT_CREATOR epSOS Friendly documents
  - NCP is a consumer of epSOS pivot documents
  - CONTENT_CONSUMER is a consumer of NCP epSOS translated documents.
- Test cases:
  - Scrutiny test for CONTENT_CREATOR epSOS Friendly documents
  - Scrutiny test for NCP epSOS pivot documents
  - Scrutiny test for NCP epSOS translated documents

Each kind of document (eP, eD, ePS) is tested with the same methodology.

XDS-SD profile, used to communicate *.pdf documents, needs a scrutiny test and a CONTENT_CREATOR to CONTENT_CONSUMER test (for correct rendering).

5.3.3 Authorisation test

The purpose of this test is to verify the responses of the NCP-A to NCP-B requests, testing the responses or no responses according to the role of the user on the NCP-B side. The participant needs to prove (by meanings of log files) that an authorisation procedure effectively took place. In practice, NCP-A is asked to show the content of the assertion received from NCP-B (show the role) and to show that it responded according to the policy in place.

Several requests that combine multiple transactions (patient identification, ePrescription, Patient Summary) and multiple roles of NCP-B users (Doctor, Pharmacist, Nurse, Admin) are sent from NCP-B to NCP-A, and NCP-A is tested to act according to its national policies.

In addition, IHE-Europe provides the participants a set of XACML 2.0 policies that can be tested during Projectathons and PPT-slots, if the participants are already implementing national level XACML 2.0 policies. These tests are required only if they apply with individual participants. These policies are:

ALL-PERMIT.xml - for all subjects, for all actions, for all resources, the authorisation decision is ”Permit". This policy allows the access to all documents for all roles.

ALL-DENY.xml - for all subjects, for all actions, for all resources, the authorisation decision is “Deny”. This policy denies the access to all documents for all roles.

5.3.4 HP Authentication with Identity

This test verifies that the HP identity assertion, created by an identity provider (part of national infrastructure); is validated by the NCP. A SOAP Fault is thrown if the assertion is wrong.

5.3.5 ATNA Expired Certificate List

This test can be performed with any communication. It needs to be executed with an expired certificate.

6 Testing Tools

The list of the testing tools needed for the pre-Projectathon, Projectathon and Pre-Pilot Testing was defined after reviewing the epSOS specifications and the test plan definition.

Four types of tools have been selected:

- Gazelle® management tool: this test bed suite is an advanced set of tools that better integrates existing tools on a common platform, provides new functions and a single user interface. Gazelle is designed to support on demand interoperability testing of a single application or network as well as to enhance face to face testing of multiple systems in a Connectathon setting.
- Simulators: the simulators are tools that act as a connection partner in order to test a System Under Test's (SUT) behaviour. Simulators emulate the behaviour of a SUT implementing a specific combination of actors/profiles.
- External Validation Services (EVS): this tool allows the validation of messages or documents produced by the SUT.
- Data servers : this tool provides testing data such as demographic data or certificates (from a testing PKI)

These tools are under the responsibility of IHE-Europe.

6.1 Gazelle® Management Tool

The Gazelle® Management Tool is already used for the IHE Connectathons. Dedicated epSOS sessions are created in Gazelle® Management tool in order to manage the necessary testing processes and results. Its major functionalities include:

- Participant registration
- User management (participants and testers)
- SUT management
- Test management
- Simulator and validator management
- Test engine
- Configuration management
- Samples sharing management

- Pre-Projectathon test management (including the test grading)
- Connectathon test management (including the test grading)
- PPT-slot test management (including the test grading)

For more information see: **http://gazelle.ihe.net/content/gmm-gazelle-master-model**. To access the Gazelle® Management Tool a login is required. It is possible over the following link to register oneself and obtain a login: **http://gazelle.ihe.net/EU-CAT/**. Click on the hyperlink "Create an account" and complete the required fields.

6.2 Test Simulators and External Validation Services

To support the testing of individual components or systems, simulators and external validators are made available. The following lists those simulators and external validators with their intended purpose:

Simulators

Simulators	Purpose	Responsible Organisation
eDispensation Service	actors from IHE-XDR profile are extended and simulated	IHE
Patient Service	actors from IHE-XCA profile are extended and simulated	IHE
Identification Service	actors from IHE-XCPD profile are extended and simulated	IHE
Consent Service[16]	actors from IHE-XDR profile are extended and simulated	IHE

Simulators are accessible via URLs. For example, the following URL allows the user to access the XCPDINIT Simulator: **http://gazelle.ihe.net/XCPDINITSimulator/home.seam**

There is also a work in progress (as of October 2012) which collects all available simulators in one place: **http://gazelle.ihe.net/XDStarClient**. It is suggested that the simulators and validators are accessed from this page starting from the 2nd PPT-slot in September 2012.

