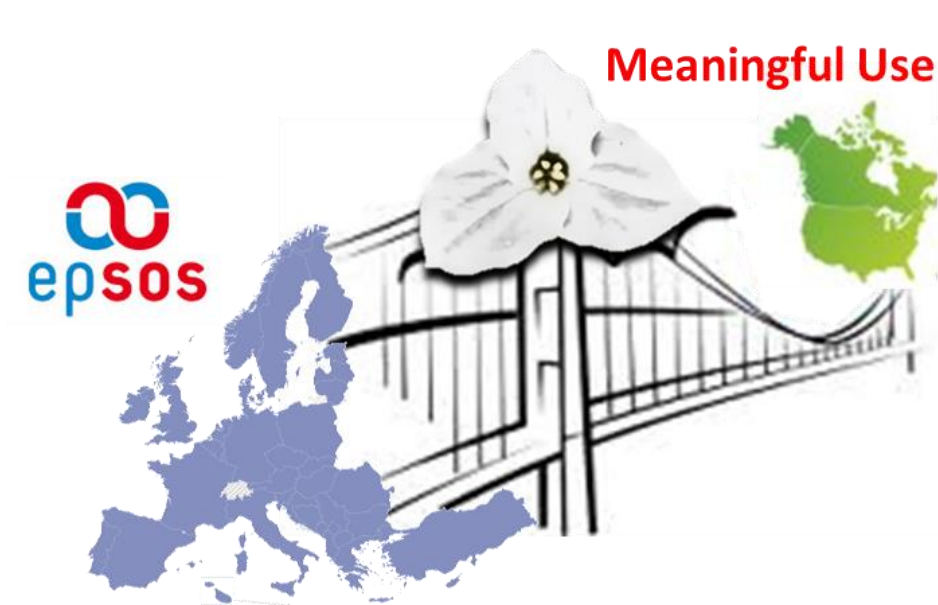


Trillium Bridge

Bridging Patient Summaries across the Atlantic



WP 4

Deliverable 4.1

Interoperability testing plans, tools, data sets

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1 Executive Summary

Trillium Bridge addresses Objective ICT-2013.5.1 e4: "Interoperability of patient summary between EU and US". According to the FP7 ICT Call 10, page 57, the aim of proposals submitted under this line is "To compare specifications of EU and US patient summaries with the aim of developing and testing common and consistent specifications and systems allowing the interoperability of electronic health records across the Atlantic."

The exchange of patient summaries between the EU and US will serve as a case study for exploring possible extensions of the eHealth Action Plan 2012-2020³, which will foster EU-US collaboration on topics of common interest in the area of health-related ICT. *Trillium Bridge's* game-changing approach employs patient- and provider-mediated user scenarios to address all aspects of interoperability (clinical, technical, semantic, organizational, and legal) as detailed in the eHealth Action plan 2012-2020 and the ISA eHealth Interoperability Framework report⁴. The project will create a community of knowledge, identify knowledge gaps and mobilize resources to help bridge those gaps, and assemble interoperability assets. This will foster synergies and collaborations that will catalyze a common understanding that will drive wide adoption of common global eHealth standards and specifications. The bridging effort of *Trillium Bridge* will ensure sustainable healthcare systems and delivery of high quality care unlocking the market potential for innovative solutions.

Work Package 4 "Testing Tools and validation reports" presents evidence of the results of the project. The main goals are to:

- Define the testing strategy, test methods including test scripts or test plan and testing tools for the validation of the implementation of the use cases defined in the previous work packages;
- Use and Extend tools mainly developed by IHE-Europe for the validation of the Patient Summary during the preparation of the Trillium Bridge projectathon;
- Validate the ability to import patient summaries produced at the other side of the Atlantic according to the agreed upon use cases.

Mobilization of EU and US resources from Trillium Bridge Beneficiaries (SPMS, LiSPA, MoH Spain, Kaiser Permanent, Prosocial, etc.) and interested supporting parties such as the OpenNCP community and more specifically GNOMON (Greece), IUZ (Portugal), and others (IHE, HL7, epSOS partners,...) has allowed to develop a prototype Trillium Gateway to show the feasibility of exchanging Patient Summaries between the two sides of Atlantic based on concrete use cases for the evaluation of the usability.

Starting for functional and use acceptance requirements for the patient and provider mediated use case, deliverable D4.1 starts with description of a generic architecture that allows communication between US and EU, while also addressing patient summary transformation (syntactic and semantic). A mapping of the coding systems across Atlantic was realized in the WP3 and the associated functional requirements are used as input to this document. In this document, the mapping of the transactions used to exchange medical data, completes the architecture. The testing strategy and test methods are presented and to achieve the targeted architecture, several implementation steps were described with their impact in the testing strategy. Demonstrations based on use cases defined in the previous deliverables were organized in Europe and in US in order to show the technical feasibility of such implementations. It was a success and helps to better refine understanding and develop mappings (differences and similarities) between the two sides of Atlantic. The

³Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: eHealth Action Plan 2012-2020: Innovative Healthcare for the 21's century
http://ec.europa.eu/information_society/newsroom/cf//document.cfm?doc_id=1252

⁴ ISA eHealth Interoperability Framework program and recent workshop report: http://ec.europa.eu/isa/documents/isa_action2-12.pdf http://ec.europa.eu/isa/actions/documents/isa_2.12_ehealth1_workprogramme.pdf; Presentation and report from the Nov 7, eHealth EIF workshop organised on 8/11 in Brussels; final project report is about to be released.

extension of test tools will be developed during the preparation phase of the projectathon. Finally the deliverable concludes with future perspectives on the deployment of the ehealth services across Atlantic.

2 Objectives

The objectives of the Work package 4 are listed in the Description of Work of the Trillium Bridge project and are:

- Define the testing strategy, test methods including test scripts or test plan and testing tools for the validation of the implementation of the use cases defined in the previous work packages;
- Extend tools mainly developed by IHE-Europe for the validation of the Patient Summary during the preparation phase of the Trillium Bridge Projectathon;
- Validate the ability to import patient summaries produced at the other side of the Atlantic according to the agreed upon use cases.

Two deliverables are defined and among them the D4.1 that the aim corresponds to the first two objectives of the work package.

The testing strategy will be based on previous experiences on epSOS project and all the knowledge and best practices accumulated since than more than 10 years by IHE-Europe on the testing methods, tools development and testing sessions. If we consider Trillium Bridge as an extension of the epSOS project, the testing methodology described in this document will confirm the robustness of the epSOS testing strategy developed during the last three years.

Existing interoperability test methods (test plan, test scripts and test tools) are today used in several projects in US and Europe and will be adapted for Trillium Bridge in order to cover the specific use cases. It is very important to note that the previous investment on such tools can be easily reused by extension. The benefit is easy to understand

- Test methods are robust and well known by industry and stakeholders;
- Less development but extension with new features to the test bed environment;
- Time saving by making the test methods readily available;
- Tests only for the new features or functional extension.

The main set of functional tests is already covered by other programs (ONC-EHR certification program in US, Eurorec certification program in Europe for example). What it is called functional tests are the tests that show the complete transformation/translation of the document at the end-user and this transformation/translation provides a well formed and correct document corresponding to the origin and enable the healthcare professional to take the right decision for the benefit of the patient.

The present document will describe more in details how we achieve such results by

- In section 3, the testing methodology is described at high level;
- In section 4, acronyms and concepts are listed;
- In section 5, references used in the document are presented;
- The section 6 describes what we want to test: use cases and general architecture;
- The testing strategy with the three phases pre-projectathon, projectathon and pre-pilot phase is described in section 7;
- The testing plan and test methods including test scenarios, test scripts and tools in detail implements the test strategy (section 8);
- Section 9 reports the two demonstrations that were held: one in Europe (Athens in May) and one in US (Boston in October);

- The last section 10 will provide an overview of the next steps for continuing the project;
- Annexes provide detailed specifications related to the WP4.

3 Methodology

The methodology used to describe the testing strategy in the first part and test methods, test tools and testing sessions is based on the epSOS proof of concept and the IHE testing approach. The authors have also a good practice and knowledge of standards (ISO 17 00X and ISO/IEC 9126 and ISO/IEC 25000⁵) and best practices (ISTQB) in this domain.

The first step of the approach is to scope the use cases that have to be tested and the targeted architecture of communication. The organizational and legal aspects are not covered at this stage. The document will also address the step beyond the ideal architecture that can be achieved in the timeline of the project.

The testing strategy gathers the criteria that contribute to the phases of testing from the technical point of view. To facilitate the integration of Trillium Bridge approach with the cross border approach in Europe, the TB testing strategy extends the epSOS testing strategy for this specific usage. Multiple benefits are already listed such a mutualized efforts, facilitation of the implementation, knowledge available, etc.

After an inventory of the specifications that shall be tested, the test methods, test scripts and test tools are described by listing the existing test methods and specifying the additional features required to meet the Trillium Bridge use cases.

The objective of the deliverable 4.2 is to use the methodology of testing that the task 4.1 is defining: validation in Member states should be one of the main results of the proof of concept of Trillium Bridge. It will demonstrate the feasibility of the project.

This testing approach wraps up with a case study (demonstration) related to the evaluation activity describing the ongoing step of Trillium Bridge proof of concept. This step would allow and offer materials for the definition of a new project where the objective is the implementation of the target (use cases and architecture) by Pilot sites wanted to exchange medical Patient Summary between US and Europe extending the paradigm established with epSOS medical exchanges among European countries.

⁵ See references

4 Glossary

4.1 Acronyms

This section provides the list of the acronyms used in this document.

Acronym	Description
CDA	Clinical Document Architecture
CCD	Continuity of Care Document
c-CCD	Consolidated CCD
C-CDA	Consolidated CDA
CDA R2	CDA Release 2
Country A	Country of Affiliation
Country B	Country of Treatment
EHR-S	Electronic Health Record System
epSOS	European Patients - Smart Open Services
HL7	Health Level 7
ICT	Information and Communication Technology
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
ISTQB	International Software Testing Qualifications Board
ITI	Stands for IT Infrastructure. IHE Domain that supplies infrastructure for sharing healthcare information
NCP	epSOS National Contact Point
PS	Patient Summary
SAML	Security Assertion Markup Language
SUT	System Under Test
TB	Trillium Bridge
WG	Working Group
WP	Work Package
XCA	Cross-Community Access
XCPD	Cross-Community Patient Discovery
XDR	Cross-Community Reliable Interchange

4.2 Concepts

Test scripts

Automated test procedures that describe the sequence of actions for the execution of a given test.

Test methods

Include test cases or test scenarios, test procedures, test tools and test data that allow a test laboratory to evaluate systems

Test strategy

High level description of the test levels to be performed and the testing within those levels for the project. For the purpose, we include the test plan.

User acceptance testing

It verifies the fitness for use of the system by business users (ISTQB definition)

Integration testing

Test of the complete system against the other systems following test scenarios and test scripts defined in the test plan for checking the interoperability between them

System testing

System testing is concerned with the behaviour of a whole system/product as defined by the scope of a development project or program. (ISTQB definition)

Test summary report

Document summarizing testing activities and results. It also contains an evaluation of the corresponding test items against exit criteria. (IEEE 829)

Tester

A skilled professional who is involved in the testing of a component or system (ISTQB)

Testing tools

Software or product that supports one or more testing activities. Different categories of test tools are available

Use case

Sequence of transactions in a dialogue between actors where an actor can be a user or anything that can exchange information with the system (ISTQB)

V-model

A framework used to describe the software development lifecycle activities from requirements specification to maintenance.

5 Reference

1. Standard glossary of terms used in software testing. Version 2.1 (April 1st, 2010). ISTQB
2. Certified Tester. Foundation level Syllabus. ISTQB
3. ISO/IEC 17025:2005 Testing and Calibration laboratories- Management Requirements and Technical Requirements
4. D3C.1 Proof of concept testing Strategy V1.0. www.epsos.eu
5. D3.4.2 Final common components specification v1.0 www.epsos.eu
6. D3.1 Testing tools overview v1.1. www.antilope-project.eu
7. D4.1 Quality label and certification processes. www.antilope-project.eu
8. D2.2 Comparing patient summaries in the EU and US: gap analysis and Pilot use case definition.v1.0
9. D3.1 Trillium Terminology assets v0.3

6 What do we have to test?

The scope of the testing strategy covers the use cases and their implementations defined during the kick off meeting in Boston in September 2013 (see D2.2. Inventory of Patient Summaries in the EU & US: Use Cases, Projects, Specs, Terminologies, Privacy & Security).

Use cases and reference architecture are presented in this section.

6.1 Use cases

The use cases that were defined are synthesized in two main use-cases (see WP2), objects of the testing strategy as followed:

1. **Patient mediated** exchange of Patient Summary
 - The patient gets a copy of his/her Patient Summary and transforms it into a format suitable for being used abroad. The Healthcare Professional visualizes this translated document on his/her own or on patient's device.
 - This use case may include the exchange of a translated printable copy.
2. **Provider Mediated** exchange of Patient Summary
 - While providing unplanned care, the healthcare professional accesses the transformed Patient Summary via his/her own EHR-S (or through a portal).

The Patient Summary specifications reviewed by Trillium Bridge are

- For Europe, the epSOS Patient Summary pivot document. This Patient Summary contains the patients' general information, medical summary, and medication summary. It is already a transformed document from the Patient Summary provided by the country of patient's affiliation. The electronic format used for the specification of the document is the standard CDA r2.
- For USA, the Continuity of Care Document (CCD) is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounter. The selected document is the CCD MU2 (meaningful use stage 2 CCD). See D2.2 for explanation of the selection. The electronic format used for the specification of the document is c-CDA (consolidated CDA).

Gap analysis between the two documents was described in the workpackages 2 and 3.

Based on the concepts defined in the epSOS project, these two use cases can be transposed as

- The **country of affiliation** of the patient is called Country A and provides – thorough the Trillium Bridge Services - the transformed document in the format of the **country of care** called Country B.

Country A could be USA or Europe when they provide the transformed documents and country B when they request the document.

