DELIVERABLE

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Authors:

Karima Bourquard, IHE-Europe

Charles Parisot, IHE-Europe

Alexander Berler, IHE-Europe

Review:

Catherine Chronaki, HL7 Foundation
Gerard Freriks, EN 13606 Association
Stephan Schug, Ehtel
Alen Vrecko, NIPH**Aucune entrée d'index n'a été trouvée.**

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Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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Glossary: Definitions and Abbreviations

Abbreviation	Explanation
CAB	Conformance Assessment Body
CEN	European Committee for Standardization
CHA	Continua Health Alliance
DMP	Dossier Médical Personnel /Partagé
EHR QTN	Thematic Network on Quality of Electronic Health record systems
EIP AHA	European Innovation on Partnership on Active and Healthy Ageing
EA	European Accreditation
ETSI	European Telecommunications Standards Institute
HL7	Health Level Seven
HITCH	Healthcare Interoperability Testing and Conformance Harmonisation
IAF	International Accreditation Forum
IHE	Integrating the Healthcare Enterprise
NEN	Nederlandse Norm (Netherlands Standardization Institute)
ISO	International Standards Organisation
MLA	Mutual Recognition Arrangement
QL or C	Quality Label or Certification

Executive Summary

The eHealth European Interoperability Framework, interoperability with the first study published in 2012 by the European Commission, is now considered as a priority for the deployment of the eHealth technologies in Europe. There is today no doubt that interoperability will be the key challenge to be addressed in the forthcoming years.

To develop a unified market in Europe, the stakeholders need to be confident that ICT solutions that are procured meet specific standards and profiles in a way that ensures interoperability, even if the solutions are proposed by companies coming from other countries than the country of the healthcare provider. Promoting a quality label or certificate at the European level, will leverage the integration of solutions and offer a good opportunity to the industry to sell their products in Europe within one recognized testing process, avoiding redundancy among different testing processes that are not compliant.

Even if projects are using standards and profiles described in the eEIF (eHealth European Interoperability Framework), their deployment at the national/regional or local level have to take into account the local regulations, the organizational schemes (for example innovative activities or new use cases that are not described at the European level), semantic specificities (for example local coding systems) or technical requirements for their success. These extensions have to be developed harmoniously with what were already defined at the European level and therefore the European testing processes shall be extended.

All these issues have to be analysed from the point of view of interoperability testing. During the preceding three years, European projects such as HITCH and EHR-Q^{TN} provided recommendations for the success of the future quality label or certification processes at the European level. Among them, the flexibility of the testing processes, the development of an ecosystem by promoting one interoperability framework and the definition of a European Conformance Assessment in line with ISO standards were the major key points upon which the results of this work package were built.

This deliverable provides description of quality label or certification processes, gives models, concrete examples and guidance that can be implemented in Europe and recommendations and guidelines for the deployment of such processes.

Starting by the functional model of the Conformance Assessment governance, it describes all the bodies that need to be involved in the quality label or certification processes. The past studies presented an overview of how this model was used in the European countries or by profiles consortia such as IHE and Continua Alliance. The deliverable continues by describing two implementations selected in Europe are presented as two concrete examples: the national project called DMP (national EHR) in France and the epSOS project (exchange of medical data for a patient travelling in Europe).

The flexibility between European and national/regional levels is also considered. Directions and recommendations are presented, based on the reusability of the testing plan, test cases and test tools. Extensions are allowed and will be challenging at a European level for their integration in newer versions of the eHealth European Interoperability Framework.. In addition, test methods developed for these extensions shall be available on open licenses for better dissemination in Europe. Guideline to establish a Quality label or certification processes completes the approach.

To maintain and sustain such processes in Europe, governance rules have to be established. A reasonable approach based on the existence of stakeholders ecosystems composed by eHealth application users, vendor associations, local, regional and national authorities, centres of competences and independent experts ready to cooperate, consists to create a coordination that will operate under the supervision of the group. EXPAND project already proposes a governance based on maintenance shops that will sustain epSOS assets before their endorsements by the CEF.

In conclusion, the results of the deliverable build upon and expand all the previous recommendations that were raised in the past. The processes are now ready to be implemented. The three key messages that were developed in this study are:

- *Stimulate the creation of European market based on the evolving European eHealth Interoperability Framework associated with a modular European Conformance Assessment Program;*
- *Harmonise the quality label and certification processes in Europe and among countries and regions;*
- *National or regional interoperability testing processes maintain their flexibility while being harmonised with a modular European Conformance assessment scheme*
- *European quality label or certification processes still allow flexibility in national or regional approaches.*

1 Introduction

The eHealth European Interoperability Framework, interoperability with the first study published in 2012 by the European Commission, is now considered as a priority for the deployment of the eHealth technologies in Europe. There is today no doubt that interoperability will be the key challenge to be addressed in the forthcoming years.

The identification of the profiles by the multi Stakeholder Platform for ICT is now in progress and these profiles do cover a large spectrum of use cases. They can be easily implemented by existing ICT products deployed within the European market. To meet regulation such as the directive 2007/47/EC on medical devices or simply to ensure that interoperability is taken in consideration, testing processes shall be one of the main challenges for the success of the eHealth solution deployment in the forthcoming years.

To develop a unified market in Europe, the stakeholders need to be confident that ICT solutions that are procured meet specific standards and profiles in a way that ensures interoperability, even if the solutions are proposed by companies coming from other countries than the country of the healthcare provider. Promoting a quality label or certificate at the European level, will leverage the integration of solutions and offer a good opportunity to the industry to sell their products in Europe within one recognized testing process, avoiding redundancy among different testing processes that are not compliant.

1.1 Purpose of this document

This deliverable is one of the results of the WP4 of the Antilope project. The goal of this deliverable is to design testing, quality label or certification processes that support, at the European level, the common interoperability requirements and at the level of each European country or region, their own specific or extended interoperability requirements. This testing processes will increase the level of interoperability between solutions and subsequently the quality of eHealth software products and services across Europe, while respecting flexibility and policy setting by each of the member states.

The main benefits of such a testing and QL or C processes are:

- *For healthcare providers* (hospitals, health insurance, national program) and healthcare professionals
    - To broaden their choice between various eHealth solutions available in the European market;
    - To have eHealth solutions that are better integrated;
    - To be able to exchange medical data at the regional, national and cross border levels.

- *For the eHealth IT industry*

    - To obtain a European seal approval across the Union and recognised by all the European countries;

    - To expand the European seal in order to address specific needs at the national /regional level;

    - To avoid redundancy (duplicative testing) among country certification or quality assurance programs;

    - And therefore to optimize their investments in interoperability for better quality of care.

1.2 Document structure

This deliverable starts with a review of the rational for this study (section 02), it is followed by the presentation of concepts and definitions used commonly to describe the field of assessment of solutions (section 3). A description of the functional model and its implementation is discussed in the section 4. A review of main recommendations of the previous studies in this field is also presented. The two level QL or C processes and the governance that will maintain and sustain the model is presented in the section 6. Concrete examples provide a better understanding but also demonstrates that the model presented is realistic in Europe (section 6.4) The document ends by focusing on recommendations and guidelines for the deployment of a Conformity Assessment Program Scheme (CAPS) at European and national/regional levels whose allows mutual recognition for the benefit of healthcare providers and Industry (section 7). In the conclusion, the HITCH roadmap is updated considering the results of the Antilope project.

2 Rationale

The quality label or certification processes that are presented in this document results from the previous analysis and the conclusions of the HITCH project (see section 0). Based on a State of Art and the review of the processes that are used in several Member States or more largely in international organisations and in other domains (telecom, …), the previous study shows the interest to deploy such quality label and certification processes in the eHealth domain.

In this section we will summarize the most relevant and suitable conclusions that have led our work in Antilope's project. These conclusions are divided in two axes:

- The most common benefits and impacts that were highlighted by the different experimentations of the QL or C processes over countries;
- Market and QL or C processes: how to start such a deployment.

The previous study was built on 13 countries in Europe and US and 5 European and International organizations experiences.

2.1 Benefits and Impacts

Several benefits and impacts of QL or C processes have been mentioned in the different countries or international organisations. They are synthetized in this table (from HITCH project and reviewed):

Table 1: Benefits and Impacts

General	Improve the quality, safety, efficiency of health Reduce health disparities Ensure adequate privacy and security protections for personal health information Promote the conformity to the clinical regulation Decrease the treatment cost for the same level of quality
Functionality	Enhanced functionalities, harmonisation of systems Improve vendor reliability Support the end-user (prescriber) Improve quality of "content" and "output"
Interoperability	Improves interoperability (implementation of standards) Conformity with regulation Zero paper (electronic claim document/ Healthcare information) Reduces delay of reimbursement/ Healthcare information available to the right person
Financial	Receive financial incentives (users)

For example and more deeply, the benefits and impacts of IHE Quality Label processes considered as relevant for our purpose, demonstrate the interest of deploying these testing processes and are presented below.

The IHE Stakeholder communities cover all the stakeholders interested by the deployment of eHealth interoperability. They are various: Health Professional Organizations, Provider Organizations, Provider Developers, Open Source Developers, Vendors, Consultants, Trade Associations, Government Agencies, Consumer Organizations, Standards-Developing Organizations, Healthcare Services Purchasers or Employers, Health IT Promotion Organizations, and Health Research Organizations.

The value proposition for the vendors and software implementers is to foster the creation and the deployment of Healthcare IT products which become a trusted source for interoperable health solutions for healthcare providers, and which are easily installable and deployed in the healthcare provider's IT infrastructure.

The value proposition depends heavily on the acceptance and extensive deployment of the IHE integration profiles in the industry and in the IT infrastructure healthcare providers.

The value proposition for Healthcare Authorities is (from HITCH and revised):

- The promotion of the adoption of HIT products and the improvement of the quality and the reduction of the patient care cost;
- The good execution of an incentive program;
- The definition and the benchmark of the required interoperability functionalities (between products);
- The insurance that the expected benefits (e.g products are interoperable) are obtained.

The value proposition for Patients is:

- The insurance that their safety and quality of care is safeguarded;
- The privacy and Security of their personal data is guaranteed.