[16] Is based on the BPPC Profile.

External validation services

Documents and messages	EVS	Responsible Organisation
Medical Documents: ePS, eP, eD	CDA Schematrons	IHE
Consent Document, pdf documents	Consent Document, pdf documents	IHE
Medical Documents: ePS, eP, eD	Schematrons (SD)	IHE
Consent Document , pdf documents	Schematrons (SD)	IHE
epSOS profiles using HL7 V3 messages	HL7 v3 evaluator	IHE
Audit Trail Events	Event evaluator	IHE
XAML Assertions	XAML evaluator	IHE

External Validators are accessible via URL's. For example, the following URL allows the user to access the CDA Validation: **http://gazelle.ihe.net/EVSClient/cda/validator.seam**.

In addition, all External Validators can be accessed through a single link: **http://gazelle.ihe.net/EVSClient/**. All epSOS related validators are available under the epSOS group.

Schematrons check both syntax and coded values of the documents, verifying the adoption of the epSOS Coding Systems. The currently used Master Value Set Catalogue (MVC) can be accessed at URL: **http://gazelle.ihe.net/epSOS/codes/epSOS-pivot.xml**.

As the end of July 2012, IHE-Europe has also introduced model based validation of the documents, for the first time only for epSOS pivot documents. IHE will gradually switch from Schematron based validation to model based validation. Yet, the Schematrons are still available and can be used.

It should be noted that these simulators and validation services are almost 7/24 available online, and all the PNs are encouraged to use them, even during their development.

6.3 Data Servers

The data servers will provide dummy data during the test execution. Two types of data servers are available:

- Demographic data service provides demographic data from each European country to the SUTs. The demographic data service is accessible via the following URL: **http://gazelle.ihe.net/DDS/home.seam**
- PKI server provides certificate, CRL, and other services linked to a PKI environment. The PKI service is accessible via the following URL: **http://gazelle.ihe.net/pki/**. This service has been used for November 2010 and April 2011 Projectathons, but not used any more since the certificates provided by this PKI are not epSOS compatible.

7 epSOS Projectathon

7.1 Projectathon Overview

To prevent confusion with the IHE Connectathon, epSOS has renamed it to Projectathon. While the approach is the same, the actors and profiles have been adapted to the requirements of epSOS.

The IHE Connectathon is the healthcare IT industry's only large-scale interoperability testing event. Connectathons are held annually in Asia, Europe and North America. During the Connectathon, systems exchange information with complementary systems from multiple vendors, performing all of the transactions required for the roles they have selected, called IHE Actors, in support of defined clinical use cases, called IHE Profiles. Thousands of vendor-to-vendor connections have been tested overall, and tens of thousands of transactions passed among the systems tested. The sponsoring organisations publish the results of this testing for public review (see below).

The Connectathon provides detailed validation of the participants' interoperability and compliance with IHE profiles. Participating companies prepare for the event using testing software—the MESA test tools—developed for this purpose. It offers vendors a unique opportunity for connectivity testing—removing barriers to integration that would otherwise have to be dealt with 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.[17]

During the Bordeaux 2010 Connectathon, the MESA tools were substituted by the GAZELLE® tools. epSOS has adopted the GAZELLE® tools for testing events (pre-Projectathon, Projectathon, Pre-Pilot Testing).

The following figure shows the process employed by a Projectathon:

[17] Copyright © 2010 IHE International

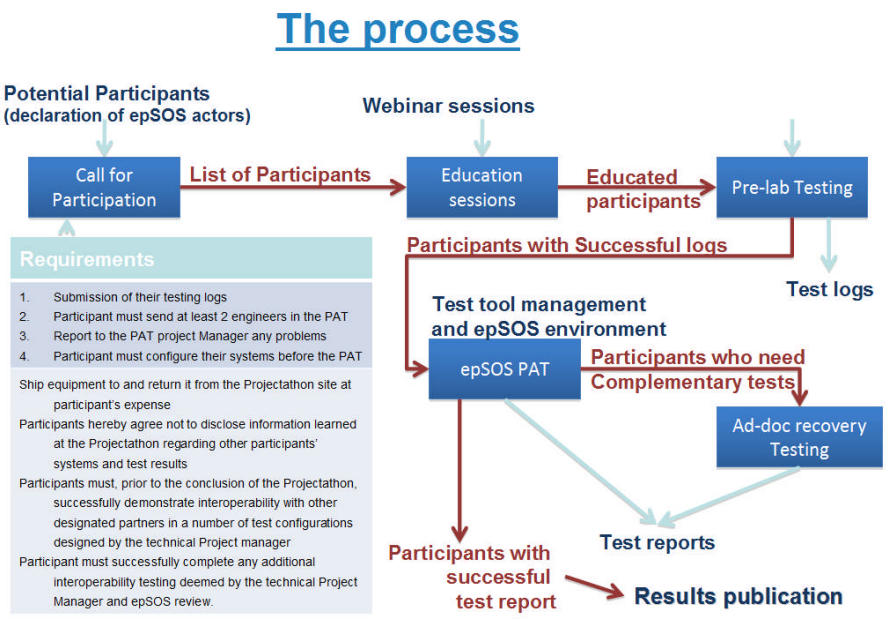


Figure 6 - Projectathon Process

7.2 Logistical Organisation of the Projectathon

In order to support the Projectathon, the epSOS project has to launch logistical activities, in cooperation with IHE-Europe. It is part of the epSOS Testing Strategy to organize Projectathons together with European Connectathons. There was only one exception to this common principle so far, namely the first Projectathon that was a dedicated epSOS testing activity in Slovakia in November 2010. After that, so far all the Projectathons have been held together with European Connectathons (Pisa in 2011, Bern in 2012) and the next one will be in Istanbul in April 2013. The idea is to make epSOS testing part of the Connectathons, even after the end of the epSOS Project. If it is found absolutely necessary to organize a dedicated Projectathon though, epSOS can decide in this respect; subject to WP3.C, TPM and PSB approval.

7.2.1 Description of the requirements

7.2.1.1 Duration

The length of the Projectathon is five working days, following the duration of regular Connectathons. The duration of pre-Projectathon is much longer, not strictly specified, but starts after registration in Gazelle for Projectathon and lasts till the Projectathon. IHE-Europe checks and validates pre-PAT tests latest two weeks before the PAT.

7.2.1.2 Facilities

The PAT must be hosted by a vendor-neutral organisation / institution including the organisation team, i.e. IHE-Europe in the case of epSOS. This team must have sufficient technical background in order to follow the technical requirements of the PAT such as the establishment of the network. All the technical requirements are delivered by the IHE-Europe.

The facilities need to include the following items (not a restrictive list):

- Room with video projector and microphone(s)
- Room to stock the servers hosting the testing applications
- Small room for organisation team
- Tables and chairs (one table (at least 1,40 X 0,80 m) and two chairs per system)
- Power
- Network
- Catering (water availability, break morning and afternoon and lunch) for the participants (note: vegetarian meals must be included)
- Signals (to sign the table/systems, room, restrooms…)
- Registration services and badges for participants
- Security and insurances
- Other

When the PAT is organized in conjunction with a Connectathon, all these are taken care of by IHE-Europe.

7.2.2 Description of the tasks before the PAT

The following tasks must be completed prior to the PAT:

- Call for the participants: this call must be open at least six months and closed three months before the PAT is scheduled to begin. The number of participants is the first element needed in order to determine the size of the facilities.
- Detailed description of the required facilities and Request for Proposal (RFP) if needed (size of the room, number of tables/chairs, all the catering for the number of participants including the testing management (Project Manager, monitors, …)
- Detailed description of the technical infrastructure (power and network) and all the support needed during the PAT and RFP if needed

- Selection of the location, and all providers in order to satisfy the requirements
- Selection of the security provider and insurance

7.2.2.1 Tasks prior to and during the PAT

The following are the list of task that takes part immediately before and during the PAT:

- On the day(s) before the PAT, the environment is built according to the requirements of the different logistical aspects that the network is built upon.
- During the PAT, the organisation team must follow all the logistical aspects of the PAT including the support of the network and all other requirements.
- An online questionnaire can be provided by the organisation team to participants in order to evaluate the facilities of the PAT.

7.2.2.2 Tasks post PAT - Feedback and report

The organisation team will provide a report to the epSOS project by compiling the questionnaires completed by the participants, adding their own feedback and comments.