6.2 Functional requirements for transformation of syntax and terminologies

In the deliverables of the WP3, a detailed mapping of the syntax and semantic components was developed and allowed the comparison and transformation of the document, and associated vocabulary, from the epSOS Patient Summary to the US C-CCD and vice versa. To support the translation from one side of Atlantic to other, a transformer was also specified and developed. The transformer is a XSLT processor that

transforms the epSOS into C-CCD summaries and the C-CCD documents into the epSOS ones. The Trillium Transformer focuses also on transforming the elements (meaning they have a value set from which a value can be chosen for that particular data element) and which have equivalence on both sides (they are found on both sides with the same semantic meaning).

Requirements was developed such as:

N°	Element	Requirement
1	Same structure	No
2	Same structure with mapping of the value set	Mapping of content
3	Different structure and same value set	Transformation with rules (1)
4	Different structure and mapping of value set	Transformation with rules and mapping
5	No structure (text format)	No

(1) Rules are described in the D3.2 and could be various. For example, rules describe how to represent the forms after mapping and transformation.

After mapping and transformation, the document shall be available and displayed to the end-user in proper format and readable.

In term of technical architecture, the transformer is part of the Trillium Bridge gateway and the testing strategy will consider this component as a black box. Only the input or the output will be tested, meaning that we will consider the results of the transformation and mapping e.g. the complete document (epSOS PS or CCCD). The test methods (test scripts and test tools) shall embed the rules as described in the D3.1.

More details are developed in section 7.

6.3 User Acceptance requirements

Patient and health professionals look after the results of the mapping and transformation and are only interested by the documents. The end-user shall be comfortable when the document is displayed and the document shall be easy to read. In term of acceptance it means for an end-user that

- The application which displays the document, is ergonomic;
- The transformation and mapping provides a correct content.

In epSOS project, the user acceptance was analysed by using a questionnaire that the end-user has to fill after each request. The questionnaire is composed of different categories of information:

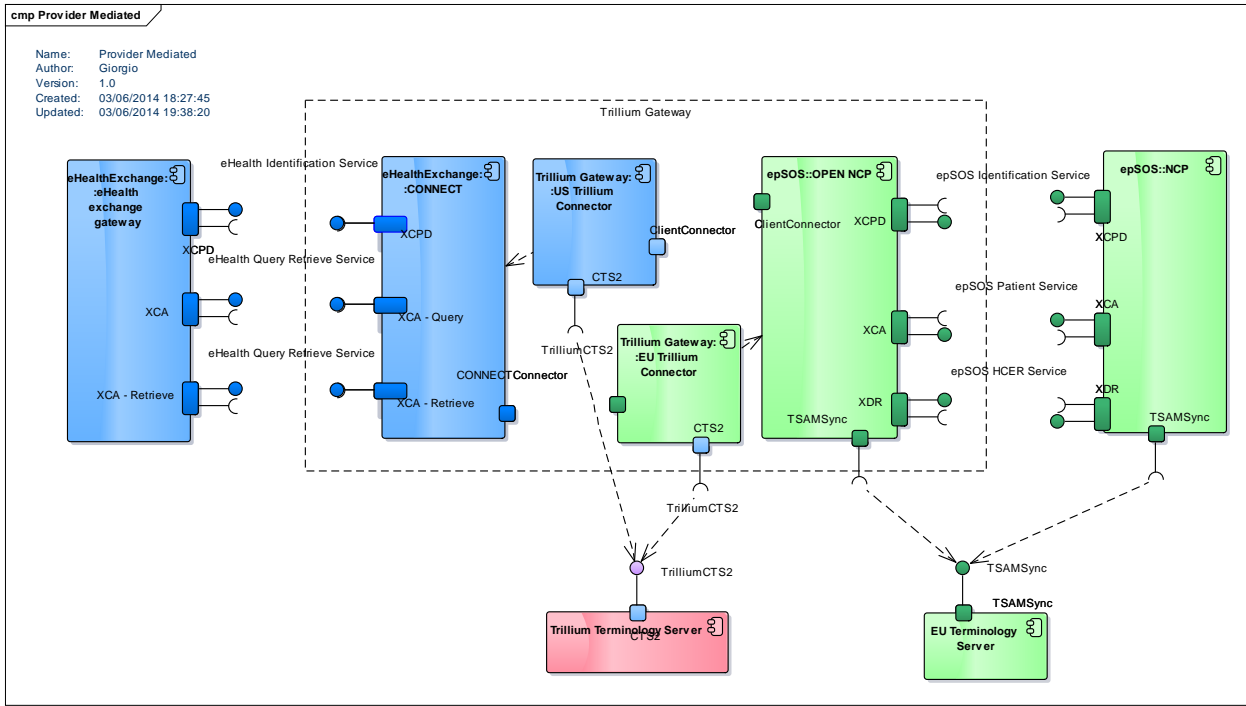
- Information content: is the content correctly displayed (semantic is correct and well structured),
- Presentation of the content: are the field correctly filled?
- Other aspects such as legal aspects (data privacy, safety), security.

The results are then studied one by one and when the number of questionnaire is sufficient, a statistical approach allow a relevant analysis.

The epSOS questionnaire modified for the needs of Trillium Bridge is available as an example in the annex II.

6.4 Functional requirements for Patient Summary exchange - Targeted high level architecture

The following schema gives a high level of the architecture in the case of the Provider Mediated Use Case. In the case of the Patient Mediated Use Case, the document transformation services, provided by TB are offered externally to be used by authenticated consumers⁶ (see D2.2. for additional details).



Schema 2: High level of the Trillium Bridge logical architecture.

The Trillium Bridge logical architecture presented here is composed of

- The Trillium Bridge (TB) gateway containing
 - On the USA side (in blue) the eHealth exchange gateway and US TB connector. These components serve on CCD any gateway within the US environment and transform the documents and the European messages on US messages if needed. Indeed with the maturity of the solutions, the transformation of messages will be less and less necessary once the messages are aligned. Other aspects should be considered such as security aspects, configuration or transcoding.
 - On the European side (in green), the epSOS open NCP and the European TB connector. These components have the same role for the Europe side.
- The TB terminology server has the responsibility to transcode the selected set of codes from US codes to European codes and vice versa.

Several variants of this architecture can be implemented: from distribution of these components among the two sides of Atlantic to a centralized TB gateway in the “middle of Atlantic” offer all the necessary functionality. A distributed architecture would split the gateway in two parts: all the blue components available in the US side while the green components are located in Europe. A centralized architecture is

⁶ The Trillium Portal in the tested scenario.

composed with the TB gateway in one side of Atlantic or both sides. In this case, depending of the way, the components are more or less active.

The Transactions used in both sides to exchange medical documents are IHE transactions:

- IHE XCPD: Cross Community Patient Discovery
- IHE XCA: Cross Community Access
- IHE XDR: Cross Reference Reliable Interchange
- IHE ATNA: Audit Trail and Node Authentication

6.4.1 IHE XCPD (Cross Community Patient Discovery)

This profile “complements the XCA profile by supporting the ability to locate communities which hold a patient’s relevant data and the translation of patient identifiers across communities holding the same patient’s data”. Two actors and two transactions are involved in this profile:

1. Initiating Gateway actor initiates the Cross Gateway Discovery (ITI-55 transaction) and optionally the Location Query (ITI-56) transaction.
2. Responding Gateway actor receives the Cross Gateway Discovery (ITI-55 transaction) and optionally the Location Query (ITI-56) transaction.

6.4.2 IHE XCA: Cross Community Access

This profile supports the mean to query and retrieve patient relevant medical information provided by other communities. In the case of TB, the community is represented by one of the two end points/ actors. The actors and transactions involved in this profile are Initiating Gateway for the query (ITI38) and Responding Gateway for the retrieve (ITI-39)

6.4.3 IHE XDR: Cross Reference Reliable Interchange

This profile allows interchange between Healthcare IT systems in absence of document sharing infrastructure (XDS infrastructure).

Two actors and one transaction are involved: the Document source Actor provides documents to the Document recipient using transaction ITI-41 (Provide and Register Document set-b).

6.4.4 IHE ATNA: Audit Trail and Node Authentication

This profile “*establishes security measures which, together with the Security Policy and Procedures, provide patient information confidentiality, data integrity and user accountability*” in a domain that can be considered as secured (establishment of mutual trust). The actor *Secure node* is grouped with any other IHE actors.

6.5 Gap analysis of the transactions

The gap analysis that was performed, checks for each message, the content of the sections header, body and content of the fields.

The analysis of these messages shows slight differences on their implementations in the two sides of Atlantic. The next step of the TB is to align these messages to IHE profiles in order to be able to send directly from one side to the other without using the connector for transformation.

In terms of security, a secured channel shall be implemented using certificates and tokens allowing secure access to information. epSOS specifications provide a good basis of discussion. It will be further investigated for a common solution in the next step of TB.

In the annex I, the gap analysis of EU/US transactions are presented as well as the issues and solution when it is available at this stage. This mapping was realized by the experts from Kaiser Permanente in one side and the experts of the open NCP Community and authors of the epSOS specifications in the other side.

6.6 From Proof of concept to mature implementation

For practical reasons, three testing steps are investigated from the first implementation (where we are) to the mature implementation (when EU-US harmonization is effectively achieved):

1. Proof of concept: the TB gateway transforms documents and messages from one eHealth gateway or one openNCP gateway belonging to one organization (for example, Kaiser Permanente) or a country in Europe;
2. A complete TB gateway is distributed in each side of Atlantic;
3. A light gateway (e.g. with the least transformation as possible) is distributed in one or two sides of Atlantic.

In this section, we analyze the impact of such a deployment strategy on the architecture.

6.6.1 Proof of concept

This step is the first step where the two parts of the bridge are connected with the least impact as possible. In each side, the TB gateway supports all the transformation and transcoding needed to demonstrate the feasibility of Patient summary exchange for a patient travelling in Europe or vice versa. Security policies are not completely compliant and security requirements are specific to these exchanges.

In this case, transformation will impact

- Documents from c-CCD to epSOS Pivot document and vice versa. Including
 - Coded concepts transcoding (Code Systems Mapping)
- Transactions and Metadata
- Security: SAML tokens, audit messages

Connectors called EU or US national connectors are directly embedded in an NCP representing TB-Europe or in the eHealth Exchange in US representing TB-US.

The mapping presented in annex 1 is in support of the specifications for the connectors.

6.6.2 Intermediary Solution

In the Intermediary Solution, the Trillium Bridge Gateway could be simplified with the alignment of the IHE transactions and the XDS metadata. Transformation will be needed for the

- Documents from c-CCD to epSOS Pivot document. Including
 - Coded concepts transcoding (Code Systems Mapping)
- Security: SAML tokens, audit messages and other security requirements

6.6.3 Final version Trillium Bridge gateway

A centralized TB gateway for each region allows the transformation and transcoding of the documents and ensures trust of confidence according to the security policies and agreement between the two sides. Various solutions can be implemented that are loosely or closely coupled.

The final version of Trillium Bridge gateway shall be a light solution used only for the transformation of documents and transcoding of the coding systems. Transactions will be all aligned to IHE profiles.

7 The testing strategy

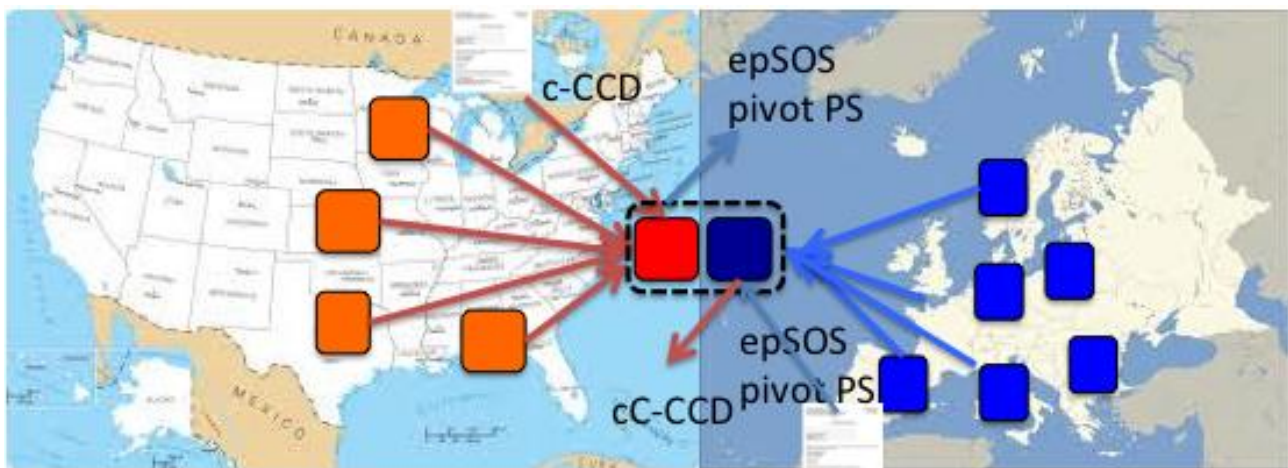
7.1 Introduction and principles

The testing strategy of Trillium Bridge is based on the following principles. We use the word “region” to name US or Europe.

1. There is one and only one logical TB gateway that allows exchanges between Europe and US, in other word, the test covers only what it is exchanged from one region (Europe vs US) to another;
2. The transformation of the documents is under the responsibility of the region of the affiliate country or state in other words, the transformation of epSOS pivot document to c-CCD by Europe and the transformation of c-CCD to epSOS document by US. The test will check that the document is well formed after the transformation and before it will be sent. Under specific circumstances, this responsibility can be assumed by the Trillium Bridge Gateway;
3. European countries or States/organizations in US shall be connected to the TB gate if they want to exchange medical data with US or Europe;
4. The testing environment, test methods and test tools shall be the same or equivalent in each side of the Atlantic;
5. In the case where the testing environment are equivalent, this equivalence shall be demonstrated (see ISO/IEC 17025 requirements);
6. The testing strategy shall take into account the recruitment of new countries or states at any time, in other words, the test tools shall be available to a new comer wanted to prepare and test its own implementation.