The value proposition for Care Providers is:

- The product has better quality and the users receive the product as promised;
- To be comfortable with the introduction of HIT products in their care delivery processes.

The value proposition for Standard Development Organizations (Secondary Stakeholder)

- The development, the use and the deployment of standards that are relevant and benefit to the healthcare communities.

2.2 How to deploy QL or C processes?

Three scenarios of QL or C processes were previously analysed in order to demonstrate the relationship between the maturity of the market and the choice of one of these scenarios described below:

- QL or Certification of products: a third party called CAB (Conformity Assessment Body) organizes the testing session of the products and the requirements are based on a certification or quality label schema provided by the scheme owner;

- Self-assessment with external reference: the evaluation is not only focused on the results of testing but also on the testing processes endorsed by the organisation. The requirements are coming from ISO standards such as ISO 9000X or ISO/IEC 17025. The assessment is performed by a competent and relevant third party. The process will issue a QL or C of the organisation and ensures that the test of the products performed by this organisation follows a well described testing process and compliant with the best practises.
- Self-assessment of products: the software provider has its own testing processes and is sufficiently competent to deliver products with high level of quality. The evaluation is generally obtained in real life when products are used with other products. In this case, the market will recognize the welfare of the organisation.

The following schema extracted from HITCH's project shows when one or the other scenarios is appropriate regarding the maturity of the market.

Figure 1: scenarios and market maturity (from HITCH, 2011)

The first scenario is more appropriate in the case of the introduction of new innovative technologies in an emergent market and when the stakeholders want to accelerate the adoption of these technologies. It helps the SMEs to adopt them by offering the necessary "test toolkit" provided by the third testing parties considered as "single point of contact".
As written in HITCH D4.3, "If expected market sizes are significantly greater than real sales and customer hesitation is mainly due to unstable/unspecific interface specifications, it may be considered a societal interest to avoid or reduce fragmentation and to improve customer confidence by prescribing an identified specification and establishing a label to state conformance towards that specification. So, good market analysis and the ability to assess relevant candidate specifications need to be available". However in terms of cost, this scenario is the most expensive scenario.

The second scenario is adapted for market belonging more and more mature. The quality process in place allows the customer to be confident to the product, limits their technical knowledge and

allows them to focus on their user needs. They also have access to a list of products presenting all the necessary requirements.

The third scenario is well adapted for a mature market and was observed in the Telecom field for example. Most of the products in the field have already adopted the interoperability standards and the testing toolkits are also available and widely distributed. Compliance to standards is the requirements to enter in the market. Customers are fully aware of the interoperability issues if the products are not compliant with the most common standards used in the field and these standards become a tick mark in advertising.

In conclusion, for an emerging market such as the eHealth where high expectations for interoperability, are today the drivers, QL or C processes as described in the first scenario are most appropriate in order to develop and deploy interoperability with high quality of products. This is why in the following sections, a functional model is developed and explained.

3 Terms and Definitions

Terms and definition used in this document refers to the ISO 17 000 and documents coming from different sources such as

- Deliverables from HITCH project (Healthcare Interoperability Testing and Conformance Harmonisation)
- EHR-Q^{TN} project
- Other ISO standards (see references)
- Presentations, workshops and discussion in progress in the eHealth interoperability domains (IHE, NIST, countries….)
- Workshops with experts and accreditation authorities, ….

ACCREDITATION

third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessments tasks (ISO/IEC 17000)

ACCREDITATION BODY

authoritative authority that performs accreditation (ISO/IEC 17000)

AUDIT

audit is an independent, objective assurance and consulting activity designed to add value and improve an organisation's operations. It helps an organisation accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes. Based on the definition of The Institute of Internal Auditors on June 29th 1999)

CERTIFICATION

third-party attestation related to products, processes, systems or persons. (ISO 17000) Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves to which accreditation is applicable

CONFORMITY ASSESSMENT

demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (ISO/IEC 17000)

CONFORMITY ASSESSMENT BODIES (CABS)

body who performs conformity assessment services (ISO/IEC 17000)

INSPECTION

examination of product, design, service, process or plant, and determination of their conformity with specific requirements or, on the basis of professional judgment, general requirements […] (ISO/IEC 17000)

CONFORMITY ASSESSMENT SCHEME

conformity assessment system related to specified objects of conformity assessment to which the same specified requirements, specific rules and procedures apply. (ISO/IEC 17000)

4 Testing, Quality label and certification processes

4.1 Functions to support the Interoperability QL or C processes

A quality label or certification processes define all requirements, activities and tasks that allow any entity that wants to organize a quality assurance procedure and for the entities that want to seek this quality label or certification. Following the best practise, certification or quality label processes require:

- A *QL or C*: a party that sets the QL or C program or system;
- A *Certification Body*: a party that issues the quality label or certificate on the basis of the conformity assessment performed by a Conformity Assessment Body;
- A *Conformity Assessment Body*: a party that assesses the conformity of products, services and/or suppliers (sometimes called a testing laboratory)

Although the Certification Scheme Owner, the Certification Body and the Conformity Assessment Body are described as different bodies, in practical/real life it is common to find organisations performing more than one of these roles depending on their conformity assessment scheme. In the case where two of three functional activities are supported by the same organisations, these functions shall be clearly separated (supported by different entities or departments within the organization).

A functional decomposition of these three entities is shown in figure 2 below on the left handside. This is the part that the product/service developer interacts with as it submits its product/service to the conformance assessment to obtain certificate/label.

Note that the right hand-side of this figure introduces the entities that perform the inspection and "accredit" the left hand-side entities that perform the conformity assessment and issue certificates/labels. When an accreditation of a body is required, it is expected that the accreditation is performed by an independent third party. To accredit a body means to recognize the competency of this body and their business processes meet the requirements of dedicated standards. For example a testing laboratory whose wants to be accredited, the requirements described in the ISO/IEC 17025 standard are those served as a reference to audit the testing laboratory.

This is a functional depiction in the sense that each QL or C scheme owner may organize the entities in many different ways and set drastically different levels of rigors in performing their role.

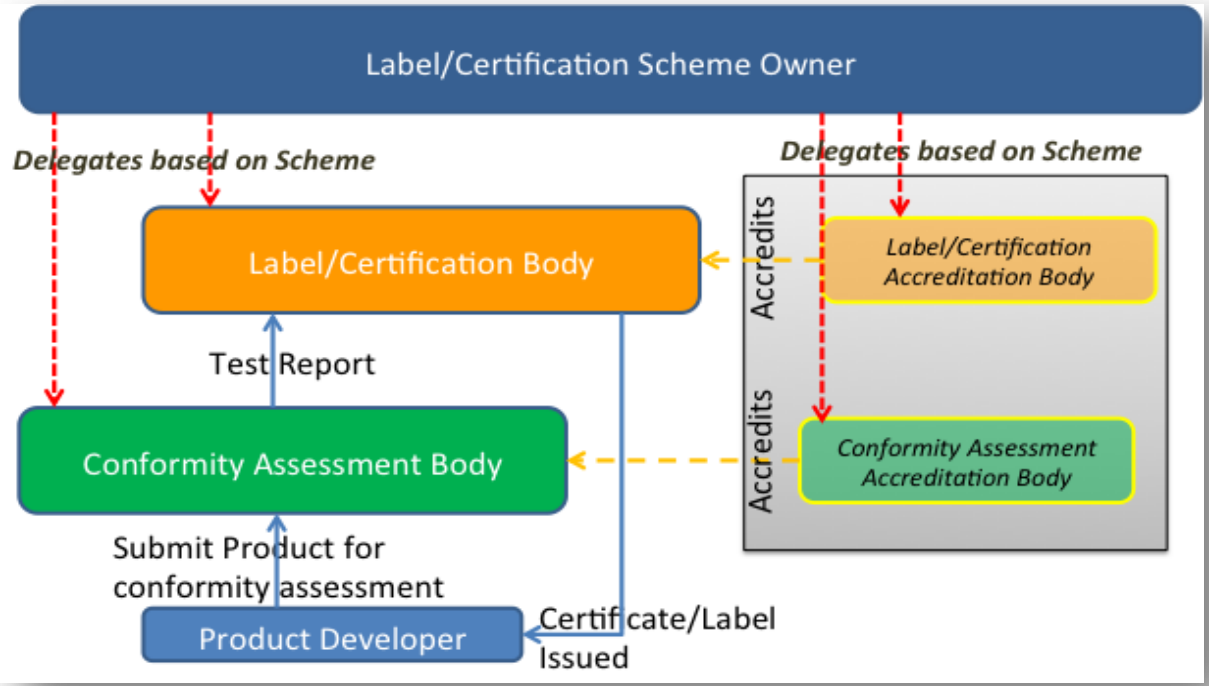

Figure 2: Certification and testing functional model

The QL or C scheme owner initiates the QL or processes and defines the label/certification program and processes. The owner defines the requirements and criteria, the testing or the inspection processes relevant to the assigned objectives and specifies the business model that the owner wants to apply.

To be conformed to the best practice, this body delegates to the label/certification body the activity of issuing the label or certificate. This body should be an accredited body (conformed to ISO/IEC 17065 in eHealth interoperability) and is able to deliver a certificate following its own processes. The QL/certification body selects the Conformity Assessment Bodies whose the role is to evaluate the tests realised by the products and report to the QL/Certification body that grants or refuses the certificate. The testing laboratory (or the inspection body, depending on the specifications of the certification scheme) shall be accredited ISO/IEC 17025 when a certification scheme is mandatory (It is not required for the quality label scheme). Several testing laboratories can be selected since they have all the necessary skills, processes and test methods and are able to perform the relevant tests.

In the following section, a brief description of the processes is presented.

4.2 Conformity Assessment Process

This process is launched by a Conformity Assessment Body (CAB) –in green in the schema- generally played by a testing laboratory or inspection body. Their role is to perform tests or audit for example to assess the interoperability requirements e.g interoperability specifications such as IHE profiles that are implemented by eHealth solutions.

The CAB is the body that organizes the tests, using existing or developing test plans and test cases and test tools (called also test methods) that are specified in the QL or C Scheme. The CAB reports the results of the tests to the certification body.