7.2.3 Participating Nation Activities

The Participating Nations who want to test their systems (NCP and part of the national infrastructure) at a Projectathon have to prepare themselves by taking into account the following:

- epSOS specifications
- the instructions given by IHE-Europe
- the education session organised by IHE-Europe
- pre-Projectathon test

7.2.3.1 Prior to the PAT

The first PN task is to register their candidature along with their team members to the epSOS Projectathon. A call for candidates is launched six months before the Projectathon. Each PN can register in the Gazelle® management tool their system and the role (Country A or B) that they wish to assume in the Projectathon.

Following the registration of the PN and their team members, they must participate in an IHE-Europe organised education session. The education session will present to the PN the test environment, the tools and the test plans, and provide the information needed to prepare for the Pre-Projectathon tests. IHE-Europe gives the access rights to the test tools and a specific space where they can upload their own results.

Following the education session, the PN can access the test plans and test data together with the test tools. They need to familiarise themselves with the Gazelle® management tool and test their NCP in their own lab.

According to the PN role, they execute their lab tests by executing the test plans and uploading their test logs to the Gazelle® management tool. During the lab test, interactions between IHE-Europe and the PN are encouraged and facilitate an understanding of the test environment and prepare the PN for the actual Projectathon.

Following the lab test, IHE-Europe will verify the results of the PN uploaded test logs and given that the PN has passed the required tests will be provided authorisation to participate in the Projectathon.

7.2.3.2 During and Post the PAT

The Projectathon is closed and secure, and access is granted only after a prior registration. The PN participants must be registered in the Gazelle® management tool, which is the responsibility of the PN. Participants need to present themselves at the Projectathon reception in order for them to receive their identification that authorises them to enter the secure areas of the Projectathon.

A specific area will be designated to each PN. The PN bring their NCP and infrastructure to the Projectathon and build it in the designated area. For logistical reasons, the PN has to declare if a part of their system is to be connected to the internet.

As is the case of the Pre-Projectathon tests, the PN executes the Projectathon test plans and load their results to the Gazelle® management tool. IHE-Europe will verify those test results.

Following the Projectathon, PN who failed tests or who were unable to complete some tests are provided the possibility to finalize them during a remote recovery session, which is known as PAT Grace Period. This period starts right after the Projectathon and lasts for 1 or 2 weeks. The duration is determined according to the observations during the Projectathon. The test results are recorded in the Gazelle® management tool and the results are verified by the IHE-Europe test team.

Annex

A1 References

[AnnexI] Annex I – "Description of Work"

[D3.1.2] epSOS D3.1.2 Final definition of functional service requirements – ePrescription, Version 1.1, 27.10.2009

[D3.2.2] epSOS D3.2.2 Final definition of functional service requirements – Patient Summary, Version 0.6, 13.05.2010

[D3.3.2] epSOS D3.3.2 epSOS System Technical Specification, Version 1.4, 30.04.2010

[D3.4.2] Common Components Specifications, Version 2.2, 15.11.2011

[D3.5.2] Final Semantic Services Definition, Version 0.0.6, 31.05.2010

[D3.6.2] Final Identity Management Specification Definition, Version 1.1, 06.04.2010

[D3.7.2] Final Security Services Specification Definition, Version 0.4, 02.02.2010

[D3.9.1] epSOS Pilot System Components Specifications – Version 1.0, 01.10.2010

[D3.9.1 - App. B1/B2] epSOS Semantic Implementation Guidelines MVC/MTC – Version 1.4, 25.07.2011

[D3.10.1 - App. 8] epSOS end-to-end Functional Testing for Projectathon and Pre Pilot Testing: Guidelines for HPs and PNs – Version 1.0, 28.09.2011

[D3.C.1] Proof of Concept Testing Strategy, Version 1.5, 21.12.2012

[D3.C.1 - App. A] Revised Requirements of epSOS Testing Environment, Version 1.0, 21.12.2012

[ISTQB] International Software Testing Qualification Board, Standard glossary of terms used in Software Testing, Version 2.1, 01.04.2010: **http://istqb.org/downloads/glossary.html**

A2 Glossary

The general epSOS Glossary will not be exhaustively explained in this document, because it is accessible on the Projectplace. This section is focused on specific terms related to WP3.9 / WP3.C.