Three levels of maturity of the system is also considered (see section 6.6):

- The two regions implement their own solutions (eHealth exchange in US and open NCP in Europe) without any update or extension. The Trillium Bridge Gateway shall implement the necessary transformation and provide transactions and other requirements (security) as expected in each region.
- Transactions and documents are mapped and alignment to profiles and standards is done in order to simplify the TB gateway.
- Complete alignment is performed. Transactions are aligned to standards and profiles. The terminology is also aligned.



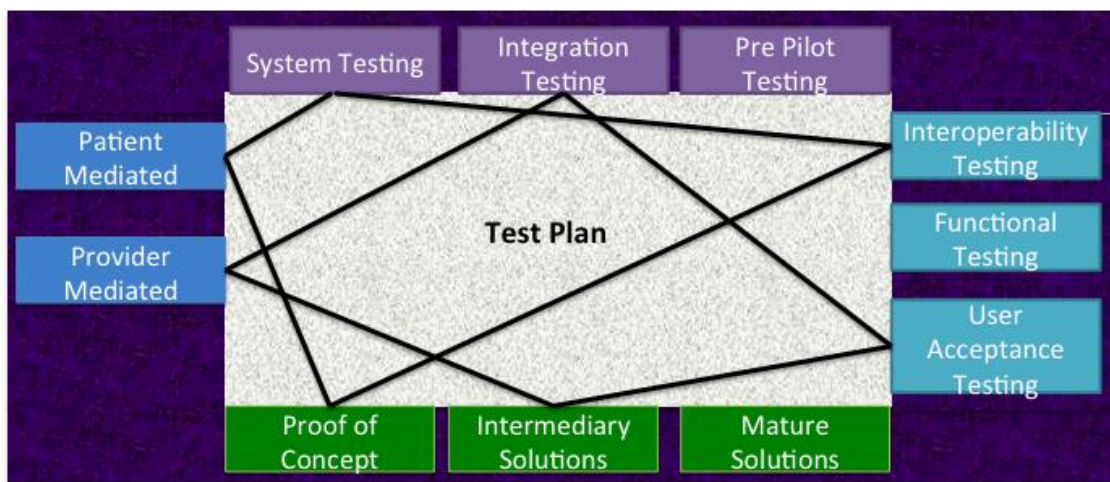
Schema 3: the EU-US Trillium Bridge Gateway

Considering these requirements, the testing strategy shall be designed as

- Independent of the maturity of systems;
- Flexible and open to new entrance;
- Independent of the regions by using the same or the equivalent test methods.

Moreover the test plan is designed considering the following axes (schema 1):

- The main use cases: Patient Mediated and Provider Mediated and the infrastructure;
- The implementation phases: from proof of concept to mature implementation (in green in the schema);
- The three category of test and validation: interoperability, functional and user acceptance testing;
- The three levels of testing: System testing, integration testing and pre-pilot testing.



Schema 4: Configuration for the test plan depending of the parameters

A testing plan will be configured considering the needs of tests that the tester wants to design.

For example, if the tester decides to perform the first Trillium Bridge Projectathon, where 2 or 3 European countries exchange test data with one US organization and using the TB gateway, the tester has to consider

- The scope: the Projectathon is a integration testing event
- The use cases: do we test one or two use cases? (see section 6.1)
- What are the level of maturity of the SUT’s implementation (System Under Test)?
- Do we want to test only the interoperability, or interoperability and functional testing?

When the tester has the answers of this questions, the test plan coverage is known and can be described in detail.

7.2 Testing strategy approach

The testing strategy describes

- The Scope and requirements related to the use cases as developed in section 6.1
- The test methodology (see section 7.3)
- The testing plan (see section 8) which describes

- The tests scenarios
- Resources, effort and planning
- Test methods including test design) and test tools to be used
- Test session
- Test management
- Maintenance

7.3 Scope

The testing strategy is used for testing the exchange of Patient Summary across Atlantic for the two use cases and covers:

- The interoperability testing of Patient Summary exchange e.g. transactions and messages;
- The content of documents that are exchanged.

Note that the terminology mapping is not testing but only the results of the mapping by:

- Checking if the document is well formed and the correctness of the content (semantic including);
- Checking that the display document reflects the source document with the end-to-end functional testing.

The support for testing is the Trillium Bridge projectathon.

7.4 Testing methodology

The testing methodology will consider the following items

- Interoperability testing covers the transaction conformity and interoperable tests using validators and simulators. Test data set will be used and contain test demographic data, documents samples, coding systems, etc.
- Functional testing: a questionnaire is submitted to the tester who is a Healthcare professional or Patient. The role of the tester is to check whether the transformed document is compliant with the document source.
- User acceptance testing (UAT)

The testing strategy is based on the well-known testing strategy developed by epSOS⁷.

7.4.1 Interoperability testing

The objective of the testing is to verify that the objects and transactions that are exchanging are conformant to the specifications and the workflows supporting the use cases are interoperable.

The best practices define at least three steps. We exclude in this section the unit tests that implementers organize themselves when they develop their system. We only consider the integration tests when a complete system is ready to test against another system by exchanging transactions and documents as described in the use cases.

⁷ D3C.1 Proof of concept testing Strategy V1.0. www.epsos.eu

7.4.1.1 Objects of the test

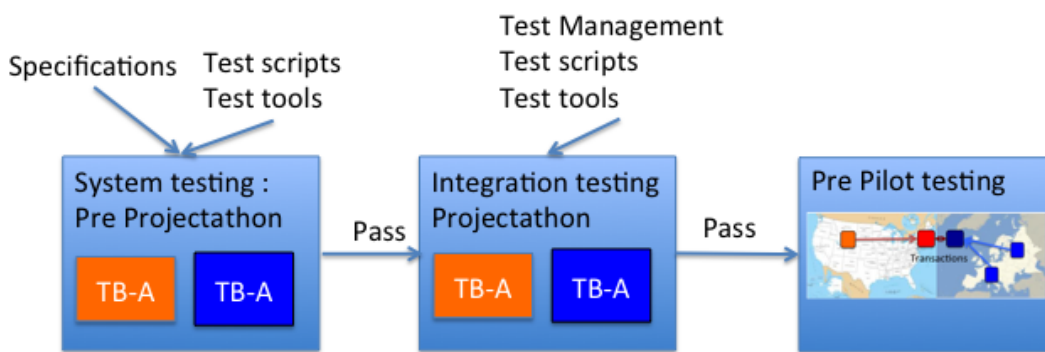
The object to be tested is the Trillium Bridge-A gateway called “TB-A” in this section. The role of the TB-A is

- To provide transactions from one region to another;
- To provide transformed documents;
- To receive documents.

Transactions can be aligned to IHE profiles or be different regarding the maturity of the systems.

Three phases are defined

- Phase 1 - System testing (Pre Projectathon): the TB-A gateway is tested standalone against simulators and used validators to test if it the gateway meets requirements.
- Phase 2 - Integration testing (Projectathon): a testing environment is in place and includes epSOS gateways of EU participative countries in one side and ehealth exchange US in other side and the TB-A gateway. The tests will verify whether the transactions received and transactions sent by the TB-A are correct and if medical documents are well transformed.
- Phase 3 - Pre Pilot Testing: tests in real environment with test data



Schema 5: testing strategy steps

The testing process is equivalent of the testing process described in epSOS project⁸. Each step of the testing shall be passed before going to the next step.

7.4.1.2 Phase 1 – System testing (Pre Projectathon)

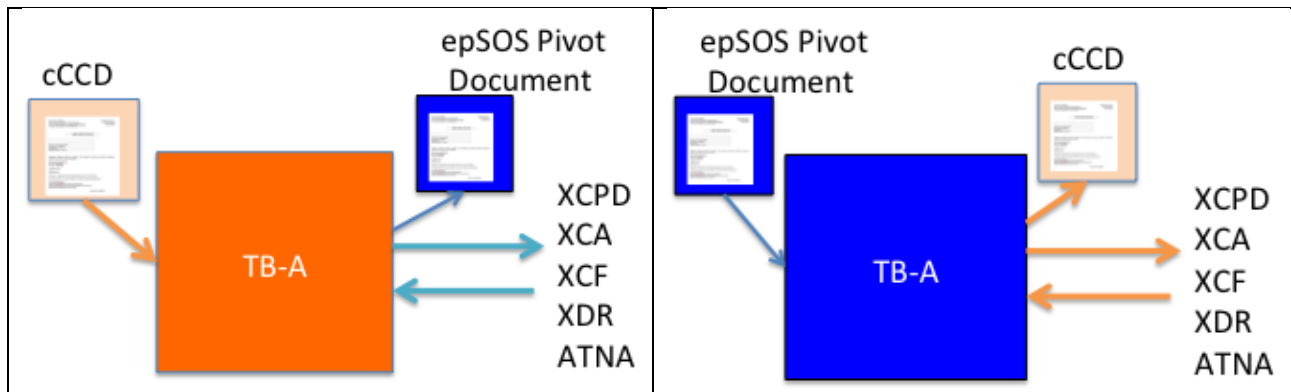
A system called TB-A in Trillium Bridge is a system able to transform Patient Summary from c-CCD to epSOS Pivot PS (TB-A_US) or epSOS Pivot PS to c-CCD (TB-A_EU) and exchange transactions as defined in section 6.2 and compliant with the TB specifications. The system could be able to play the two roles. The system shall be versioned and shall be installed following the test configuration documentation.

The testing environment provides different category of test scripts (for example, see <http://gazelle.ihe.net/epSOS-doc/>) and test tools for verifying if the solutions is able to participate to a testing session with other solutions. The testing tools are described and listed in the section 8.4.

The Gazelle management tool provides test summary report for each test scripts. The test validation is performed by the technical test manager. After checking the results of the test, the technical test manager

⁸ D3.C.1 – Proof of concept Testing strategy v1.4

reports and allows the partner to go to the next phase if he succeeds the tests. The test criteria are provided for each test scripts for transparency and reported in the test summary report.



Schema 6: US TB Gateway and EU TB Gateway

7.4.1.3 Phase 2 - Integration testing (Projectathon)

The main purpose of this phase is to verify that the TB-A system is able to receive or to deliver documents and messages that are provided by another system in a controlled test environment simulated one or the two regions (US or Europe). This phase could be done separately in each side of the Atlantic with other NCPs (countries) or eHealth exchange gateways (States) available in the region. The testing session is a face-to-face testing event using test Gazelle Management tool and generally will benefit of the IHE connectathon for logistics.

The systems is registered in Gazelle Management tool. Test methods (test scripts and test tools) are provided to each participant during the testing session and shall be equivalent or equal for test sessions that are conducted in parallel (same period of time estimated at three months). Test summary report provides all information of the test session for each SUT (System Under Test). These reports shall be equivalent (same template) in order to easily compare them if the test sessions are split in each region.

Two approvals will be organized:

- Technical approval: the validation is under the responsibility of the technical project manager;
- Validation: the validation is organized by the Board of the TB project. After receiving the technical report, the Board considering the reported results accepts the entrance of the partner to the next phase e.g. the Pre Pilot testing.

7.4.1.4 Phase 3 - Pre Pilot Testing

Pre Pilot testing is a continuous test process where data are test data with real infrastructure. Test slots of two weeks will allow all the participants to test at the same time for checking and validate the global infrastructure. From experience of epSOS, the first PPT was overestimated in term of workload and technical issues. Even if many of the issues are now solved and the team has developed new skills, this phase should be considered carefully and relevant resources shall be identified for leading this phase.

This phase is not in the scope in Trillium Bridge project. However it is described in order to maintain consistency with the epSOS strategy which is one of the major testing activity. It allows any country implementing Trillium Bridge features to test in one shot the epSOS and Trillium Bridge.

7.4.2 Functional testing

7.4.2.1 Healthcare Professional

For the Healthcare Professional, end-to-end functional testing with virtual test data and a demo TB infrastructure allows checking of the data displayed in the application. The functional testing can be set up during the testing session (projectathon).

The main requirements that will be focused are based on how the documents will be translated and displayed in the devices (computer, devices or print document) related to the use cases.

The methodology that will be adopted is the same as was adopted in epSOS project. It means:

- Definition of the questionnaire: this questionnaire is in support of the end-users and helps them to check if the document displayed in its device is correctly returned, well translated and well formed. Questionnaires after filled by the end-users serve as the test result. Questionnaire could be extended with further questions on the usability of the solution as a first step of the user acceptance.
- Analysis by the validation monitor: the selected monitor has an expertise on the CDA documents and coding system in eHealth. He is able to analyze the results provided by the end-user.
- Validation of the results: the monitor will provide a report for each implementation of the use case.
- Statistics are available on the Gazelle management tool.

In the following picture, an extract of the list of submission is showing as an example. The tool allows analysis of the results that can be downloaded and used for the validation report.

The screenshot shows a web interface for the 'epSOS CDA Evaluation Form (current)'. At the top, there are tabs for 'View' and 'Results'. Below these are buttons for 'Submissions', 'Analysis', 'Table', and 'Download'. The main content area displays a table of submission records. The table has columns for '#', 'Submitted', 'User', 'IP Address', and 'Operations'. Three rows are visible, all with the user 'begovic' and IP address '31.45.163.170'. Each row has a 'View' link in the 'Operations' column.

#	Submitted	User	IP Address	Operations
633	04/30/2014 - 16:57	begovic	31.45.163.170	View
632	04/30/2014 - 16:37	begovic	31.45.163.170	View
631	04/30/2014 - 15:55	begovic	31.45.163.170	View

Schema 7: list of epSOS CDA submission

7.4.2.2 Patient

For the patient (in the patient mediated scenario) the patient checks the transformed Patient Summary and uses a questionnaire similar to that defined for the Healthcare Professionals. He checks if the returned document displayed in his device or the print document, is correctly transformed.