The value of the seal depends of the quality and the competencies of the CABs and their ability to perform high quality tests specified in the label/certification scheme. These competencies are evaluating regarding ISO/IEC standards (see table 2).

By accrediting several CABs across Europe for the same scheme, the equivalency of their results can be more easily recognized at the European level as well as at National, country or regional level.

Table 2: Applicable standards for Conformity Assessment Process

Applicable Standard	Scope and applicability of the standard
ISO 17025: 2005	General requirements for the competence of testing and calibration laboratories
ISO 9001:2008	Quality Management systems - requirements

4.3 Certification Assessment Process

The label/certification –orange in the schema- body carries out certification process for a scheme owner (whose the role is to define the interoperability requirements), and delivers, when accredited, a consistency and impartial service that meets the appropriate, internationally recognized standards (IAF). In many countries, the Label/certification body is not accredited. Process and requirements are described in standards (see table 3).

The list of accredited certification bodies are published for example at the IAF website (http://www.iaf.nu) or at the EA (European co-operation Accreditation) website (www.european-accreditation.org) .

Table 3: Applicable standards for Certification Assessment Process

Applicable Standard	Scope and applicability of the standard
ISO 17065: 2012	Conformity assessment -- Requirements for bodies certifying products, processes and services
BS EN 45011:1998	General Requirements for bodies operating product certification systems
ISO/IEC 17020: 2012	Conformity assessment –Requirements for the operation of various types of bodies performing inspection
ISO/IEC 17024: 2012	Conformity assessment – General requirements for bodies operating certification of persons

4.4 Accreditation Processes

These processes are at the European level supported by the EA (European co-operation for Accreditation) whose the main mission is "to coordinate and lead the European accreditation infrastructure to allow the results of conformity assessment services in one country to be accepted

by Regulators and the market place in another country without further examination, for the benefit of the European community and the global economy."

Consumers want to buy goods, products or services with confident and trust. Development of European or international standards applied to products, processes and services are one of the consequences of such requirements. To facilitate the life of consumers and to make easiest the selection of the products, technical bodies organize the assessment of the products and services. The bodies must have all the technical competences, processes and integrity to carry out these assessment services. When a body is accredited by one of the EA network, it demonstrates its skills and its independency and impartiality. Generally there is one accreditation body per country and is named by national authorities in charge of this topic. The list of accreditation bodies is available at http://www.european-accreditation.org/ea-members .

The EA has defined an EA policy for Conformity Assessment schemes (with sector schemes) and will cooperate with scheme owners. The EA members provide accreditation of laboratories (testing with ISO/IEC 17025), inspection bodies, certification bodies (products with ISO/IEC 17065) and verification bodies according to the European Management and Audit Scheme (EMAS) or EU/ETS Regulations.

In order to harmonize the label quality or certification processes in eHealth interoperability, requirements must follow the EA policy for the accreditation of the CABs.

Table 4: Application standards for Accreditation Process

Applicable Standard	Scope and applicability of the standard
EA-1/22 1-1B:2006	EA Policy for conformity assessment schemes http://www.european-accreditation.org/publication/ea-1-22-a-ab

4.5 Mutual recognition

Mutual Recognition Arrangements (MRA) can be implemented in a case of certification process.

Through Mutual Recognition Arrangements (MRAs), national/regional certification bodies can actively promote the European and worldwide acceptance of test reports and calibration assessment from European certification scheme owner.

In accordance with these MRAs, accredited test laboratories meet the requirements of ISO/IEC 17025. The MRAs serve to demonstrate the equivalence of the operation of signatory member accreditation bodies. As a consequence, the competence (within the accredited scopes) of test laboratories accredited by these bodies, is demonstrated and recognised by one of the signatory accreditation bodies. The European market place can then be more confident in accepting assessment and test reports issued by accredited laboratories.

It is the reason why we strongly recommend testing laboratories in the eHealth interoperability field to be accredited ISO/IEC 17025. With the promotion of the eHealth European Interoperability Framework (eEIF), and related test methods at the European level, eHealth companies that have

assessed their solutions by such testing laboratories will be able to propose their products in European countries with the same level of trust. A harmonised European market will be more easily raised and developed.

4.6 Implementation of the model

In the real life, the reference model as described in section 4.1, is not often adopted in eHealth interoperability field. Several models were compiled in the HITCH and EHR-Q^{TN} studies. Two frequently models are generally implemented:

- Model-1: the same organization defines the QL or C scheme, organises the label/certification processes and issues the label/certificate;

- Model-2: the same organization organises all the processes including the Conformity Assessment e.g. in our case provides the assessment services (it plays the role of the testing laboratory).

4.6.1 Implementation of the model-1

In this model, the Conformity Assessment Bodies, accredited or not, are separate entities from the scheme owner whose plays also the role of label/certification body (see figure 3). This is one of the two most common implementation models. For example, this model was applied to validate the conformity of the country's NCP before running pilot in the epSOS project.

In this example, the two roles scheme owner and the label/certification body was taken by the project or more precisely by the steering committee. In the role of scheme owner, this committee validates the requirements (interoperability specifications, content specifications, …), the testing strategy, the test plan and the test methods. In the role of label/certification body, the committee validates the testing report of each country implementation provided by IHE-Europe who plays the role of Conformity Assessment Body. For more detail see annex I.

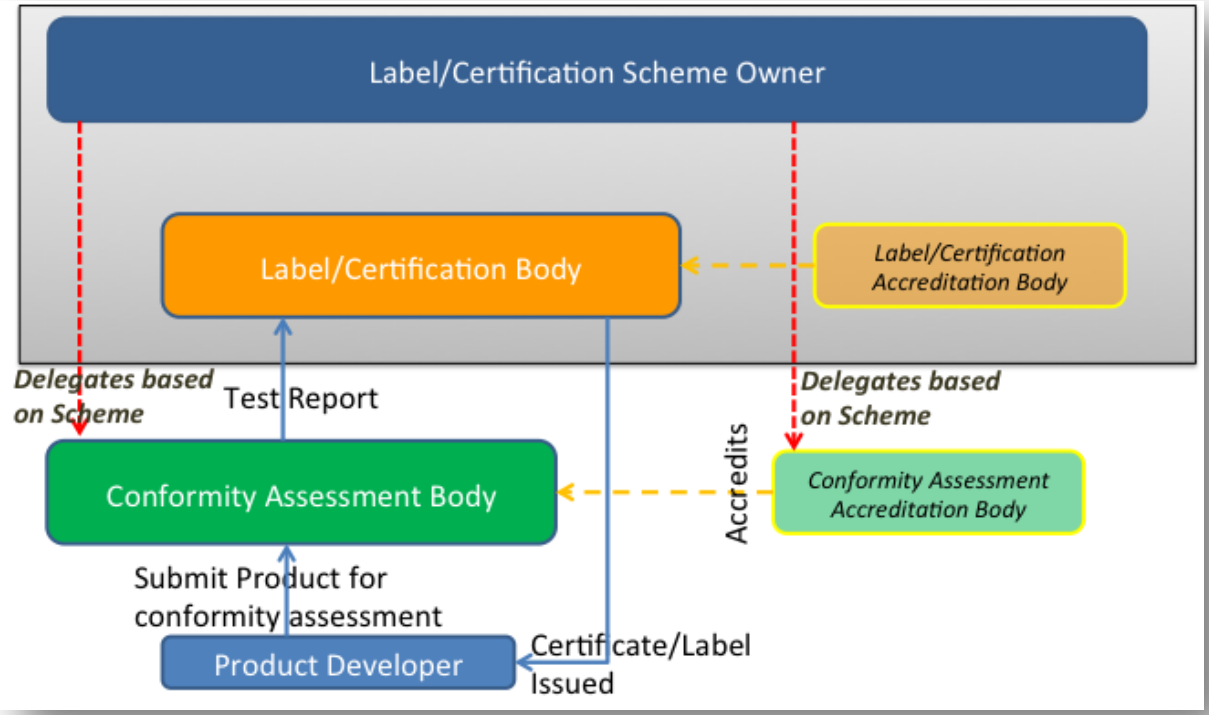

Figure 3: Implementation Model-1

4.6.2 Implementation of the model-2

In this implementation model, all the roles are playing by one and only one entity. The entity defines the scheme (specifies the requirements, organizes the testing process, grants the seal).

This model is often implemented by national/regional competence centre, generally under the supervision of a dedicated national authority. The issued certificate, label or seal does not aim to have international recognitions: its goal is to fulfil the country legal and regulatory framework.

In the example given in annex II, the competence centre ASIP Santé plays the three roles:

- Scheme owner: ASIP Santé specifies the interoperability transactions used to exchange medical data with the DMP, defines the testing processes, and defines the process to issue the seal;
- Label/certification body: a dedicated committee within ASIP Santé validates the testing report and all other requirements (financial, organisational, …) before issuing the seal;
- Conformity Assessment Body: ASIP Santé defines the test plan and test methods, executes the testing process, reports technically to the committee in charge of issuing the homologation.