Term	Description
Common Software Components	Software components that are supported centrally by epSOS and used within the NCPs
Component	For the purpose of epSOS it can be a discrete software module or a sub-system
Component Integration Test (CIT)	The phase foreseen to test the interaction between two tested systems. Its objective is to expose defects in the interfaces and the interaction with other previously tested systems and to verify that they are interoperable with one another. This phase can only take place when a software producer develops a component that is required to be integrated with another system (actual or reference).
Component System Test (CST)	The phase foreseen to functionally and non-functionally test a software component. Its objective is to expose defects in the functional and non-functional behaviour of the software system under test. The systems are treated as black boxes and as such should be tested using appropriate black box techniques.
Component Unit Test (CUT)	The phase foreseen to test the software components. Its objective is to expose defects in the internal behaviour of the software component under test. The components are treated as white boxes and as such should be tested using appropriate white box techniques.

Term	Description
Conformance Test (CCT)	The phase foreseen to test a component or system against the pre-defined epSOS test cases as the pre-requisite for entry into the Service Interoperability Test (Projectathon). Its goal is to verify that all pre-defined test cases pass successfully when executed against the component or system under test.
Connectathon	The healthcare IT industry's only large-scale interoperability testing event organised and managed by IHE. It provides detailed validation of the participants' interoperability and compliance with IHE profiles. It is a face-to-face event, and lasts for a week.
end-2-end Functional Testing	Testing activity that has to be carried out by HPs and/or semantic experts from PNs during PAT and PPT-slots for assessing the clinical validity of the exchanged medical data. The information (observation, feedback, etc.) from PN experts are collected via electronic questionnaires, and evaluated by epSOS semantic experts.
epSOS Interoperability Profiles	Subset of IHE profiles adapted to the epSOS project use cases.
epSOS Portal	Web portal providing a simple interface to be used by Country B for retrieving Patient Summaries (PS), ePrescriptions (eP) as well as for issuing eDispensations (eD).
Gazelle® Management Tool	Test tools provided by IHE-Europe to prepare the Connectathon events where validation of the participants' interoperability and compliance with IHE profiles is performed.
IHE profiles	Workflow models of the various business processes that take place in healthcare on a daily basis. These profiles describe “actors” and “transactions.” IHE actors are systems or parts of systems that create or process data. Actors interact and share data by means of IHE transactions.
Laboratory Test	Test environment where the testers from epSOS, Participating

Term	Description
Environment (LTE)	Nations, suppliers or vendors perform functional, integration and conformance test on their components or systems and each of them is responsible for its creation and management. The test environment is typically made up of virtual or actual test systems, with supporting test software.
MESA	Test tools formerly provided by IHE to prepare the Connectathon events where validation of the participants' interoperability and compliance with IHE profiles is performed. These test tools have been substituted by Gazelle® tools.
National Connector	Entity that encapsulates the Nation-Specific NCP Components. The National Connector is implemented as a black box having its subcomponents hidden from the NCP.
National Contact Point (NCP)	Entity in each participating country to act as a bidirectional technical, organisational and legal interface between the existing different national functions and infrastructures. The NCP is legally competent to contract with other organisations on its territory in order to provide the necessary services which are needed to fulfil the business use cases and support services and processes. The epSOS NCP is identifiable in both the epSOS domain and in its national domain and acts as a communication gateway and establishes trust in the Trusted Domain. As such a NCP is an active part of the epSOS environment if and only if it is compliant to normative epSOS interfaces in terms of structure, behaviour and security policies. The epSOS NCP also acts as a mediator as far as the legal and regulatory aspects are concerned.
National infrastructure	The healthcare IT infrastructure, which manages patient and HP identification and health care records in Participating Nations.
NCP-in-a-Transparent-Box	A modular set of software components (Common Software Components) intended to facilitate a NCP implementation that

Term	Description
	can be used completely or partly by any PN to fulfil NCP obligations. This implementation is not mandatory.
Portal Adapter	Adapter located in the NCP for enabling the communication between the NCP and the epSOS Portal without using the unknown National Connector (specific for each country).
Pre-Pilot Testing (PPT)	The remote testing activity that is similar to a combination of Pre-Projectathon and Projectathon considering the scope of testing activities; i.e. it includes conformance, interoperability and end-to-end functional testing. The main difference is that the NCP has to be connected to the real national infrastructure, but with virtual data. Its goal is to ensure that there are no problems or issues with the setup and configuration of the pilot environment of a PN. PPT is a conformance gate to pass before going into real operation. According to the needs of the PNs, two weeks long PPT slots are organized a few times in a year for completing these tests. However, PPT is a continuous process and the PNs need to operate their testing environments even after starting real operation.
Pre-Pilot Test Environment (PTE)	It is a conglomeration of pilot systems from Participating Nations where Pre-Pilot Tests are performed to validate the systems before the pilot operation phase.
Pre-Projectathon	The online (i.e. remote) conformance testing activity that is held prior to a Projectathon. The focus is on checking the compliance of the PN and vendor implemented systems to each relevant epSOS Interoperability Profile. For this purpose, the systems are tested against simulators and validators provided by the epSOS Project in cooperation with IHE-Europe. Completing the Pre-Projectathon is necessary for being allowed to go to the proceeding Projectathon.
Projectathon (PAT)	An interoperability testing event similar to Connectathon, organised and managed by the epSOS Project in cooperation with IHE-Europe, to assure the interoperability of the PN and