7.4.3 User Acceptance testing (UAT)

At this stage of the project e.g. demonstration phase, the user acceptance testing is adapted and a evaluation questionnaire is defined and submitted to the patient and healthcare professionals (see D4.2) , the solution

is not used and only tested in term of feasibility. However, the test methods are available and can be used at any time.

8 Test plan

In this section, we describe the items necessary for the test plan of the first implementation of the TB-A gateway for demonstration.

8.1 Scope

Several aspects of the ISO/IEC 9126 Software engineering - Product Quality standard will be out of scope and we will concentrate on

- External Quality V&V where the testing focuses on technical and semantic interoperability;
- Quality in use with the end-to-end testing for Healthcare Provider including the regression tests
- User acceptance test by providing a survey to the Healthcare Professionals that are volunteers to test in both side of Atlantic.

8.2 Tests scenarios

The test scenarios are extensions of the epSOS scenarios for Patient Summary exchanges. The main use cases that have to be tested is the following:

- A Patient abroad gives an access to his/her Patient Summary to the Healthcare provider who will visualizes the Patient Summary in his language directly in his EHR.
- Or a Patient abroad visualizes his Patient summary in his device using his/her PHR.

In the following list, the complete list of test scenarios is presented (when the reference architecture is in place). The test scenarios will be available on the Gazelle Management tool. Depending of the implementation the list of tests should be lower and adapted.

In the patient mediated use case, for example, only the TB-03-1 and TB-03-2 will be used.

Id	Title	Description	Option/ Required	Evaluation exit Criteria
TB-01	Patient consent	The Healthcare Provider registers the patient consent that is sent to the country of affiliate	O	Pass/failed 3 patients with 3 pass tests
TB-02	Patient identification	This test evaluate the capability if the TB-A gateway to receive a request and to provide responses corresponding to the patient abroad	R	Pass/failed 3 patients with 3 pass tests
TB-03	Patient Summary Workflow	This test evaluates the capability of the TB-A gateway to receive a request and to provide the Patient Summary <ul style="list-style-type: none"> a. if the request comes from US, in C-CCD format b. if the request comes from Europe, in epSOS pivot document format 	R	Pass/failed 3 patients with pass TB-03-1 Advanced: 3 patients from 3 countries/states with 3 pass tests

Id	Title	Description	Option/ Required	Evaluation exit Criteria
TB-03-1	Patient Summary Transformation document	This test evaluates the capability of the TB-A gateway to provide original and a transformed Patient Summary document	R	Pass/failed 3 different patient summaries with 3 pass tests Advanced: 3 different patient summaries from 3 countries/states with 3 pass tests
TB-03-2	Audit messages generation	This test evaluates the capability of the TB-A gateway to generate audit messages	O	Pass/failed 3 patients with 3 pass tests
TB-03-3	Certificate conformity	This test evaluates the capability of the TB-A gateway to generate certificate following the recommendations of the TB specifications	O	Pass/failed 3 patients with 3 pass tests
TB-03-4	SAML assertions	This test evaluates the capability of the TB-A gateway to generate SAML assertions conform to the TB specifications	O	Pass/failed 3 patients with 3 pass tests

Table 2: test scenarios

8.3 Human resources, effort and planning

8.3.1 Human resources

The team is constituted with:

- The technical test manager who is responsible of the testing project in TB. He has a good experience on IHE connectathon and test process and test tools development.
- A testing team with the following skills:
 - Neutral: the testers will not belong to any of the system providers and have any conflicts of interests;
 - Competent on the TB environment: the testers shall have a good overview of the TB project, objectives and challenges as well as a good knowledge of the specifications;
 - Skill on testing: having a ISTQB certificate is a good manner to prove the level of testing competencies;
 - Knowledge on TB testing process and test methods used for TB project.
 - A team belonging to an organization having an ISO/IEC 17025 certificate is appreciated.

8.3.2 Effort

We consider only the effort needed to test systems during a test session such as projectathon or slot during a Pre Pilot testing. The effort for depends of

- The degree of the automation of the tests;
- The number of systems to be tested;
- The number of test scenarios to be performed;
- The level of the knowledge of the team tester.

For information with these figures:

- Duration of the test sessions: 3 days

- Number of systems: 5
- Number of Monitors (testers): 2
- Number of scenarios: 5 to 7
- Number of days for the tester team: 15-20 days including validation of the registration, Training and support, Test scripts preparation, documentation, Test session configuration, Test performed, Validation report, test validation.

8.3.3 Planning, control and risk analysis

Test planning for TB testing is defined according the testing strategy. In the best case, the planning is an annual planning that allows flexibility in term of deployment of the solutions and adjustment during the pilot phases. The standard planning is synthetized in the following schema:

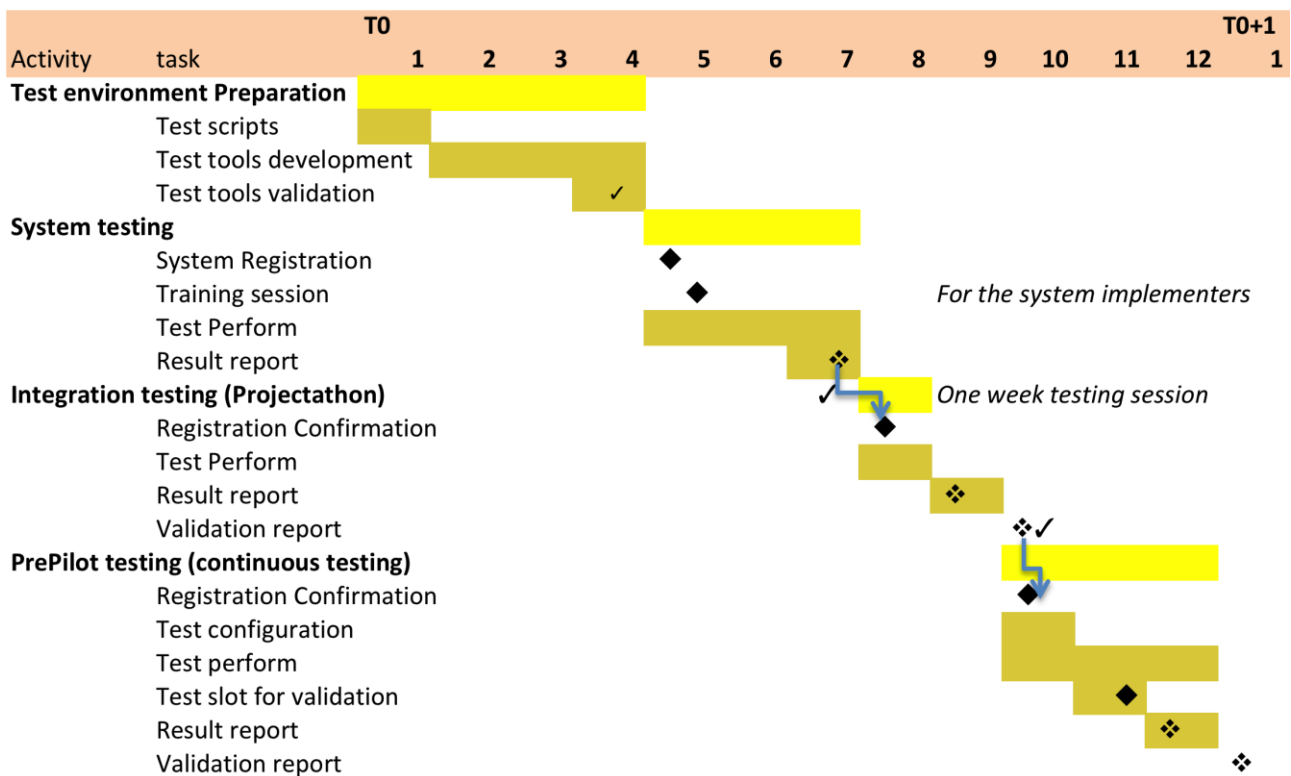


Table 3: testing planning

Test control is the ongoing activity that checks if the planning is followed and allows adjustment if deviations are checked. The risk analysis generally supports the planning and is presented here.

Date: July 2014

N°	type	Description	Status	Gravity	occurrence	criticity	Actions	Gravity
1	MG	Skills and competencies of the implementers		1	1	1	Training to be set up	Low 1
2	MG	Planning of development available	OP	3	4	12	Define the planning	Middle 2
3	MG	Organisation of the test sessions not planned	OP	2	4	8	Plan the test session	High 3
4	OG	No CAT available till April 2015	OP	2	4	8	Test session standelone	Occurrence
5	OG	No budget available for test sessions	OP	3	4	12		
6	TC	No clear view of the demo and its feasibility	OP	3	4	12	Define the scenario, architecture and specifications	26-50 2
7	TC	Test methods are not all available	OP	2	2	4	Organise manual tests	51-75 3
8	SY	Systems are not sufficiently ready for tests		1	1	1		76-100 4
		Average				7		

Table 4: Risk analysis example.

8.4 Test tools including test design and test tools

8.4.1 Test tools

There are different categories of tools that were used successfully in MU in US and in epSOS in Europe. In the following table, the tools that will be used are classified by categories and origin. For more information the categories of tools are described in details in the D3.1 testing tools overview of the Antelope project.

Category	Tool	Description	Used	Source
Management tool	Gazelle Management Tool	Manage the test session Register the system Manage the test scripts Manage the samples Perform the tests Register the logs Provide the results Provide the test summary report per system	Test System Integration testing Projectathon Pre Pilot Test	http://gazelle.ihe.net/EU-CAT/home.seam
Interoperability validator	CDA validation tool	Validate the conformity of the epSOS Patient Summary pivot document	This tool checks the content of the document against the specifications of the epSOS pivot document	CDA Validator in EVS client: http://gazelle.ihe.net/EVSClient/cda/validator.seam?extension=IHE
	Schematron-based validator	-id-	-id-	http://gazelle.ihe.net/SchematronValidator/schematrons/manageSchematrons.seam?cid=2441
	CDA validation tool	Validate the conformity of the c-CDD document	This tool checks the content of the document against the specifications of the c-CCD document	CDA Validation Tool: http://hit-testing.nist.gov/cdavalidation/validation.html http://gazelle.ihe.net/EVSClient/cda/validator.seam?extension=IHE&cid=32514 PCC-Common templates
Data generator and Interoperability validator	Certificate	Validate the validity of the certificate	Tool generating the certificates and validate the certificate	http://gazelle.ihe.net/tls/home.seam
Simulator	Syslog test message sender		Tool sending the audit message	http://gazelle-gold.wustl.edu/SyslogSender/Sender.jsf
	TLS	Test the TLS-based transactions		http://gazelle.ihe.net/tls/home.seam
Interoperability validator	Audit message	Check the audit message contents	Test the audit message content against the specification	epSOS audit messages: http://gazelle.ihe.net/EVSClient/atna/validator.seam?extension=epSOS&cid=6755 IHE: http://gazelle.ihe.net/EVSClient/atna/validator.seam?extension=IHE&cid=6758

Support	Syslog message browser			-
Interoperability validator	SAML validation	Validation services for SAML	Validate the SAML assertions for epSOS	http://gazelle.ihe.net/EVSCient/saml/validator.s?extension=epSOS&cid=6759
Interoperability validator	XDS toolkit			http://ihexds.nist.gov
Simulator /interoperability validator	XD*client	Validation	Simulate initiators on XD* profile	http://gazelle.ihe.net/content/xdstarclient

Table 5: List of test tools

8.4.2 Coding systems

In the following table, comparisons between the code systems that were analyzed in WP2 from the two sides of Atlantic are presented. This mapping will be used for updating the list of codes used in the test environment and used for the validation of the messages.

Code System	EU/US	Coverage with common value
HL7 AdministrativeGender	No mapping	100%
ISO 3166-1 Country Codes	No mapping	100% epSOS coverage
HL7 EntityNamePartQualifier	No mapping	100% CCD coverage
Healthcare Professionals Roles	Mapping	ISCO and NUCC
HL7 Confidentiality	No mapping	100% CCD
Language (ISO 639-1)	No mapping	100% epSOS
Contact relationship (HL7RoleCode)	No mapping	100% epSOS
Telecom (HL7AddressUse)	No mapping	100% CCD
Emergency Contact (HL7RoleClass)	No mapping	100% epSOS
Allergic Response (SNOMED CT)	Extension	67% epSOS, CCD 0,04%
Adverse Event Response (SNOMED CT)	No mapping	100%
Allergen	Mapping	ATC and RXNorm/NDF-RT
Allergen (Non medication)	Mapping	SNOMED CT and UNII
Medication	Mapping	EDQM and NCI thesaurus
Units per Intake (UCUM)	No mapping	100%epSOS
Problem	Mapping	ICD10 and SNOMED CT
Problem type (SNOMED CT)	No mapping	100% epSOS
Clinical Status (SNOMED CT)	No mapping	100% CCD
Health status (SNOMED CT)	No mapping	100% CCD
Procedures (SNOMED CT)	-	epSOS only
Medical devices (SNOMED CT)	-	epSOS only
Vaccinations	Mapping	SNOMED CT And CVX
Social History (SNOMED CT)	No mapping	100% epSOS
Pregnancy Observation (LOINC)	-	epSOS only
Results (SNOMED CT)	-	epSOS only
Visit signs (LOINC)	No mapping	100% epSOS

Table 6: Coding system comparison.

Seven coding systems need to be mapped or extended. Instructions to monitors to check the transformation of the coding system shall be explicitly described in the test scripts.

8.5 Test session

The test session is the step where systems are tested in a control environment, virtually or on the testing platform. In the section 7, the testing strategy is described.

All the test methods, test plan and procedures shall be validated and ready to use. Samples and test data shall be also available. Monitors and testers led by the technical test manager shall be well educated and ready to test. The use of A test management tool such as Gazelle Management tool facilitates the preparation, execution and reporting of the testing session. A technical validation report will be provided automatically for the systems. A test session report based on quality indicators will also provide feedbacks during the execution of the session in order to improve this step.

8.6 Test management

All the step of the process shall be managed. The technical test manager of IHE-Europe has all the competencies to organize such a testing process for Trillium Bridge. If the Trillium Bridge projectathon is launched at the same time and place of the IHE connectathon, the technical test manager will take care of the planning and all the needed activities for organizing the TB projectathon.