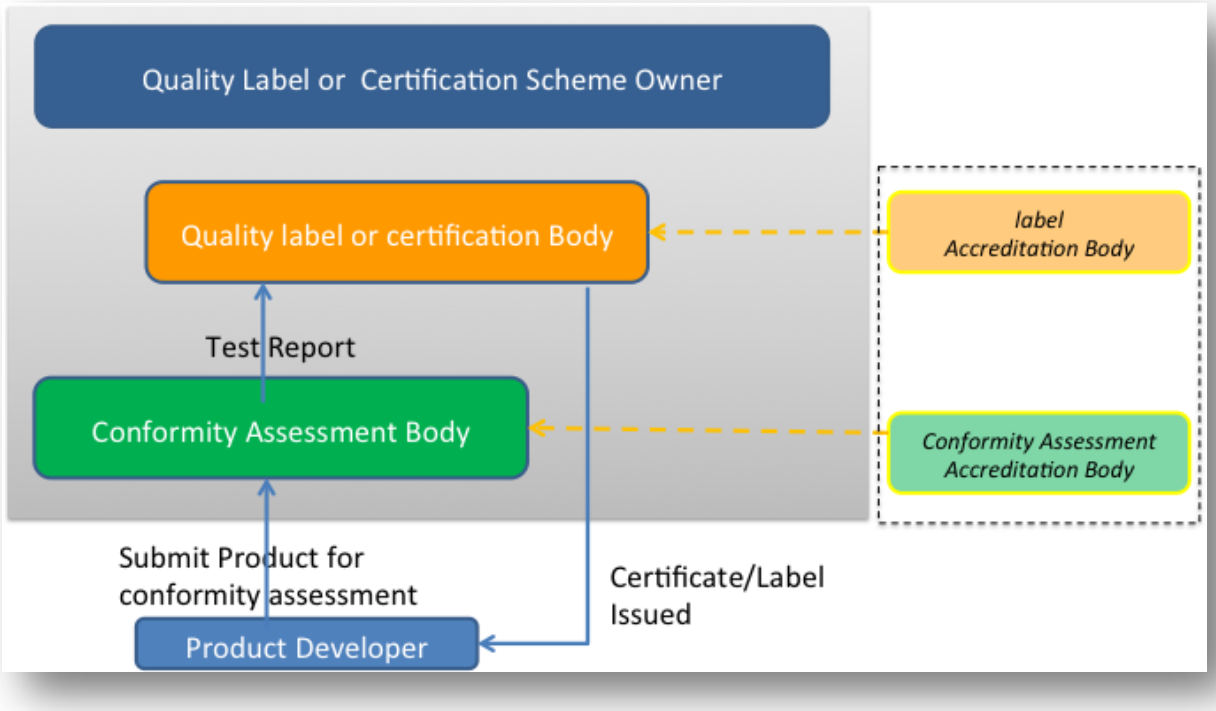

Figure 4: Implementation Model-2

Many other variants exist. Note that QL and C use same processes and their distinction is based on the level of the recognition of the involved bodies vis-à-vis the accreditation bodies (see schema 4). When the certification body and the Conformity Assessment Bodies are accredited, they are able to grant certificates and these certificates can be recognized widely when the accredited bodies are also part of the EA network (see section 4.4).

When an organisation is the owner scheme e.g. it defines the requirements (specifications) that have to meet products or services and wants to specify a process of Quality Label or Certification, it has to determine the level of the recognition of the bodies involved in the process and should always analysed carefully impacts (costs, complexity, implementation, rigor, neutrality and integrity) according to its **objectives**. Indeed, the impact is quite different if it is for a regulatory purpose or for the development of a market.

In the case of eHealth, it is expected to develop products and services using international standards and profiles. It is also expected that the certification processes shall increase the trust of the products within the European market for the benefit of the patient and his/her safety.

To facilitate the selection by a decision maker, recommendations and guidelines are presented further in this document.

5 Recommendations from previous research studies

During the last three years, two European FP7 projects analysed the state of art of the quality label and certification and provided recommendations and roadmap for the development of the interoperability in eHealth.

HITCH (Healthcare Interoperability Testing and Conformance harmonisation) is a European project from FP7 program and **EHR-Q^{TN}** is a FP7 European Thematic Network. The two projects were running at the same time during the years 2010-2011. The first project focused some of its activities on Interoperability labelling and certification and the second on quality labelling of EHRs.

Both projects described the certification and labelling environment, its principles and concepts, departing from a different application domain. HITCH focused on data exchange and interoperability while EHR-Q^{TN} focused on EHR functional quality assessment.

Both projects highlighted the importance of Quality and Quality Assessing eHealth products not only for quality of care but also for market accessibility of the health information products. They both resulted in a set of recommendations and a roadmap for implementation of these recommendations.

5.1 HITCH project

The HITCH project (Healthcare Interoperability Testing and Conformance Harmonisation) is an European project that provides recommendations and a proposed roadmap for achieving sustainable and effective deployment of the testing and certification/labelling processes to enable interoperability in health information exchange within and between European member states. One of the recommendations is the “Establishment a two-level Labelling and Certification processes (European Level and National/project Level)”, one of the main objectives of the Antilope project. This recommendation is related to the “preservation of flexibility across the proposed Labelling and Certification schemes” which is another recommendation of the project.

Various approaches of labelling and certification schemes were analysed in the HITCH project in terms of benefits and limitations. It was concluded that the choice of one or another depends of the

- The maturity of the market;
- The cost of product development and administrative processes;
- The scale of diffusion of interoperability and the emergence of new interoperability profiles;
- The legal framework relating to patient safety and security of exchanged or shared medical data.

The two level QL and C concept was defined for encouraging the deployment of the eHealth Interoperability Framework and the related recognized profiles and standards in the countries or regions.

It was also proposed to develop European ecosystem by building and evolving the European IHE testing process. By promoting European recognized standards and profiles, test plans and test tools, this will ensure that harmonisation at the European and national/regional levels.

The roadmap that was described in the HITCH project, proposes refinement of the eEIF and the labelling/certification process in 2012-2013.

5.2 EHR-Q^{TN}

One of the work packages of the project was dedicated to propose a state of art of the national certification processes as well as of the EuroRec quality labelling procedures and scenarios. Even if this study is not oriented towards interoperability assessment but focuses in procedures on testing functions of the EHR systems including data exchanges, it gives a clear overview on the quality labelling and certification process and clarifies concepts, definition and deployment as well as such a process.

One of the conclusions of the study was to propose generic criteria that all quality labelling or certification initiatives must follow:

- Independence, encompassing discretion and confidentiality, impartiality, openness and a clear and distinct role of each of the stakeholders involved in the process;
- High quality documentation of the initial set of criteria, of the evaluation rules and of the testing results;
- The involvement of all stakeholders in defining priorities and feasible goals, considering national and regional variation;
- Rules regarding validity and use of the Quality Label or Certificate and possible measure against misuse.

The EHR-Q^{TN} project heavily focused on structuring the Quality Labelling and Certification process based on and ruled by international standards, distinguishing

- Accreditation Body, mandatory member of the IAF – International Accreditation Form and regulated by law, based on **ISO/IEC 17011** and accrediting the Certification Bodies;
- Certification Body, organising quality labelling and certification processes and according either quality labels or certificates, compliant to **ISO/IEC 17020**. Certificates are only granted by accredited certification bodies;
- Conformity Assessment Bodies, recognised and/or contracted by the Certification Bodies to perform the effective testing of products and services in a way compliant to **ISO/IEC 17010**.

The EHR-Q^{TN} project issued a number of recommendations addressing legal and regulatory framework, involvement of the different stakeholders, the technical framework as well as the quality labelling and certification process as such.

The EHR-Q^{TN} project highlighted the important role of the European and National Authorities initiating the process, based on incentives and a third party quality assessment.

Quality labelling and certification sustainability was also discussed. The starting point for any quality assessment or certification depends of the decision to go for it. The business model depends on who takes the decision (it means who is the owner of the assessment scheme).

Sustainability of quality labelling and certification activities is possible in the medium long term (3 to 5 years) depending on the political, social and economical pressures as well as on the availabilities of the resources from industry, buyers or authorities.

5.3 In Synthesis

Distinction between quality label and certification is based only on the qualification of the body that provides the certificate or seal. QL and C uses the same processes, functions and roles as described in section 4.

Sustainability and consistency are today the most important criteria that countries are looking for in order to develop a common European market with better quality and a large amount of solutions. The harmonization of the QL or C processes that were recommended in both the HITCH and the EHR-Q^{TN} projects is one of the answers of the user or authority expectations.

6 Harmonisation of the Quality label or certification processes in Europe

This section describes a proposed testing and QL or C processes that support the development of the interoperability at the European level for the common interoperability requirements and at the level of each European country or region specific or extended requirements. This model shall support flexibility and policy setting by the member states.

Indeed a two level quality label or certification was initially proposed by the HITCH project. It is further refined by Antilope based on experience gained since the completion of the HITCH Project.

6.1 Harmonisation of the QL or C processes and Conformance Assessment process.

The following schema describes the process:

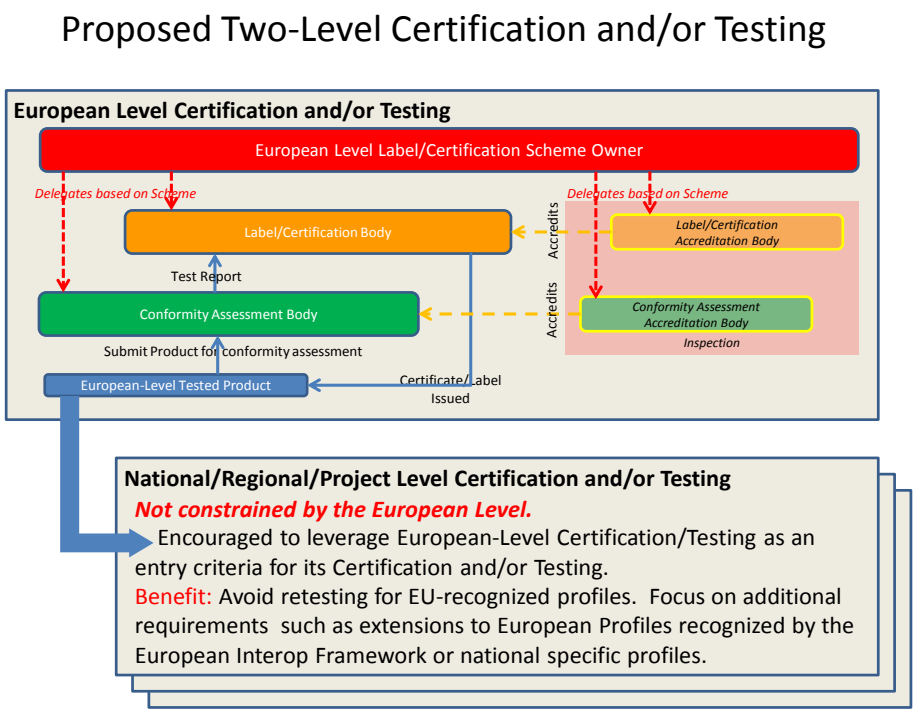

Figure 5: Proposed QL or C processes harmonisation in Europe

6.1.1 European testing processes

At the European level, it is proposed to establish:

- A Conformance Assessment Scheme related to and associated with the European eHealth Interoperability Framework (eEIF) that covers the point 2 & 3 below;

- A Conformance Assessment process that allows any entity to tests the capabilities of its products and related services in any accredited testing laboratory against the requirements of a set of standards and profiles that are recognized and listed in the European eHealth Interoperability Framework;
- In order to offer a choice of testing laboratories, while ensuring consistent testing results, the European Assessment Scheme should require: (1) an ISO/IEC 17025 accreditation for these testing laboratories, (the quality management system defined by Antilope (D2.1 and D2.2) can be a support for the preparation of the accreditation and (2) the establishment of the conformity assessment scheme will include requirements, test methods and test tools that should be used by all testing laboratories;
- Suitable QL or C processes associated with this Accredited Conformance Assessment process, to provide the successfully tested products to display the corresponding trusted label/certificate;
- In order to ensure a good level of trust for the certificate issued by the Certification Body that reviews test reports provided by the Conformance Assessment Bodies, the corresponding certificate, a customisation of the ISO/IEC 17065 appropriate to the eHealth market should be applied (For an example, see the IHE Conformity assessment[1] at http://www.ihe.net/Conformity_Assessment.aspx).