Term	Description
	vendor implemented systems according to the epSOS Interoperability Profiles. It is usually held together with European Connectathons. In addition to conformance and interoperability testing, Projectathon includes end-to-end functional testing with the involvement of HPs. PNs need not to participate with their actual national infrastructures to a Projectathon; a simulation of the national environment is accepted as well. Only the PNs who become successful at a Projectathon are allowed to go to the Pre-Pilot Testing.
Projectathon Test Environment (CTE)	Test environment used in the Projectathon, where Participating Nations, suppliers and vendors can test the interoperability of their components and systems against components and systems of other Participating Nations, suppliers and vendors.
Reference Test Environment (RTE)	Test environment where developers and testers of Participating Nations, suppliers or vendors have the possibility to connect and integrate their components and systems by applying well-defined test plans, tools and processes.
Service Interoperability Test (SIT)	The phase foreseen to test the pre-defined test cases as defined by epSOS. The SIT is conducted in the Projectathon.
Unit Test Environment (UTE)	A test environment where the developers from epSOS, Participating Nations, suppliers or vendors unit test their components. These parties are responsible for the creation and management of their UTE. The test environment is typically made up of developers' machines with supporting testing software. The test phase Component Unit Test would use such a test environment.

A3 Abbreviations

Abbreviation	Description
ATNA	Audit Trail and Node Authentication
CA	Certificate Authority
CCT	Conformance Test
CDA	Clinical Document Architecture
CIT	Component Integration Test
COTS	Commercial off-the-shelf
CRL	Certificate Revocation List
CST	Component System Test
CTD	Critical Test Data
CTE	Projectathon Test Environment
CUT	Component Unit Test
eD	eDispensation
eP	ePrescription
ePS	Electronic Patient Summary
EQ	External Quality
EVS	External Validation Services
F.E.T.	Fraunhofer ISST / Elga Team
FR	Functional Requirement
GP	General Practitioner
GUI	Graphical User Interface

Abbreviation	Description
HP	Health Professional
HLDD	High Level Design Document
ICT	Information and Communication Technologies
ID	Identifier
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Health Care Enterprise – Europe
IQ	Internal Quality
ISO	International Organisation for Standardisation/
ISTQB	International Software Testing Qualification Board
IT	Information Technologies
LSP	Large Scale Pilot
LTE	Laboratory Test Environment
MS	Member State
MSI	Microsoft Installer
MTC	epSOS Master Translation/Transcoding Catalogue
MVC	epSOS Master Value Sets Catalogue
NCP	National Contact Point
NCP-A	National Contact Point of Country A
NCP-B	National Contact Point of Country B
NFR	Non Functional Requirement

Abbreviation	Description
NI	National Infrastructure
OCSP	Online Certificate Status Protocol
PAT	Projectathon
PDF	Portable Document Format
PEB	Project Executive Board
PKI	Public Key Infrastructure
PN	Participating Nation
PoC	Point of Care
PPT	Pre-Pilot Testing
PS	Patient Summary
PSB	Project Steering Board
PTE	Pre-Pilot Test Environment
QI	Quality in Use
RTD	Representative Test Data
RTE	Reference Test Environment
SAML	Security Assertion Markup Language
SCM	Software Configuration Management
SIT	Service Interoperability Test
SLA	Service Level Agreement
SOAP	Simple Object Access Protocol
TAR	Tape Archive

Abbreviation	Description
TPM	Technical Project Manager
TRC	Treatment Relationship Confirmation
URL	Uniform Resource Locator (world wide web address)
UTE	Unit Test Environment
V&V	Verification and Validation
VPN	Virtual Private Network
WG	Working Group
WP	Work Package
WSE	Web Service Enhancement
XACML	eXtensible Access Control Markup Language
XDS-SD	Cross-enterprise Scanned Document Sharing
XML	eXtensible Markup Language