8.7 Maintenance

A deployed system shall be maintained for years. New functionalities will extend the scope of the system especially at the beginning of the deployment where adjustment, corrections and updates are quite often. With the testing process based on one year testing, it is easy to retest the product as needed. Test methods should also be updated according the update of the specifications. The standard planning given in section8.3.3 supports the maintenance of TB project.

9 Demonstrations

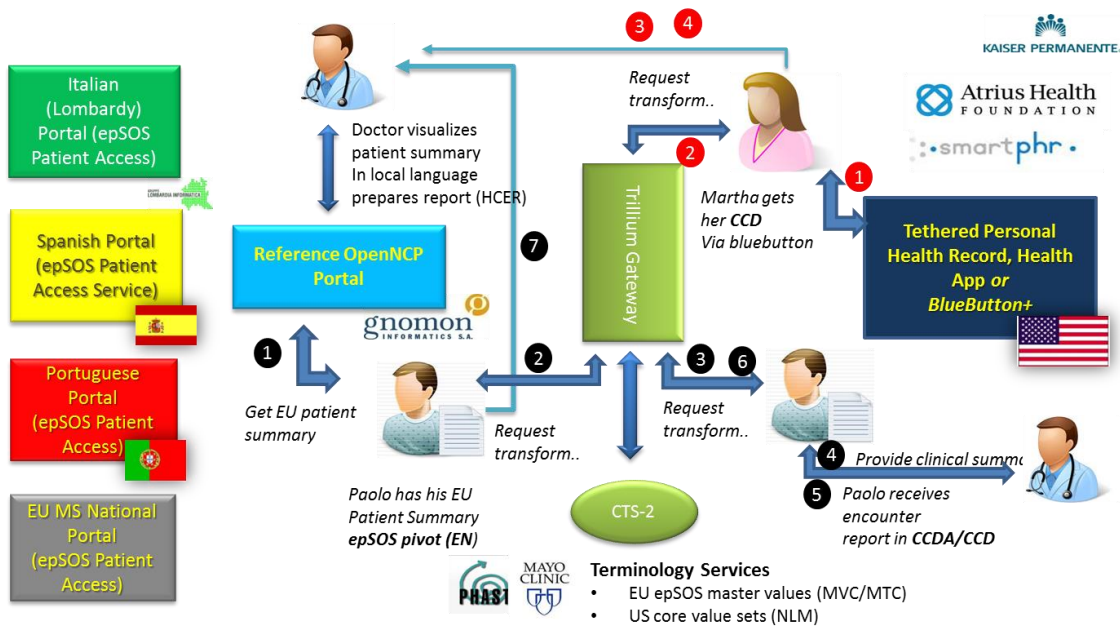
Two demonstrations were held during the year 2014:

- Demonstration in Athens in May 2014 at the eHealth Forum
- Demonstration in Boston in October 2014.

9.1 Demonstration at Athens

A demonstration of the Patient Mediated use case has been carried out with epSOS and the OpenNCP community in Athens at the eHealth Forum.

The demonstration was based on the Martha's (A US citizen visiting Europe) and Paolo's (An Italian citizen visiting US) stories (see D2.2. for details). The following figure provides an overview of the demonstration and of the components involved.



Schema 8: Athens demonstration overview (Patient Mediated)

Martha's story: Before leaving home Martha, a cancer survivor living in San Diego, obtains a copy of her C-CCD from Kaiser Permanente, and taking advantage of the Trillium Bridge Services (Transformer) gets a copy of her patient Summary in the epSOS pivot format. During a visit in Europe, walks up a hill and experiences shortness of breath, faints, and wakes up a few minutes later after hitting her head on a stone step. A passerby helps her get to the emergency department of a local hospital. An ambulance is called and she is brought to the emergency ward. During registration and admission, Martha hands in her patient summary in a USB key, in the epSOS format and in CCDA/CDD. At the hospital, Martha is evaluated by an oncologist and a cardiologist. The admitting physician (a gig) logs onto epSOS portal to import and display her patient summary in Italian.

Paolo's story: Paolo is an old retired businessman, who normally lives in the outskirts Bergamo, near Lake Como, in Lombardy. His regular physician changed his medication two weeks ago because of poor blood pressure control on his previous medication. He is on holiday going through New England. He is nearing the end of his holiday, his day bag was stolen in a market square. The bag included his hypertension medication, and he has not been able to take his tablets for two days. This morning he has woken up feeling dizzy and has blurred vision. The hotel is able to put him in urgent contact with a local general practitioner (GP). Having assessed him, the GP noted a raised blood pressure, but is uncertain about whether to attribute these symptoms to the raised blood pressure or a side effect of the new medication. Now, the GP in Boston needs to know the medication, and the past few blood pressure readings to determine how exceptional the present reading is and manage Paolo appropriately. Paolo retrieves his online European Patient Summary for emergency access can be retrieved in the US by logging into the patient portal. The patient summary document is retrieved in PDF, and EU PS Format (epSOS pivot document). Paolo transforms the patient summary in CCDA using the exploratory Trillium Bridge Transform. The GP notes that visual disturbances are a recognized side effect of this medication. No specific treatment is indicated, and Paolo is reassured that side effects will gradually subside, and his GP can prescribe a suitable antihypertensive medication upon his return to Lake Como.

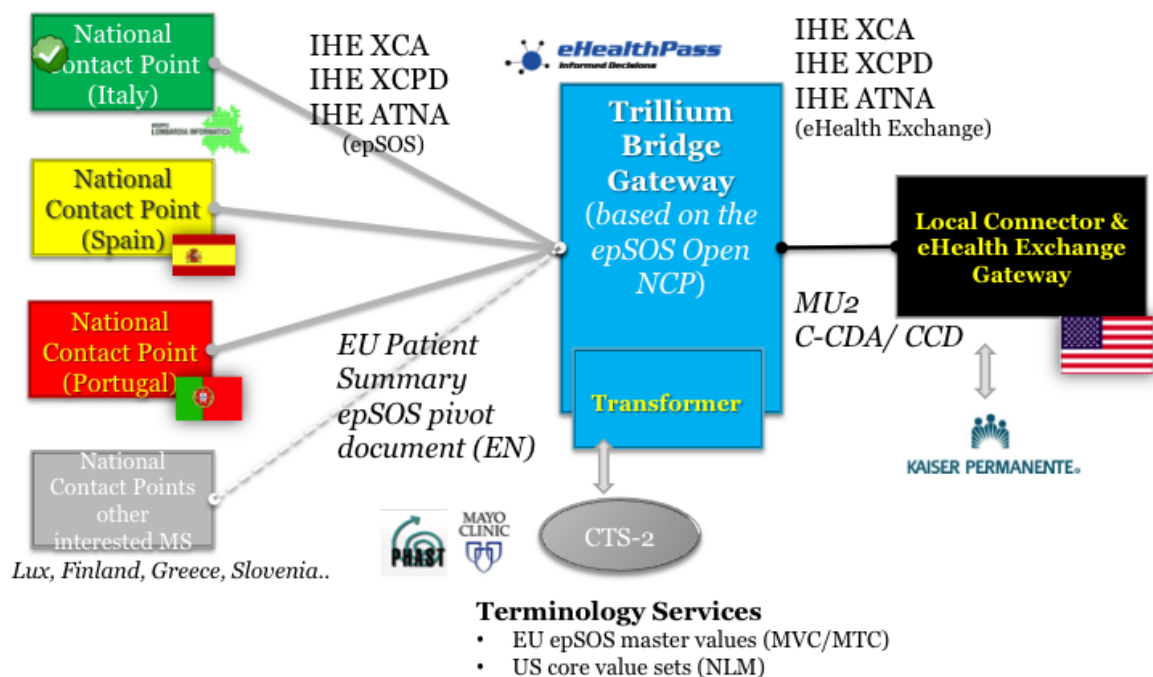
The demonstration was a success and provided the momentum necessary to address the provider mediated scenario.

9.2 Demonstration at Boston

For the second demonstration in Boston the following scenarios – based on the Provider Mediated use Case - were selected:

- The case of Martha, A US citizen visiting Europe: Martha, a cancer survivor from San Diego, had an accident during a trip to Italy, and was taken to the hospital, where the Italian physician in charge of Martha, queried for Martha’s patient summary in Italian (retrieved in HL7 CCD, and then transformed it Italian). The transformation changed the structures and transcoded the terms to the coding systems used in the EU. The physician authored a note for Martha’s physician back in the States. The Martha’s Doctor, reviewed the information together with Martha once she was back home.
- The Case of Paolo, a European visiting the US: Paolo, suffering from chronic hypertension, lost his new medication, while traveling to San Francisco and could not explain the symptoms he was experiencing. The Physician, successfully retrieved in CCD the patient summary of Paolo and identified his medication.

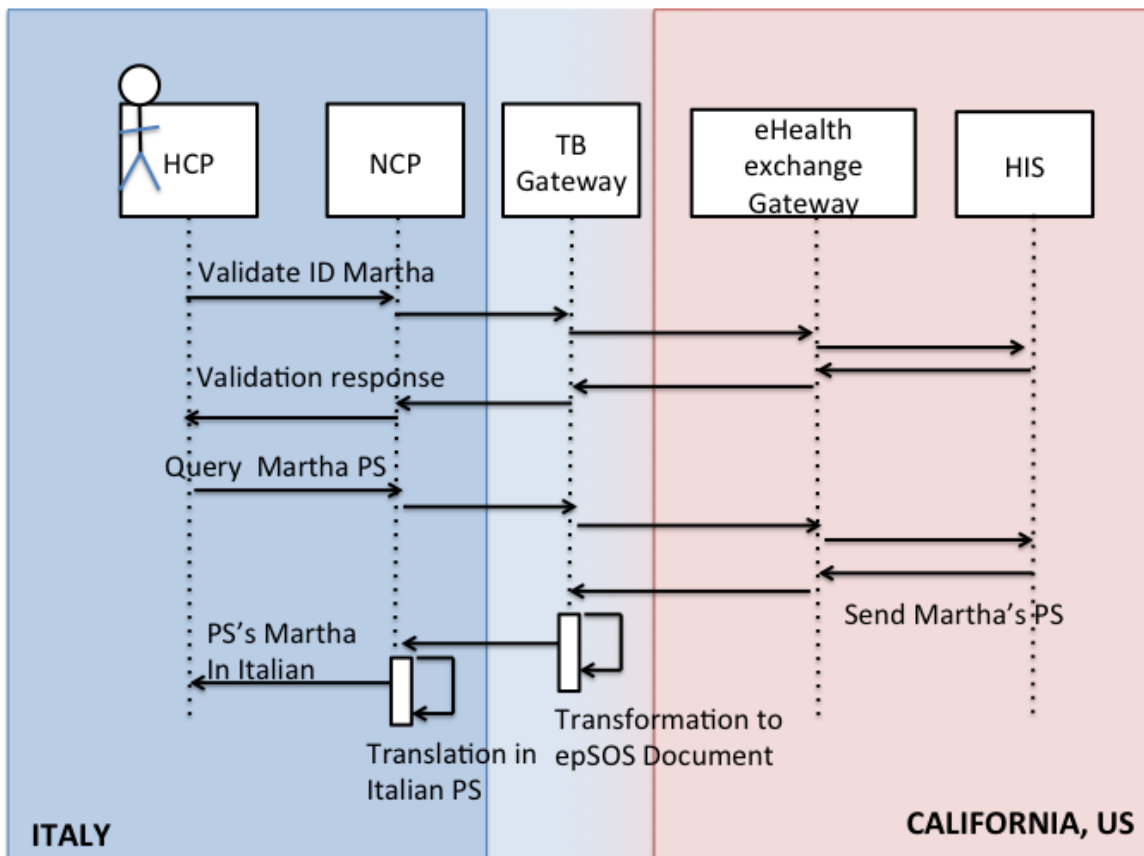
The demo architecture is described in the following schema:



Schema 9: technical architecture overview

The preparation of the demonstration shows that the same IHE profiles IHE XCA, XCPD, etc. are not totally aligned and some updates are needed. The gap analysis identifies the issues to process. A translation engine was used to meet gateway requirements.

The following schema shows the collaboration diagram for Martha’s use case:



Schema 10: collaboration diagram of the Martha's Use case

10 Next steps for future advanced project

The demonstration shows the technical feasibility of medical data exchange between the two sides of Atlantic but also the necessary alignment of the specifications of transactions and document as well as the medical coding systems. The usage of standards and profiles should be respected as far as possible. However if the next steps have to take into account these technical aspects, it should also analyze the gaps of legal and organizational aspects.

In this document we only consider the technical aspects. The next steps will focus on

- Refinement of the use cases;
- Evolution and alignment of the European NCP and US health exchange gateway to the standards and IHE profiles;
- Document specifications: reduction of the gaps (CDA section and coding systems);
- Development of the TB gateway v1.0;
- Testing: projectathon and virtual testing session.

All these steps should lead to a practical pilot between at least three European countries and one or more organizations or state exchanges in US (or more).

11 Annex 1

The tables were prepared by the openNCP community and the experts from epSOS technical specifications and the experts from Kaiser Permanente. They present the mapping of the transaction between Europe and US.