6.1.2 National/Regional/Project Level quality label/certification and/or Testing

At the national or regional level, it is proposed to

- Ensure that the European-level of testing or QL or C may be used as entry criteria, if the national/region/project has elected to leverage one or more of the eEIF recognized standards and profiles. This recommendation avoids duplicative testing for each project across Europe thus fostering consistency and efficiency;
- Allow maximum flexibility so that Certification and/or Testing may be nationally or regionally organised, or any approach may be considered (e.g. Model-1, Model-2, or a more elaborate model);
- A simple process should be included to allow, regional/national choices of profiles not yet recognized at the European level, or the submission of the needs for new use cases and/or new additional standards and profiles in the eEIF, to further extend its coverage (See Section 5.1.2 for a detailed discussion of this feeder/synchronization process.

Examples are given further in the text.

[1] The IHE Conformity Assessment Scheme is a transnational Scheme and consists on two volumes:

- IHE-CAS-1 defines the necessary processes for establishing and managing a Conformity Assessment Program
- IHE-CAS-2 defnes the standardized test methods for assessing conformity to individual profiles.

6.2 Synchronize and harmonize the European Level testing or QL or C processes

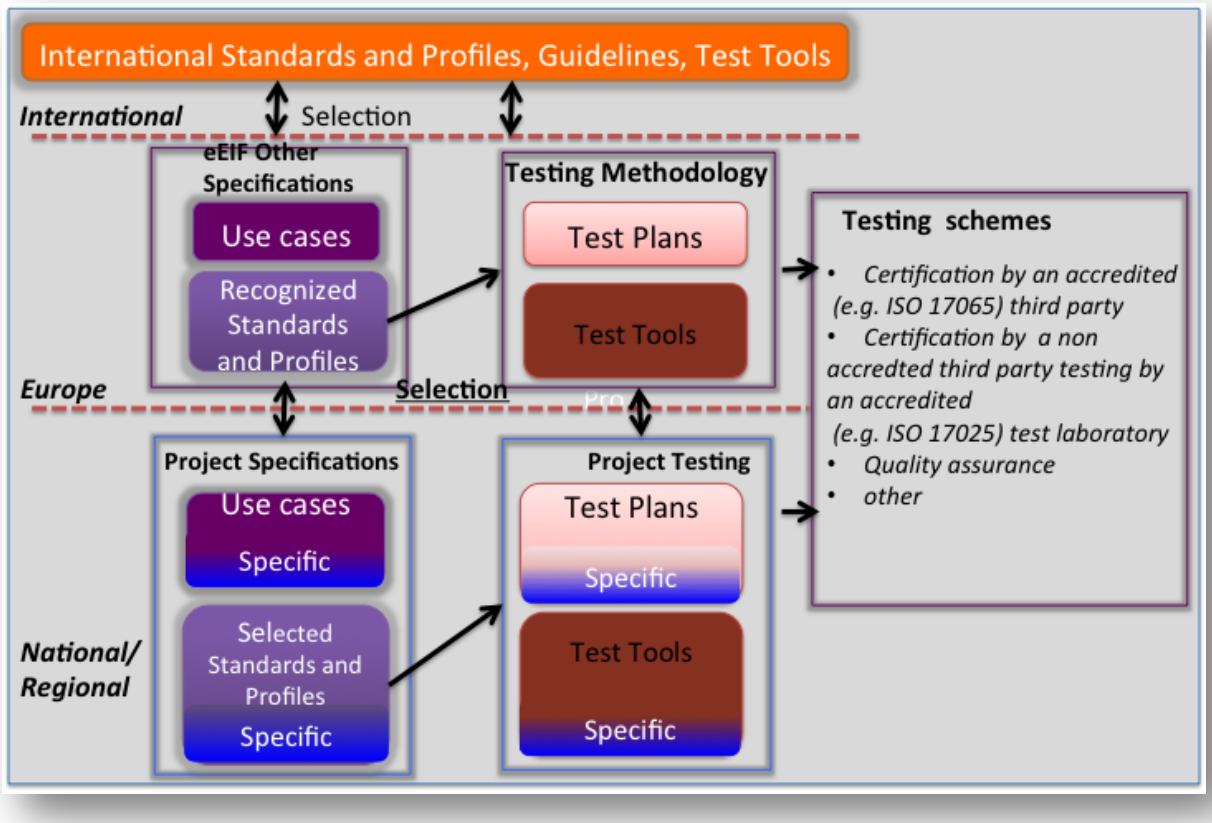

Figure 6: Quality label or Certification processes

To assure the consistency and sustainability between the three levels (International/Europe and national/regional), the following process should be in place:

- The international level provides international Standards and Profiles, guidelines, and tools validated by consensus. As a Member of the international committees of standard and profiles bodies, Europe and its representatives originating from European countries, healthcare providers and suppliers are encouraging to contribute heavily to the specification effort;
- At the European level, experts from SDOs, consortia, competence centres, users … define the eHealth European interoperability Framework (see WP1) or any other specifications that are validated at the European level and ready to be adopted. This framework describes a set of use cases and selected Standards and Profiles including the suitable semantic terminologies. Profiles are directly selected from the existing well-implemented international profiles. A testing platform such as the IHE Connectathon is the place where the implemented use cases are tested in order to verify the robustness of the specifications of the services and profiles. A Connectathon is the first step of the quality process of this implementation. International test tools are used or new test tools are developed

responding to the test plans that are provided by the international or European level (see the list of test tools described in the Antilope deliverable D3.1 as an example);

- The national/regional level develops national/regional projects that embed European services and profiles in their specifications. The project describes the information architecture and the software implementations. Specific or additional requirements are then testing within the QL or C program defined at this level.

To obtain the recognition of the certificate or label delivered within a national/regional program, and to develop a single European market, guidance to specify the additional requirements is the following:

- Use as basic requirements, the eHealth EIF that provides most of the technical services for building the national/regional architecture for similar use cases;
- Reuse and extend test tools and test methods from the European/international level to the specificities of the country/region (regulation, new needs, …);
- Select testing laboratories or inspection bodies certified by accreditation bodies, for a better recognition at the European level.

The acceptance of the seal by the end-user is based on the level of trust of the testing processes. Transparency and openness are the important criteria for a better recognition at the European level.

6.3 Governance

European governance shall be set up for the sustainability of all interoperability assets available today. It shall take into account at least:

- The maintenance, evolution and validation processes of the validated eHealth EIF resulting of the Antilope's project;
- The maintenance, evolution processes of the validated test plan and the list of the related test tools;
- The new development of the test tools corresponding to the life cycle of the extension of the eEIF with new use cases;
- The life cycle of the testing session that assures the first level of Quality label, for example a yearly testing session in parallel with IHE Connectathon;
- The creation and maintenance of the European certification scheme;
- Education and promotion at the European and national/regional levels.

The following schema gives an overview of the interoperability harmonisation and its European organisation.

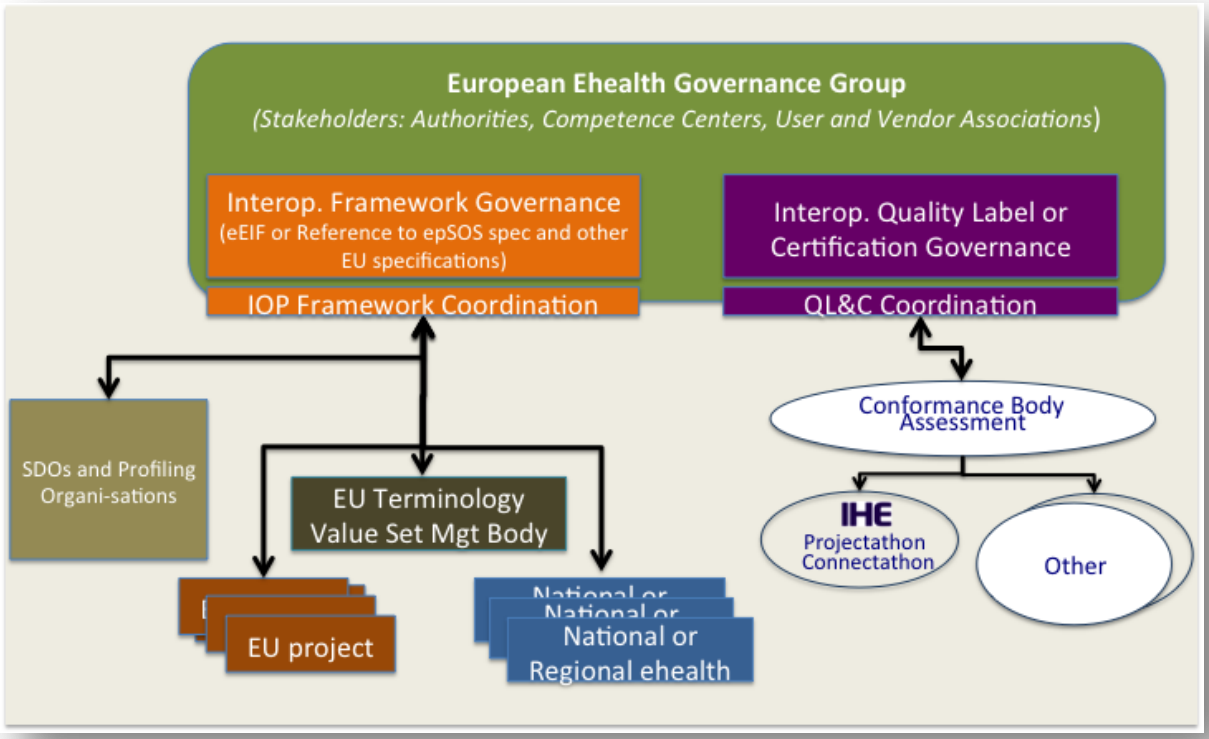

Figure 7: Proposed organisation of the governance

This proposed governance shows the necessary creation of a group of voluntary contributors from stakeholders (nations, industry, competence centers, patient, users and any other interested parties).

Three main activities and their main tasks (not exhaustive) shall be created:

- Interoperability Framework activity with the following main tasks:
  - Selection and maintenance of the specifications and the eEIF;
  - Establishment of the consensus;
  - Coordination with other activities;
- Interoperability QL or C activity:
  - Specification of the European testing and certification scheme;
  - Delegation to the testing validation to accredited testing laboratories;
  - Coordination with other activities;
- Quality Label or Certification activity: (not represented in the schema, see model-1 and ISO/IEC 17065))
  - Registration of the candidates for assessment;
  - Validation of the testing reports provided by the testing laboratories;
  - Publication of the results of testing;
  - Management of the process complains;

- Accredited Conformance Assessment activity (see ISO /IEC 17025):
    - Registration of the candidate systems and their configurations;
    - Organization the testing session and validation the technical results;
    - Report to the scheme owner or to the QL or C certification body if any.

To start the implementation, the model-1 should be selected. When the QL or C is well established, the model should be updated and reorganised by splitting the different roles within the recommended bodies in order to develop and increase the quality of products in eHealth.

At the country level, national/regional program, healthcare providers are encouraged to reuse materials and deliverables (e.g. European scheme program, test plans and test cases and test scripts, test tools, template report,…) for their own purposes. They will organize their own QL or C processes taken into account the European seal when it is in place e.g. their scheme program will specify only what it is specific for them. They will complete the test plan and tests requirements for their own extensions. By making their extensions public and providing their test methods and test tools on open licenses, they will encourage other country to reuse all or part of their own extensions. New European projects in eHealth, dedicated to innovation and development of new solutions and products are also encouraged to reuse all the existing materials (eEIF, test methods,…) for their own uses.

The new European project called EXPAND is starting to organize such a governance. The aim of the project is to maintain and deploy the already existing assets and act as a catalyst for real operational use by Member States. The first assets that are taken into account are epSOS assets that include specifications, openNCP development, terminology and configuration servers, test methods and testing session. These “pillars” called maintenance shops are all under a supervision of a competence organisation and coordinate directly by EXPAND for maintaining consistency. The eHealth Network_subgroup (eHN-SG) created early in 2014 with the Member States wanting to continue the epSOS pilots, is a subgroup of eHN and has the responsibility to organize the transition phase previously of the CEF (Connecting Europe Facility).

In order term, EXPAND is defining and testing a governance process, first step of the governance described above.

6.4 Examples

6.4.1 epSOS project

epSOS is an European Project that the goal is to demonstrate cross-border interoperability between eHealth record systems in Europe by exchanging Patient Summary and ePrescription document for a patient travelling in Europe.

The process is described in detail in annex I.

The specifications of the services are available on the www.epSOS.eu . Some of the epSOS use cases are today part of the Health European Interoperability Framework (eEIF).

The testing strategy is deeply described with four phases. The testing phase itself was delegated to IHE-Europe that develops test methods and test tools and organized the two categories of test sessions: face to face meetings (projectathon) and virtual sessions (Pre Pilot testing). IHE-Europe reports the results of the tests to the epSOS project Steering committee that the role is to validate the results for each nation or participant. The implementation model corresponds to the **model- 1**.

The question of the sustainability is still open today. A governance must be defined in order to maintain all the epSOS assets as well as the eEIF (see section 6.1.3). The new project called EXPAND is starting to take care on them (see 6.3).

6.4.2 The French QL process called "DMP-compatibility homologation"

The process called "DMP-compatibility homologation" is described in detail in the eppendix B. The goal of the « DMP-compatibility homologation » is to validate the capability of the software to interact consistently with the DMP, in conformance with the technical specification of the DMP interfaces. The DMP is a national PHR in France. The DMP collects the medical reports provided by Healthcare Professionals (GPs, radiologists, ….) and hospitals.

The specification describes the external interfaces of the DMP system to be used by any software. This specification is available at

(http://esante.gouv.fr/sites/default/files/DMP1_LPS_TEC_DSFT_des_interfaces_LPS_20120724_v1.0.zip). The specification is based on a set of IHE profiles: XDS, PDQ, DSG, ATNA, CT, XD-LAB, APSR, and the PCC content profiles. The specification also leverages a set of HL7 messages for the administrative management of the patient record.

The process carried by ASIP santé is a labeling process which ensures that each labeled product is capable to establish correct and consistent transactions with the DMP system. ASIP Santé was founded in 2009 by the French authorities. This national agency is under the supervision of the Ministry of Health and its main missions are:

- Foster the development of shared systems in the fields of health and social care, for a better coordination and quality of care;
- Build and run national ehealth services (e.g the DMP, the national PKI for healthcare providers, secured health messaging services…;
- Define, promote and homologate profiles of standards contributing to interoperability, security and usage of healthcare IT and eHealth.

The national agency ASIP Santé provides specifications, develops test tools and test plan, organises the testing sessions, reports and validates the results. ASIP Santé is neither a certified body nor a accredited laboratory/inspection body. The implementation model is the **model- 2.**

However ASIP Santé provides a guarantee of a certain level of quality of the implementation of the profiles and standards by the products, related to the DMP architecture.

The coverage of the eHealth European Framework is quite fulfilled regarding the use cases. The products homologated as “DMP-compatibible” are likely fitting easiy in other European projects.

6.4.3 The Belgian Certification of Health Information Systems

Belgium has since 1999 a running system of quality labeling and certification of health information systems, focused on all aspects of managing patient data by different types of healthcare professionals: General Practitioners, Physiotherapists and Homecare Nurses. The GP systems are actually being tested for the 4th time, the nursing systems for the 3rd time and the physiotherapist systems for the 2nd time.

The initiative is coming from the Ministry of Health, that defines the functional as well as the interoperability requirements to be met. The Ministry, holder of the specifications, identified a public not-for-profit organisation, the eHealth platform, as "certification body". This is based on a law. This means that we have to consider the eHealth platform[2] as a partner in a certification process (https://www.ehealth.fgov.be/fr/a-propos-de-ehealth/mission/la-plate-forme-ehealth).

The actual testing of compliance to the requirements is done by a subcontractor, a testing laboratory- CAB (Conformity Assessment Body) which reports to the eHealth platform.

The certification is an "incentive based" initiative, each user of a certified being granted an annual subvention.

The data exchange or interoperability aspect is based on a national standard (Kmehr: Kind Messaging for Electronic Healthcare Records) and encompasses patient summaries, ePrescription, physiotherapy prescription and reports, nursing prescriptions and reports, lab results, imaging reports, insurability data exchange, authorisation requests and grants for medicinal products and special care, imaging reports, discharge letters, referrals …

The KMEHR standard is based on earlier versions of HL7, maintained originally by the Ministry of Health, now by the eHealth platform. For more information see https://www.ehealth.fgov.be/standards/kmehr/. Today a working group is working on the specification of laboratories and patient reports in HL7 CDA standard.

The health authorities pay also attention to the semantic interoperability of the systems used, providing to the General Practitioners a multi-lingual thesaurus with code mapping to ICPC2 and ICD-10. The healthcare authorities are actually investing in a controlled multi-lingual vocabulary enabling inter-professional exchange and understanding of clinical content based on SNOMED/CT with a validated mapping to other major coding systems: ICD-9-CM, ICD-10, ICPC.

The eHealth Platform and sick-funds are organising MINI-Lab to validate application on their ability to be interoperable with national services: national locator services of clinical documents (imaging, lab, discharge), national patient summary repositories, e-Prescription services etc…

[2] eHealth platform is a national public centre of competence. The missions are to promote and support services and electronic information exchange for all Belgium Healthcare Professionals and guarantees data protection and security of the information under the medical secret.

This implementation model is related to the model-1. The scheme owner and the body whose provides the seal, is the eHealth platform and the testing laboratory is performed by a third party (not named here).

7 Recommendations and guidelines

The recommendations and guidelines provide support to any national/regional organisation in the definition of its QL or C processes. The definition includes four steps described below.

7.1 Step 1. Define the needs on Quality Label or Certification

This result of this step is to provide the Conformance Assessment Scheme Program (CASP). This scheme defines the organisation of the QL or C processes, the governance and the involved organisations such as Conformance Assessment Bodies, the scope of the conformance assessment in term of interoperability requirements.

This scheme is partly based on the European Conformance Assessment Scheme (by reusing materials and deliverables) and partly based on the specificities of the project(s) where the products will be assessed. The owner of the national/regional CASP will therefore benefit on the European framework and by doing this, he will participate to the harmonization effort in Europe.

The main activities are listed in the figure 7. The main output of this step is the *Conformance Assessment Program Scheme* and its governance.

7.2 Step 2. Setting up the quality label or certification

The objective of this step is to organise the QL or C in the country or region. Organisations and/or bodies are nominated or selected in order to implement the QL or C processes. Test plans and test methods including testing tools are specified and selected and the new tools will be specified for a tender (if needed). All the procedures are defined and implemented.

The main outputs of this step are the selection of the organisations or companies that will develop the needed new test methods, and the testing laboratory (ies).