11.1 XCPD request

Location	Required / Optional	Element	Field Name	eHealth Sample	Comments
Header	O; but eHealth gateway validating	WS-Security	Timestamp	<pre><wsu:Timestamp xmlns:ns17="http://docs.oasis-open.org/ws-sx/ws-secureconversation/200512" xmlns:ns16="http://schemas.xmlsoap.org/soap/envelope/" wsu:id="_1"> <wsu:Created>2013-06-20T18:50:14Z</wsu:Created> <wsu:Expires>2013-06-20T18:55:14Z</wsu:Expires> </wsu:Timestamp></pre>	Not present in epSOS message.
Header	R	WS-Security	SAML Issuer	<pre><saml2:Issuer Format="urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName">O=Social Security Administration,L=Baltimore,ST=Maryland,C=US</saml2:Issuer></pre>	Present in epSOS, but epSOS Format of "urn:epSOS:wp34:assertions" is not supported.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Subject NameID	<pre><saml2:NameID Format="urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName">UID=KP</saml2:NameID></pre>	Present in epSOS, but epSOS Format of "urn:oasis:names:tc:SAML:1.1:nameid-format:unspecified" is not supported.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Subject SubjectConfirmation	<pre><saml2:SubjectConfirmation Method="urn:oasis:names:tc:SAML:2.0:cm:holder-of-key"> <saml2:SubjectConfirmationData> <ds:KeyInfo> <ds:KeyValue> <ds:RSAKeyValue> <ds:Modulus>BQRp7gdQk9saf8db2VJ/EGmB0wjosZmsoMKVIt0y1Hm0xlQp5Qc3Ec/IRGxJchb yG6DYHa2Q14mgwgx32Td9Oob0n/MzDZADdsrfIOM3H8vTFEXOgkzH0jHfsl1gsbXjdLH8hlZGZlLbJd5QBTTZS ulW/nF6rjPUKopWwRkNRcsIzTQ95LvHUy72MasdfyeIFEVjqwCsfo4zL92QZVExasdffSwNpEraQEXEYasdfnsN7q 2UG5aUQ14i8XL20dXujtyjmAVGVrYgn5MQNtINykojS/uBb+R3izx0HxjDUJHNDAY/u2Kc820rWxz1CWVf2IMFI 85FQ==</ds:Modulus> <ds:Exponent>AQAB</ds:Exponent> </ds:RSAKeyValue> </ds:KeyValue> </ds:KeyInfo> </saml2:SubjectConfirmationData> </saml2:SubjectConfirmation></pre>	Present in epSOS, but epSOS message defines "Method="urn:oasis:names:tc:SAML:2.0:cm:sender-vouches" and eHealth defines "Method="urn:oasis:names:tc:SAML:2.0:cm:holder-of-key".

Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AuthnStatement AuthnContext	<pre><saml2:AuthnStatement AuthnInstant="2013-06-20T18:50:09.334Z" SessionIndex="1"> <saml2:AuthnContext> <saml2:AuthnContextClassRef urn:oasis:names:tc:SAML:2.0:ac:classes:X509</saml2:AuthnContextClassRef> </saml2:AuthnContext> </saml2:AuthnStatement></pre>	epSOS message defines an AuthnContextClassRef of "urn:oasis:names:tc:SAML:2.0:ac:classes:PreviousSession".
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AttributeStatement Subject	<pre><saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:subject-id"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">MEGAHIT</saml2:AttributeValue> </saml2:Attribute></pre>	epSOS messages define Subject field with name value "urn:oasis:names:tc:xacml:1.0:subject:subject-id" and not "urn:oasis:names:tc:xspa:1.0:subject:subject-id".
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AttributeStatement Organization ID	<pre><saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:organization-id"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">urn:oid:1.3.6.1.4.1.26580.10</saml2:AttributeValue> </saml2:Attribute></pre>	epSOS organization ID does not being with "urn:oid" prefix.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Attribute Statement Home Community ID	<pre><saml2:Attribute Name="urn:nhin:names:saml:homeCommunityId"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">urn:oid:1.3.6.1.4.1.26580.10</saml2:AttributeValue> </saml2:Attribute></pre>	Not present in epSOS message.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Attribute Statement Subject Role	<pre><saml2:Attribute Name="urn:oasis:names:tc:xacml:2.0:subject:role"> <saml2:AttributeValue> <hl7:Role xmlns:hl7="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" code="106328005" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED_CT" displayName="Social worker" xsi:type="hl7:CE"/> </saml2:AttributeValue> </saml2:Attribute></pre>	epSOS does not define role using SNOMED CT code system.

11.2 XCPD Response

Location	Required / Optional	Element	Field Name	eHealth Sample	Comments
Header	R	WS-Addressing	To	<To xmlns="http://www.w3.org/2005/08/addressing">http://www.w3.org/2005/08/addressing/anonymous</To>	Not present in epSOS message.
Header	O; but eHealth gateway validating	WS-Security	Security Timestamp	<wsu:Timestamp xmlns:ns15="http://docs.oasis-open.org/ws-sx/ws-secureconversation/200512" xmlns:ns14="http://schemas.xmlsoap.org/soap/envelope/" wsu:id="_1"> <wsu:Created>2013-06-20T18:50:59Z</wsu:Created> <wsu:Expires>2013-06-20T18:55:59Z</wsu:Expires> </wsu:Timestamp>	Not present in epSOS message.
Body	O	PRPA_IN201306UV02	Sender Device asAgent	<asAgent classCode="AGNT"> <representedOrganization classCode="ORG" determinerCode="INSTANCE"> <id root="1.3.6.1.4.1.26580.10"/> </representedOrganization> </asAgent>	Not present in epSOS message.
Body	R (in eHealth Spec, may be optional in IHE XCPD)	PRPA_IN201306UV02	ControlActProcess authorOrPerformer	<authorOrPerformer> <assignedDevice> <id root="1.3.6.1.4.1.26580.10.1.100"/> </assignedDevice> </authorOrPerformer>	Not present in epSOS message.

11.3 XCA List Request (DQ)

FP7-610756 Trillium Bridge - Interoperability testing plans, tools, data sets

Location	Required / Optional	Element	Field Name	eHealth Sample	Comments
Header	O, but eHealth gateway validating	WS-Security	Timestamp	<wsu:Timestamp xmlns:ns17="http://docs.oasis-open.org/ws-sx/ws-secureconversation/200512" xmlns:ns16="http://schemas.xmlsoap.org/soap/envelope/" wsu:id="_1"> <wsu:Created>2013-06-20T18:50:14Z</wsu:Created> <wsu:Expires>2013-06-20T18:55:14Z</wsu:Expires> </wsu:Timestamp>	Not present in epSOS message.
Header	R	WS-Security	SAML Issuer	<saml2:Issuer Format="urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName">O=Social Security Administration,L=Baltimore,ST=Maryland,C=US</saml2:Issuer>	Present in epSOS, but epSOS Format of "urn:epSOS:wp34:assertions" is not supported.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Subject NameID	<saml2:NameID Format="urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName">UID=KP</saml2:NameID>	Present in epSOS, but epSOS Format of "urn:oasis:names:tc:SAML:1.1:nameid-format:unspecified" is not supported. It should not be there. To be checked on the EU side. Incorrect.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Subject Confirmation	<saml2:SubjectConfirmation Method="urn:oasis:names:tc:SAML:2.0:cm:holder-of-key"> <saml2:SubjectConfirmationData> <ds:KeyInfo> <ds:KeyValue> <ds:RSAKeyValue> <ds:Modulus>I8QRp7gdQk9safd8db2VJ/EGmB0wjsozmsMKVIT0y1HmOxIQpSQcl3Ec/IRGxJchb yG6DYHa2Q14mgwgx32Td9Oob0n/MzDZADdsrfIOM3H8vTFEXOOgkzH0jHfls1gsbXjdLH8hIZGZILbjd5QBTTS uIW/nF6rjPUKopWwRkNRcszTQ95LvHuy72MasdfyeIFEVjqwCsfo4zL92QZVExasdfswNpEraQEXEYasdfN7q 2UG5aUQ14i8XL20dXujTjymAVGvYrYGn5MQNtINykoJS/uBb+R3izX0HxJDUJHNDAY/u2Kc820rWxz1CWVf2IMFI 85FQ==</ds:Modulus> <ds:Exponent>AQAB</ds:Exponent> </ds:RSAKeyValue> </ds:KeyValue> </ds:KeyInfo> </saml2:SubjectConfirmationData> </saml2:SubjectConfirmation>	Present in epSOS, but epSOS message defines "Method="urn:oasis:names:tc:SAML:2.0:cm:sender-vouches" and eHealth defines "Method="urn:oasis:names:tc:SAML:2.0:cm:holder-of-key".
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AuthnStatement AuthnContext	<saml2:AuthnStatement AuthnInstant="2013-06-20T18:50:09.334Z" SessionIndex="1"> <saml2:AuthnContext> <saml2:AuthnContextClassRef urn:oasis:names:tc:SAML:2.0:ac:classes:X509</saml2:AuthnContextCl assRef> </saml2:AuthnContext> </saml2:AuthnStatement>	epSOS message defines an AuthnContextClassRef of "urn:oasis:names:tc:SAML:2.0:ac:classes:PreviousSession". This is not specified in epSOS. Need to investigate this one. Maybe an issue of the NCP, it should not be there (not an a specification issue)
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AttributeStatement Subject	<saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:subject-id"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">MEGAHIT</saml2:AttributeValue> </saml2:Attribute>	epSOS messages define Subject field with name value "urn:oasis:names:tc:xacml:1.0:subject:subject-id" and not "urn:oasis:names:tc:xspa:1.0:subject:subject-id".
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AttributeStatement Organization ID	<saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:organization-id"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">urn:oid:1.3.6.1.4.1.26580.10</saml2:AttributeValue> </saml2:Attribute>	epSOS organization ID does not being with "urn:oid" prefix.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Attribute Statement Home Community ID	<saml2:Attribute Name="urn:nhin:names:saml:homeCommunityId"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">urn:oid:1.3.6.1.4.1.26580.10</saml2:AttributeValue> </saml2:Attribute>	Not present in epSOS message.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Attribute Statement Subject Role	<saml2:Attribute Name="urn:oasis:names:tc:xacml:2.0:subject:role"> <saml2:AttributeValue> <hl7:Role xmlns:hl7="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" code="106328005" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED_CT" displayName="Social worker" xsi:type="hl7:CE"/> </saml2:AttributeValue> </saml2:Attribute>	epSOS does not define role using SNOMED CT code system.

11.4 XCA List Response (DQ)

Support on eHealth	Implementation Status	Location	Research	Element	Field Name	eHealth Sample
		Header		WS-Addressing	To	<pre><To xmlns="http://www.w3.org/2005/08/addressing">http://www.w3.org/2005/08/addressing/anonymous</To></pre>
		Header		WS-Security	Security Timestamp	<pre><wsu:Timestamp xmlns:ns15="http://docs.oasis-open.org/ws-sx/ws-secureconversation/200512" xmlns:ns14="http://schemas.xmlsoap.org/soap/envelope/" wsu:id="_1"> <wsu:Created>2013-06-20T18:50:59Z</wsu:Created> <wsu:Expires>2013-06-20T18:55:59Z</wsu:Expires> </wsu:Timestamp></pre>
		Body	epSOS	AdhocQueryResponse	RegistryObjectList ExtrinsicObject Slot = "languageCode"	<pre><ns4:Slot name="languageCode"> <ns4:ValueList> <ns4:Value>en-US</ns4:Value> </ns4:ValueList> </ns4:Slot></pre>
						N/A
✓	To do	Body	eHealth	AdhocQueryResponse	RegistryObjectList Description	
✓	To do	Body	eHealth	AdhocQueryResponse	RegistryObjectList VersionInfo	<pre><ns4:VersionInfo/> status="urn:ihe:iti:2010:StatusType:DeferredCreation"</pre>
?	Under Analysis	Body	epSOS / eHealth	AdhocQueryResponse	RegistryObjectList	
?	Under Analysis	Body	No concerns	AdhocQueryResponse	RegistryObjectList ExtrinsicObject Classification with classificationScheme="urn: uuid:a09d5840-386c-46f2- b5ad-9c3699a4309d"	<pre><ns4:Classification classificationScheme="urn:uuid:a09d5840-386c-46f2-b5ad-9c3699a4309d" classifiedObject="urn:uuid:62735b72-d9da-11e2-b515-dd02f7453cdd" nodeRepresentation="urn:ihe:pcc:xphr:2007" objectType="urn:oasis:names:tc:ebxml- regrep:ObjectType:RegistryObject:Classification" id="urn:uuid:a6448795-29b3-4753-b031-2ba7ff0640a5"> <ns4:Slot name="codingScheme"> <ns4:ValueList> <ns4:Value>1.3.6.1.4.1.19376.1.2.3</ns4:Value> </ns4:ValueList> </ns4:Slot> <ns4:Name> <ns4:LocalizedString xml:lang="en-us" charset="UTF-8" value="Continuity of Care Document"/> </ns4:Name> </ns4:Classification></pre>
?	Under Analysis	Body	epSOS	AdhocQueryResponse	RegistryObjectList ExtrinsicObject Classification with classificationScheme="urn: uuid:ccc5598-8b07-4b77- a05e-ae952c785ead"	<pre><ns4:Classification classificationScheme="urn:uuid:ccc5598-8b07-4b77-a05e-ae952c785ead" classifiedObject="urn:uuid:62735b72-d9da-11e2-b515-dd02f7453cdd" nodeRepresentation="394802001" objectType="urn:oasis:names:tc:ebxml-regrep:ObjectType:RegistryObject:Classification" id="urn:uuid:d9f90a68-a0c0-41c6-8d3a-372e0b7f3fe6"> <ns4:Slot name="codingScheme"> <ns4:ValueList> <ns4:Value>2.16.840.1.113883.6.96</ns4:Value> </ns4:ValueList> </ns4:Slot> <ns4:Name> <ns4:LocalizedString xml:lang="en-us" charset="UTF-8" value="General Medicine"/> </ns4:Name> </ns4:Classification></pre>

11.5 XCA Retrieve Request (DR)

Location	Required / Optional	Element	Field Name	eHealth Sample	Comments
Header	O; but eHealth gateway validating	WS-Security	Timestamp	<pre><wsu:Timestamp xmlns:ns17="http://docs.oasis-open.org/ws-sx/ws-secureconversation/200512" xmlns:ns16="http://schemas.xmlsoap.org/soap/envelope/" wsu:id="_1"> <wsu:Created>2013-06-20T18:50:14Z</wsu:Created> <wsu:Expires>2013-06-20T18:55:14Z</wsu:Expires> </wsu:Timestamp></pre>	Not present in epSOS message.
Header	R	WS-Security	SAML Issuer	<pre><saml2:Issuer Format="urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName">O=Social Security Administration,L=Baltimore,ST=Maryland,C=US</saml2:Issuer></pre>	Present in epSOS, but epSOS Format of "urn:epSOS:wp34:assertions" is not supported.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Subject NameID	<pre><saml2:NameID Format="urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName">UID=KP</saml2:NameID></pre>	Present in epSOS, but epSOS Format of "urn:oasis:names:tc:SAML:1.1:nameid-format:unspecified" is not supported.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Subject SubjectConfirmation	<pre><saml2:SubjectConfirmation Method="urn:oasis:names:tc:SAML:2.0:cm:holder-of-key"> <saml2:SubjectConfirmationData> <ds:KeyInfo> <ds:KeyValue> <ds:RSAKeyValue> <ds:Modulus>IBQRp7gdQk9saf8db2VJ/EGmB0wjosZmsoMKVIt0y1Hm0xlQp5Qcl3Ec/iRGxJchb yG6DYHa2Q14mgwgx32Td9Oob0n/MzDZADdsrIOM3H8vTFEXOOgkzH0jHfsl1gsbXjdLH8hiZGZILbjd5QBTTZS ulW/nF6rjPUKopWwRkNRcslzTQ95LvHuy72MasdfyelFEVjqwCsfo4zL92QZVExasdffSwNpEraqEXEYasdffsN7q 2UG5aUQ14i8XL20dXujtyjmAVGvYrYGn5MQNtINykojS/UBb+R3iZx0HxjDUJHNDAY/u2Kc820rWxz1CWVf2IMFI 85FQ=</ds:Modulus> <ds:Exponent>AQAB</ds:Exponent> </ds:RSAKeyValue> </ds:KeyValue> </ds:KeyInfo> </saml2:SubjectConfirmationData> </saml2:SubjectConfirmation></pre>	Present in epSOS, but epSOS message defines "Method="urn:oasis:names:tc:SAML:2.0:cm:sender-vouches" and eHealth defines "Method="urn:oasis:names:tc:SAML:2.0:cm:holder-of-key".

Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AuthnStatement AuthnContext	<pre><saml2:AuthnStatement AuthnInstant="2013-06-20T18:50:09.334Z" SessionIndex="1"> <saml2:AuthnContext> <saml2:AuthnContextClassRef urn:oasis:names:tc:SAML:2.0:ac:classes:X509</saml2:AuthnContextClassRef> </saml2:AuthnContext> </saml2:AuthnStatement></pre>	epSOS message defines an AuthnContextClassRef of "urn:oasis:names:tc:SAML:2.0:ac:classes:PreviousSession".
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AttributeStatement Subject	<pre><saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:subject-id"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">MEGAHIT</saml2:AttributeValue> </saml2:Attribute></pre>	epSOS messages define Subject field with name value "urn:oasis:names:tc:xacml:1.0:subject:subject-id" and not "urn:oasis:names:tc:xspa:1.0:subject:subject-id".
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AttributeStatement Organization ID	<pre><saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:organization-id"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">urn:oid:1.3.6.1.4.1.26580.10</saml2:AttributeValue> </saml2:Attribute></pre>	epSOS organization ID does not being with "urn:oid" prefix.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Attribute Statement Home Community ID	<pre><saml2:Attribute Name="urn:nhin:names:saml:homeCommunityId"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">urn:oid:1.3.6.1.4.1.26580.10</saml2:AttributeValue> </saml2:Attribute></pre>	Not present in epSOS message.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Attribute Statement Subject Role	<pre><saml2:Attribute Name="urn:oasis:names:tc:xacml:2.0:subject:role"> <saml2:AttributeValue> <hl7:Role xmlns:hl7="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" code="106328005" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED_CT" displayName="Social worker" xsi:type="hl7:CE"/> </saml2:AttributeValue> </saml2:Attribute></pre>	epSOS does not define role using SNOMED CT code system.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Attribute Statement Purpose Of Use	<pre><saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:purposeofuse"> <saml2:AttributeValue> <hl7:PurposeForUse xmlns:hl7="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" code="COVERAGE" codeSystem="2.16.840.1.113883.3.18.7.1" codeSystemName="nhin-purpose" displayName="Disclosures for insurance or disability coverage determination" xsi:type="hl7:CE"/> </saml2:AttributeValue> </saml2:Attribute></pre>	epSOS message does not define purpose of use using a code system. It is defined using the uri format.
Header	O	WS-Security	SAML Attribute Statement Resource ID	<pre><saml2:Attribute Name="urn:oasis:names:tc:xacml:2.0:resource:resource-id"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">2205.2179^^^&amp;1.3.6.1.4.1.26580.10.60.1&amp;ISO</saml2:AttributeValue> </saml2:Attribute></pre>	Not present in epSOS message. In the eHealth messages, this is typically the patient ID.

Header	O	WS-Security	Security Signature	<pre> <ds:Signature xmlns:ns17="http://docs.oasis-open.org/ws-sx/ws-secureconversation/200512" xmlns:ns16="http://schemas.xmlsoap.org/soap/envelope/" Id="_2"> <ds:SignedInfo> <ds:CanonicalizationMethod Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#"> <exc14n:InclusiveNamespaces PrefixList="wsse S"/> </ds:CanonicalizationMethod> <ds:SignatureMethod Algorithm="http://www.w3.org/2000/09/xmldsig#rsa-sha1"/> <ds:Reference URI="#_1"> <ds:Transforms> <ds:Transform Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#"> <exc14n:InclusiveNamespaces PrefixList="wsu wsse S"/> </ds:Transform> </ds:Transforms> <ds:DigestMethod Algorithm="http://www.w3.org/2000/09/xmldsig#sha1"/> <ds:DigestValue>3xboQ5sdfasfdfsdfasf4=</ds:DigestValue> </ds:Reference> </ds:SignedInfo> <ds:SignatureValue>asdfx8+/asdfasfdfsdfasfdfsdfasf+glFwjepwXA1Llie1bekfAgH7Nsv1cbPbW 0jveXAGLtn3kV8gA9HOHCfsdafdfasfdfsdfgDFhpxSBBps+4Wasdfasfdfsdfasfdfsdfwefwfsdvsfgasdgaspow ajfdlkj0wjjsifjkleawjfijwefeiwofmsaj=</ds:SignatureValue> <ds:KeyInfo> <wsse:SecurityTokenReference wsse11:TokenType="http://docs.oasis-open.org/wss/oasis-wss-saml- token-profile-1.1#SAMLV2.0"> <wsse:KeyIdentifier ValueType="http://docs.oasis-open.org/wss/oasis-wss-saml-token-profile- 1.1#SAMLID">_af850sdfasf2er3sdfa23</wsse:KeyIdentifier> </wsse:SecurityTokenReference> </ds:KeyInfo> </ds:Signature> </pre>	epSOS security header not signed.
Header	N/A	WS-Security	SAML AuthnStatement	N/A	This is duplicated in the epSOS message, but different contents. This is a result of the repeated SAML header.
Header	N/A	WS-Security	SAML Subject	N/A	This is duplicated in the epSOS message, but different contents. This is a result of the repeated SAML header.
Header	N/A	WS-Security	SAML Attribute Statement	N/A	This is duplicated in the epSOS message, but different contents. This is a result of the repeated SAML header.

11.6 XCA Retrieve Response (DR)

Location	Required / Optional	Element	Field Name	eHealth Sample	Comments
Header	O; but eHealth gateway validating	WS-Security	Timestamp	<pre><wsu:Timestamp xmlns:ns17="http://docs.oasis-open.org/ws-sx/ws-secureconversation/200512" xmlns:ns16="http://schemas.xmlsoap.org/soap/envelope/" wsu:id="_1"> <wsu:Created>2013-06-20T18:50:14Z</wsu:Created> <wsu:Expires>2013-06-20T18:55:14Z</wsu:Expires> </wsu:Timestamp></pre>	Not present in epSOS message.
Header	R	WS-Security	SAML Issuer	<pre><saml2:Issuer Format="urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName">O=Social Security Administration,L=Baltimore,ST=Maryland,C=US</saml2:Issuer></pre>	Present in epSOS, but epSOS Format of "urn:epSOS:wp34:assertions" is not supported.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Subject NameID	<pre><saml2:NameID Format="urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName">UID=KP</saml2:NameID></pre>	Present in epSOS, but epSOS Format of "urn:oasis:names:tc:SAML:1.1:nameid-format:unspecified" is not supported.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Subject SubjectConfirmation	<pre><saml2:SubjectConfirmation Method="urn:oasis:names:tc:SAML:2.0:cm:holder-of-key"> <saml2:SubjectConfirmationData> <ds:KeyInfo> <ds:KeyValue> <ds:RSAKeyValue> <ds:Modulus>IBQRp7gdQk9saf8db2VJ/EGmB0wjosZmsoMKVIt0y1Hm0xlQp5Qcl3Ec/iRGxJchb yG6DYHa2Q14mgwgx32Td9Oob0n/MzDZADdsrIOM3H8vTFEXOOgkzH0jHfsl1gsbXjdLH8hiZGZILbjd5QBTTZS ulW/nF6rjPUKopWwRkNRcslzTQ95LvHuy72MasdfyelFEVjqwCsfo4zL92QZVExasdffSwNpEraqEXEYasdffsN7q 2UG5aUQ14i8XL20dXujtyjmAVGvYGr5MQNtInYkojS/uBb+R3iZx0HxjDUJHNDAY/u2Kc820rWxz1CWVf2IMFI 85FQ=</ds:Modulus> <ds:Exponent>AQAB</ds:Exponent> </ds:RSAKeyValue> </ds:KeyValue> </ds:KeyInfo> </saml2:SubjectConfirmationData> </saml2:SubjectConfirmation></pre>	Present in epSOS, but epSOS message defines "Method="urn:oasis:names:tc:SAML:2.0:cm:sender-vouches" and eHealth defines "Method="urn:oasis:names:tc:SAML:2.0:cm:holder-of-key".

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Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AuthnStatement AuthnContext	<pre><saml2:AuthnStatement AuthnInstant="2013-06-20T18:50:09.334Z" SessionIndex="1"> <saml2:AuthnContext> <saml2:AuthnContextClassRef urn:oasis:names:tc:SAML:2.0:ac:classes:X509</saml2:AuthnContextClassRef> </saml2:AuthnContext> </saml2:AuthnStatement></pre>	epSOS message defines an AuthnContextClassRef of "urn:oasis:names:tc:SAML:2.0:ac:classes:PreviousSession".
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AttributeStatement Subject	<pre><saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:subject-id"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">MEGAHIT</saml2:AttributeValue> </saml2:Attribute></pre>	epSOS messages define Subject field with name value "urn:oasis:names:tc:xacml:1.0:subject:subject-id" and not "urn:oasis:names:tc:xspa:1.0:subject:subject-id".
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML AttributeStatement Organization ID	<pre><saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:organization-id"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">urn:oid:1.3.6.1.4.1.26580.10</saml2:AttributeValue> </saml2:Attribute></pre>	epSOS organization ID does not being with "urn:oid" prefix.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Attribute Statement Home Community ID	<pre><saml2:Attribute Name="urn:nhin:names:saml:homeCommunityId"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">urn:oid:1.3.6.1.4.1.26580.10</saml2:AttributeValue> </saml2:Attribute></pre>	Not present in epSOS message.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Attribute Statement Subject Role	<pre><saml2:Attribute Name="urn:oasis:names:tc:xacml:2.0:subject:role"> <saml2:AttributeValue> <hl7:Role xmlns:hl7="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" code="106328005" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED_CT" displayName="Social worker" xsi:type="hl7:CE"/> </saml2:AttributeValue> </saml2:Attribute></pre>	epSOS does not define role using SNOMED CT code system.
Header	R (in eHealth Spec, optional in OASIS SAML 2.0 Spec)	WS-Security	SAML Attribute Statement Purpose Of Use	<pre><saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:purposeofuse"> <saml2:AttributeValue> <hl7:PurposeForUse xmlns:hl7="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" code="COVERAGE" codeSystem="2.16.840.1.113883.3.18.7.1" codeSystemName="nhin-purpose" displayName="Disclosures for insurance or disability coverage determination" xsi:type="hl7:CE"/> </saml2:AttributeValue> </saml2:Attribute></pre>	epSOS message does not define purpose of use using a code system. It is defined using the uri format.
Header	O	WS-Security	SAML Attribute Statement Resource ID	<pre><saml2:Attribute Name="urn:oasis:names:tc:xacml:2.0:resource:resource-id"> <saml2:AttributeValue xmlns:ns6="http://www.w3.org/2001/XMLSchema-instance" xmlns:ns7="http://www.w3.org/2001/XMLSchema" ns6:type="ns7:string">2205.2179^^^&amp;1.3.6.1.4.1.26580.10.60.1&amp;ISO</saml2:AttributeValue> </saml2:Attribute></pre>	Not present in epSOS message. In the eHealth messages, this is typically the patient ID.
Header	O	WS-Security	SAML Attribute	<pre><saml2:AuthzDecisionStatement Decision="Permit" Resource="https://hiergauat.appl.kpl.org:443/CONNECTNhinServicesWeb/NhinService/NhinPatientDiscovery"> <saml2:Action Namespace="urn:oasis:names:tc:SAML:1.0:action:rwedc">Execute</saml2:Action> <saml2:Evidence> <saml2:Assertion ID="_555f2f20347e40549ff74cbe7de6204f" IssueInstant="2013-06-20T18:50:09.355Z" Version="2.0"> <saml2:Issuer Format="urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName">O=Kaiser Permanente,L=Pleasanton,ST=CA,C=US</saml2:Issuer> <saml2:Conditions NotBefore="2013-06-20T18:49:03.799Z" NotOnOrAfter="2013-06-21T18:49:06.495Z"/> </saml2:Assertion> </saml2:Evidence> <saml2:Attribute Name="AccessConsentPolicy" NameFormat="http://www.hhs.gov/healthit/nhin"/> </saml2:AuthzDecisionStatement></pre>	Not present in epSOS messages.