7.3 Step 3. Execute and report

The testing process is performed, starting by the selection of candidates (companies, institutions or any other organisations developing solutions enable to test against specifications, standards or profiles included in the scope of the CAPS. Their test results are validated and the main output of the step is the publication of the passed solutions.

7.4 Step 4. Assess and Communicate

The assessment of the process has the objective to give feedback that helps for the improvement of the QL or C processes. Two main objectives of the communication:

- Publication of the list of products successfully tested;
- Promotion of the extension e.g. new use cases, test methods at the European level and their availibilities for other European countries or regions.

Sharing experience and results are the main outputs.

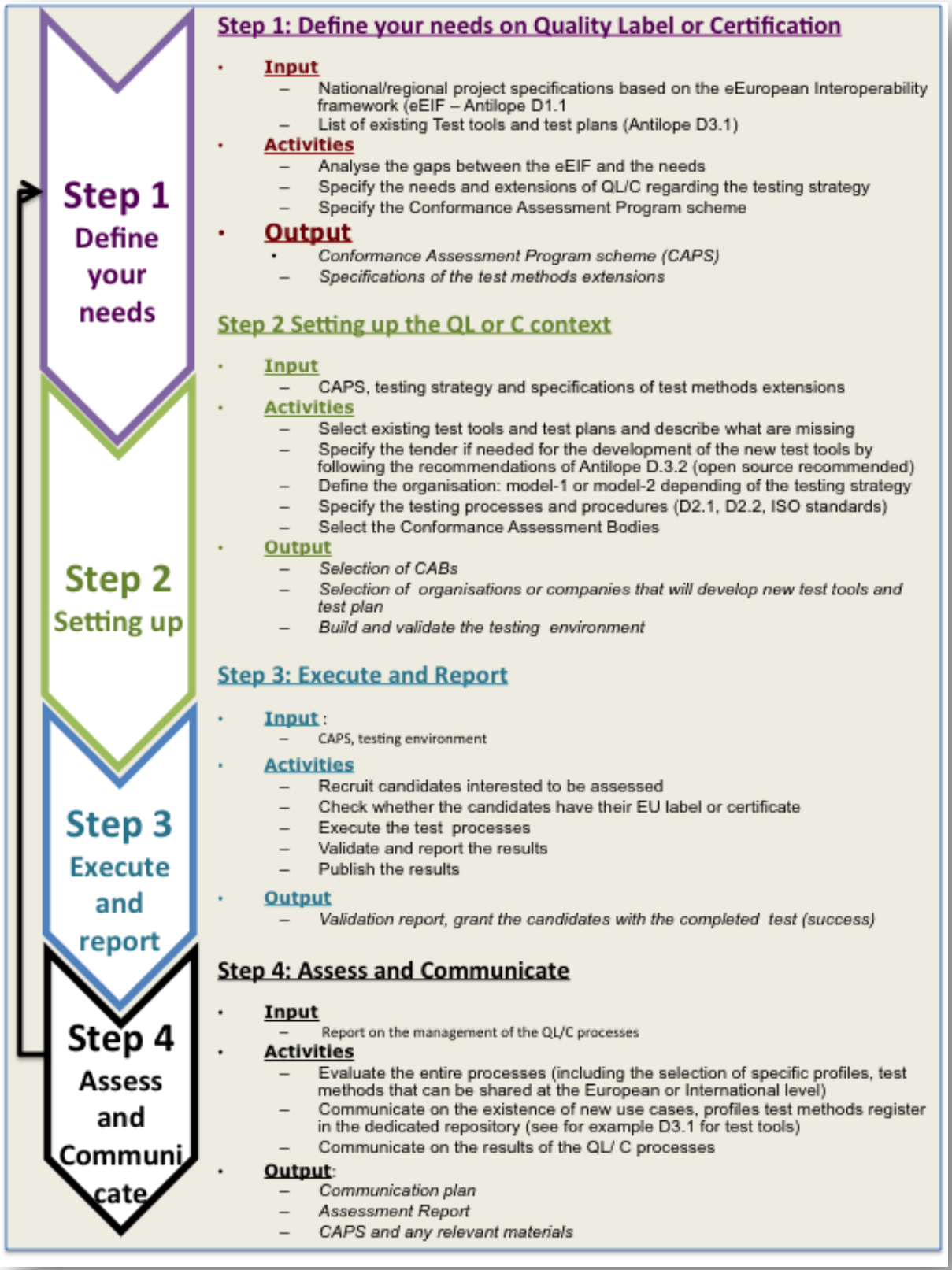

Figure 8: Four steps for deploying a QL or C processes

In the next schema, the link between each step and the Antilope deliverables is presented to facilitate the use of the documents when one wants to define its QL and C processes.

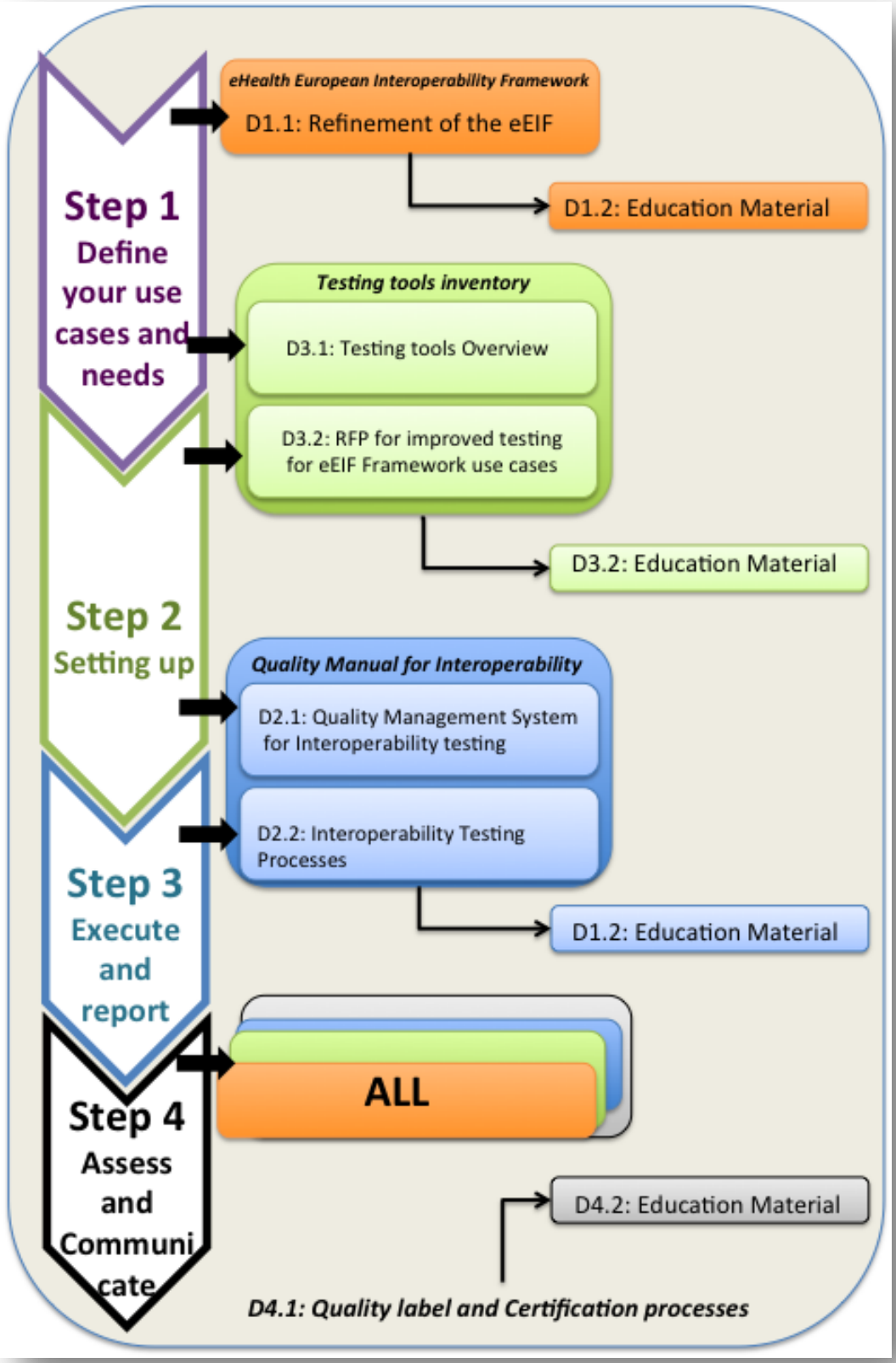

Figure 9: The four steps and links with Antilope deliverables

8 Conclusion

The following key messages synthetizes how to increase the development of the eHealth interoperability in Europe in order to allow citizens to move in Europe with the expectation of the same care as they have at home. Connecting the national healthcare systems in a secure way authorizes any citizen or patient to travel comfortable knowing that his/her EHRs are available everywhere.