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Header	N/A	WS-Security	SAML AuthnStatement	N/A	This is duplicated in the epSOS message, but different contents. This is a result of the repeated SAML header.
Header	N/A	WS-Security	SAML Subject	N/A	This is duplicated in the epSOS message, but different contents. This is a result of the repeated SAML header.
Header	N/A	WS-Security	SAML Attribute Statement	N/A	This is duplicated in the epSOS message, but different contents. This is a result of the repeated SAML header.

12 Annex 2 - Questionnaires for evaluation

The main aim of these questionnaires is to know the users opinion about some aspects of the Patient Summary service received.

The results of this study will only be used for evaluating purposes.

12.1 PATIENT QUESTIONNAIRE – PAPER BASED FOR PS V3.2– PHASE 1

ID	Question	Answers
LEGAL ASPECTS		
1	I think that my data privacy was appropriately maintained	1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know

ID	Question	Answers
2	I gave or confirmed consent	1. Yes 2. No 3. I don't know
SERVICE ASPECTS		
3	The Patient Summary service was useful for exchanging medical information	1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
4	Did the Patient Summary service facilitate the communication with the Health Care Professional?	1. Yes 2. No 3. I don't know

PATIENT QUESTIONNAIRE – PAPER BASED FOR PS V3.2 – PHASE 2

ID	Question	Answers
LEGAL ASPECTS		
1	I think that my data privacy was appropriately maintained	1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
2	I gave or confirmed consent	1. Yes 2. No 3. I don't know
SERVICE ASPECTS		
3	Did the Patient Summary service facilitate the communication with the Health Care Professional?	1. Yes 2. No 3. I don't know

4	Do you think that you received care faster than before with the Patient Summary service?	<ol style="list-style-type: none"> 1. Yes 2. No 3. I don't know
5	The Patient Summary service was useful for exchanging medical information	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
6	Would you use the Patient Summary service again?	<ol style="list-style-type: none"> 1. Yes 2. No 3. I don't know
7	Please explain why/ why not	Open answer
8	Would you recommend the Patient Summary service to a friend or family member?	<ol style="list-style-type: none"> 1. Yes 2. No 3. I don't know
9	Please explain why/ why not	Open answer

10	Do you think that the Patient Summary service is an improvement?	1. Yes. 2. No.
11	What is the most important benefit of the Patient Summary service	Open answer

HCP QUESTIONNAIRE ON LINE. PHASE I (n=10). V 3.1

N	Question	Answers
LEGAL ASPECTS		
1	Checkbox	<input type="checkbox"/> Patient summary <input type="checkbox"/> HCER
2	Did the patient?	1. Confirm his consent. 2. Refuse his consent. 3. I don't know. 4. Not possible to obtain because of emergency.
SERVICE ASPECTS		
3	The service is available to use. (if the answer is 'no', please proceed to the end of the questionnaire without replying to the rest of the questions)	1. Yes 2. No. 3. I don't know
4	The service is easy to connect to.	1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
5	The service is easy to use.	1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know

6	The help section is easy to use.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
7	The data were easy to understand.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
8	In general, titles (subheadings) for the data make sense.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
9	Did you need to contact the helpdesk?	<ol style="list-style-type: none"> 1. Yes 2. No 3. I don't know
10	If yes, what for?	Open answer
11	The response time was acceptable.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know

HCP QUESTIONNAIRE ON LINE.

N	Question	Answers
LEGAL ASPECTS		
1	Checkbox	<input type="checkbox"/> Patient summary <input type="checkbox"/> HCER
2	Did the patient?	1. Confirm his consent. 2. Refuse his consent. 3. I don't know. 4. Not possible to obtain because of emergency.
SERVICE ASPECTS		
3	The service is available to use. (if the answer is 'no', please proceed to the end of the questionnaire without replying to the rest of the questions)	1. Yes 2. No. 3. I don't know
4	The service is easy to connect to.	1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know

5	The service is easy to use.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
6	The help section is easy to understand.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
7	The data were easy to interpret.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
8	In general, titles (subheadings) for the data make sense.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
9	If yes, what for?	Open answer
10	The response time was acceptable.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
IMPACT ASPECTS		

12	You delivered faster care when using the patient summary service.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
13	You made a better clinical decision as a result of information provided by the patient summary.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know
14	Do you think the patient summary might have helped you to avoid an adverse event (allergy reaction, negative drug interaction, excessive drug dose...)?	<ol style="list-style-type: none"> 1. Yes 2. No 3. I don't know
15	Would your patients experience an adverse event (allergy reaction, drug interaction, drug excessive dose, ...) as a result of any lack of information in the Patient Summary?	<ol style="list-style-type: none"> 1. Yes. 2. No. 3. I don't know
16	If there was an adverse effect, which information might have helped you to avoid it?	Open answer
17	Did you find relevant information that the patient was not able to provide him or herself?	<ol style="list-style-type: none"> 1. Yes 2. No 3. I don't know
18	The patient summary service reduces language barriers.	<ol style="list-style-type: none"> 1. Strongly disagree. 2. Disagree. 3. Uncertain. 4. Agree. 5. Strongly agree. 6. I don't know

13 Annex 3 - End-2-end Functional Test Questionnaire

The main aim of these questionnaires is to support the end 2 end functional testing as foreseen by the defined test plan.

13.1 Common sections

13.1.1 Identification of the user filling the questionnaire and of the test

Identification of the HP filling the questionnaire

Name : *

Please provide the family name (lastname or surnam) of the person who's signing this evaluation

Firstname: *

Please provide the firstname of the person who's signing this evaluation

Email: *

Identification of the test

Type of CDA Document: * - Select -
Please select the service that you are evaluating

Date of the evaluation: * Jul 4 2011
Please enter the date at which the evaluation was performed

Country/Region of Origin: * - Select -
Please select count/region of origin of the document being evaluated

Country/Region of Destination: * - Select -
Please select count/region of destination of the document being evaluated

Your Credentials

The type of CDA evaluated (PS/CCD)

Country A Identification

Country B Identification

13.1.2 Nonfunctional requirements

Record if any service unavailability occurred during the test

Were all services available during the time the test was performed?

Yes

No

Document the response time of the services during the test as objective and subjective (your perception) evaluation.

Response Time:

	(>15s)	(<15s)	(<10s)	Not Applicable
Find Patient	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Retrieve Document	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Transform Document	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

How is your perception of the response time ?

- Not acceptable**
- Acceptable**
- Good**

Document if any error occurred during the test and in case describe it.

Did you have any error during the process? : *

- Yes**
- No**

13.2 Save as, Load and Transformation services (only for the Patient Mediated Scenario)

Record if the user was able to get correctly his/her CCD or EU Patient Summary

Have you been able to obtain (save as) correctly your CCD or Patient Summary ?

- Yes**
- No**

Record if only authenticated users was able to access to the Trillium Transformations services

Did you authenticate before accessing the Trillium Transformation Service ?

Yes

No

Record if the user was able to get correctly his/her transformed CCD or EU Patient Summary using the Trillium Bridge Transformation Services ?

Have you been able to obtain (save as) a transformed CCD or Patient Summary from the Trillium Bridge Transformation Service?

Yes

No

Record if the user was able to load and display the provided CCD or EU Patient Summary ?

Have you been able to load and display the provided CCD or Patient Summary ?

Yes

No

13.3 Identification Process (only for the Provider Mediated Scenario)

The identification process shall be accomplished before the document retrieval: you need to evaluate if the returned information is sufficient to identify the patient and if any dysfunctional behavior took place.

Could the patient be identified through the fields described by the country of origin?

Yes

No

Did you have any error during the Patient Search and Identification process ?

Yes

No

13.3.1 Patient Information

Check that Patient Information is provided and record it on the questionnaire for tracking purpose

		Is the data provided?		
		YES		NO
Patient Name				
Family Name/Surname	Required			Please provide the family name of the patient concerned
Given Name/Firstname	Required			Please provide the given name of the patient concerned
Date of Birth	Required			Please provide the date of birth of the patient concerned
Patient Identifiers				
Primary Patient Identifier	Required			Please provide the identifier used
Secondary Patient Identifier	Optional			Please provide the identifier used

(If one of the required elements is not provided)

Please explain

13.4 Patient Summary

13.4.1 Patient Summary List (only for the Provider Mediated Scenario)

Verify that a PS is retrieved for a selected patient.

Was one Patient Summary provided for the Patient?

Yes

No

Verify that you're enabled to retrieve and access - together with the receiver language document - also a PDF including information in the sender language.

Was the original PDF Patient Summary document provided?

YES

In the country A language?

YES

NO

NO

Did you have any error during the process?

Yes

No

13.4.2 Other Patient and Context Information

Following questions are made to check if some fields describing the patient and the document context are available and understandable

Are the dates of the document creation and of the last update of information present and understandable?

Yes

No

Please explain

Does the patient's contact information (address, telecom) seem to be complete and usable?

Yes

No

Please explain

Does the patient's contacts (guardian, preferred contact, other contacts) information seem to be complete and usable?

Yes

No

Please explain

Is the author of the document provided?

Yes

No

Please explain

If yes, does the author's contact information seem to be complete and usable?

Yes

No

Is the legal authenticator of the document provided?

Yes

No

If yes, does the legal authenticator's contact information seem to be complete and usable?

Yes

No

Please explain

13.4.3 Sections

For any section to be verified, it is asked if the section is present and in case if the main fields are displayed, and if the content of the section can be safely understood (including missing values).

13.4.3.1 Alerts

Is the section present?

Yes

No

Can you safely understand the medical information communicated?

Yes

No

Please explain

If yes, do you find the information useful for the care you intend to provide?

Yes

No

Please explain

Is there any null info / empty cell difficult to understand / interpret?

Yes

Please explain

No

Is there any other source of possible medical error?

Yes

Please explain

No

13.4.3.2 Diagnostic tests

Is the section present?

- Yes
- No

(IF YES)

Is the section displayed in your (Country B) language?

- Yes
- No

Please explain

Can you safely understand the medical information communicated?

- Yes
- No

Please explain

If yes, do you find the information useful for the care you intend to provide?

- Yes
- No

Please explain

Is there any null info / empty cell difficult to understand / interpret?

Yes

Please explain

No

Is there any other source of possible medical error?

Yes

Please explain

No

13.4.3.3 *List of (Current) Problems*

Is the section present?

Yes

No

(IF YES)

Is the section displayed in your (Country B) language?

Yes

No

Please explain

Can you safely understand the medical information communicated?

Yes

No

Please explain

If yes, do you find the information useful for the care you intend to provide?

Yes

No

Please explain

Is there any null info / empty cell difficult to understand / interpret?

Yes

Please explain

No

Is there any other source of possible medical error?

Yes

Please explain

No

13.4.3.4 Medication Summary

Is the section present?

Yes

No

(IF YES)

Is the section displayed in your (Country B) language?

Yes

No

Please explain

Can you safely understand the medical information communicated?

Yes

No

Please explain

If yes, do you find the information useful for the care you intend to provide?

Yes

No

Please explain

Is there any null info / empty cell difficult to understand / interpret?

Yes

Please explain

No

Is there any other source of possible medical error?

Yes

Please explain

No

13.4.3.5 Medical Devices and Implants

Is the section present?

Yes

No

(IF YES)

Is the section displayed in your (Country B) language?

Yes

No

Please explain

Are the Device and the Implant Date data displayed ?

Yes

No

Please explain

Can you safely understand the medical information communicated?

Yes

No

Please explain

If yes, do you find the information useful for the care you intend to provide?

Yes

No

Please explain

Is there any null info / empty cell difficult to understand / interpret?

Yes

Please explain

No

Is there any other source of possible medical error?

Yes

Please explain

No

13.4.3.6 Procedures

Is the section present?

- Yes
- No

(IF YES)

Is the section displayed in your (Country B) language?

- Yes
- No

Please explain

Can you safely understand the medical information communicated?

- Yes
- No

Please explain

If yes, do you find the information useful for the care you intend to provide?

- Yes
- No

Please explain

Is there any null info / empty cell difficult to understand / interpret?

Yes

Please explain

No

Is there any other source of possible medical error?

Yes

Please explain

No

13.4.3.7 List of Past Illnesses

Is the section present ?

Yes

No

(IF YES)

Is the section displayed in your (Country B) language?

Yes

No

Please explain

Can you safely understand the medical information communicated?

Yes

No

Please explain

If yes, do you find the information useful for the care you intend to provide?

Yes

No

Please explain

Is there any null info / empty cell difficult to understand / interpret?

Yes

Please explain

No

Is there any other source of possible medical error?

Yes

No

13.4.3.8 Vaccinations

Is the section present?

Yes

No

(IF YES)

Is the section displayed in your (Country B) language?

Yes

No

Can you safely understand the medical information communicated?

Yes

No

Please explain

If yes, do you find the information useful for the care you intend to provide?

Yes

No

Please explain

Is there any null info / empty cell difficult to understand / interpret?

Yes

Please explain

No

Is there any other source of possible medical error?

Yes

Please explain

No

13.4.3.9 Others Sections

Are other section present?

Yes

No

(IF YES, FOR EACH SECTION INSERT THE SECTION TITLE AND ANSWER TO THOSE QUESTIONS)

Is the section displayed in your (Country B) language?

Yes

No

Please explain

Can you safely understand the medical information communicated?

Yes

No

Please explain

If yes, do you find the information useful for the care you intend to provide?

Yes

No

Please explain

Is there any other source of possible medical error?

Yes

No

Please explain

13.4.4 General Document

Is the structure of the document logical and easy to follow ?

Yes

No

Please explain

Is the data provided generally medically coherent?

Yes

No

Please explain

Is there any content reference (English PDF, Critical Test Data Specifications,...) provided ?

- Yes**
- No**

(IF YES)

Compared to the reference document , is there any medically important difference in the information?

- Yes**
- No**

Compared to the reference document , is there any medically important information contained in the reference but not in structured PS?

- Yes**
- No**