The key messages are

- *Stimulate the creation of European market based on the evolving European eHealth Interoperability framework associated with a Modular European Confromance assessment Scheme*
- *Harmonisation of the QL or C processes in Europe and among countries and regions*
- *National or regional interoperability testing processes maintain their flexibility while being harmonised with a modular European Conformance assessment scheme*
- *European QL or C processes still allow flexible national and regional approaches*

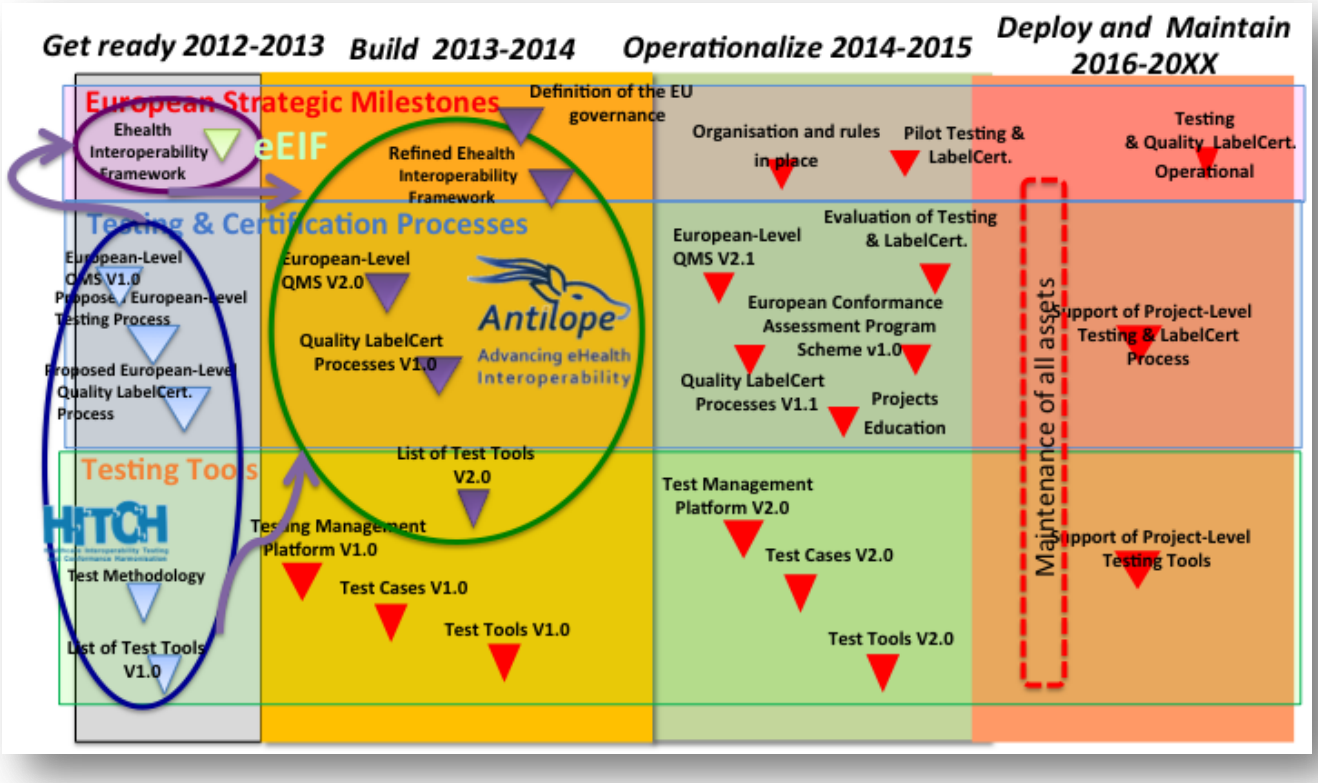

Figure 10: HITCH roadmap (revised)

This revised roadmap shows that we are in the transition phase called “operationalize in the schema” starting by organising and maintaining all the already existing assets and their operational pilots, governance and framework before the CEF starting in 2016. EXPAND and other EU projects are all working to prepare the deployment of the eHealth interoperability in Europe. This roadmap is in line with the expectation.

References

Table 5: List of ISO standards

Standard	Abstract
ISO 13485 **Medical devices - Quality Management Systems – requirements for regulatory purposes**	This standard specifies requirements for a QMS where an organization needs to demonstrate its ability to provide medical devices and related services that meet customer and regulatory requirements
ISO 17000 **Conformity Assessment – Vocabulary and general principles**	ISO/IEC 17000 specifies assessment terminology and provides a self-contained vocabulary more readily applicable within the ISO/IEC 17000 series
ISO 17011 **Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies**	ISO/IEC 17011:2004 specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs). It is also appropriate as a requirements document for the peer evaluation process for mutual recognition arrangements between accreditation bodies. Accreditation bodies operating in accordance with ISO/IEC 17011:2004 do not have to offer accreditation to all types of CABs. For the purposes of ISO/IEC 17011:2004, CABs are organizations providing the following conformity assessment services: testing, inspection, management system certification, personnel certification, product certification and, in the context of this document, calibration.
ISO 17020 **Conformity assessment - Requirements for the operation of various types of bodies performing inspection**	This International Standard requirement for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities. It applies to inspection bodies of type A, B or C, as defined in this International Standard, and it applies to any stage of inspection. NOTE: The stages of inspection include design stage, type examination, initial inspection, in-service inspection and surveillance.
ISO 17025 **General requirements for the competence of testing and calibration laboratories**	ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods. It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification. ISO/IEC 17025:2005 is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by ISO/IEC 17025:2005, such as sampling and the design/development of new methods, the requirements of those clauses do not apply. ISO/IEC 17025:2005 is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. ISO/IEC 17025:2005 is not intended to be used as the basis for certification of laboratories. Compliance with regulatory and safety requirements on the operation of laboratories is not covered by ISO/IEC 17025:2005.
ISO 17065: 2012	Specifies general requirements for third-party operating

Conformity assessment -- Requirements for bodies certifying products, processes and services	a product certification system. Replaces ISO/IEC Guide 40:1983

Appendix A: epSOS project

Objective of the epSOS Testing Strategy

epSOS is an European Project that the goal is to demonstrate cross-border interoperability between eHealth record systems in Europe by exchanging Patient Summary and ePrescription document for a patient travelling in Europe.

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

The service infrastructure will demonstrate the interoperability between two or more Electronic Health Record Systems, allowing the exchange of computer interpretable data and human understandable knowledge.

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

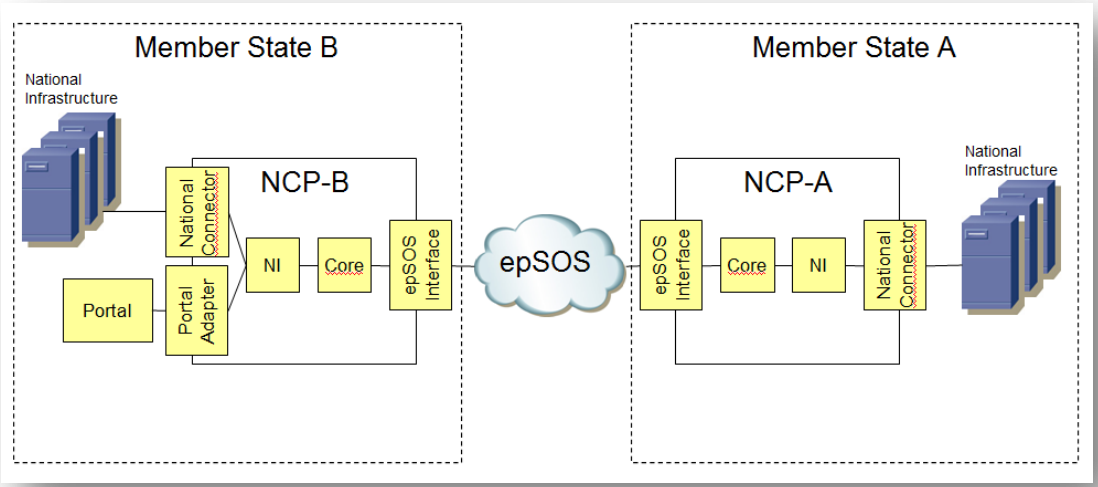

Figure 10: Basic Architecture of epSOS

In March 2012 epSOS project decided to create an openNCP platform. The architecture was slightly reshaped as follows.

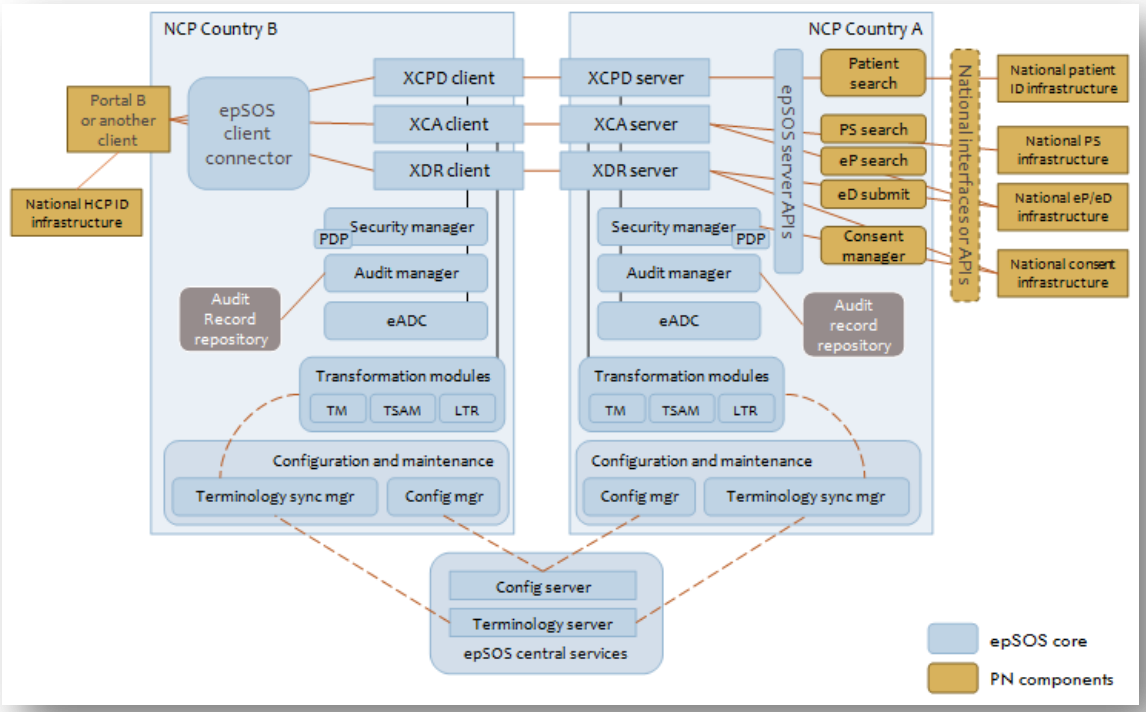

Figure 11 epSOS Building Blocks [Courtesy of OpenNCP]

The main blocks that are to be considered during epSOS test phases are as follows:

- NCP-A
- NCP-B
- Portal-B (Country-B Front-end Portal)

epSOS architecture is described in documents D.3.3.2, D.3.4.2, D.3.9.1, D.3.B.1. epSOS interoperability framework is stated in document D.3.3.3. all deliverables are located at http://www.epsos.eu/home/download-area/deliverables.html
information on epSOS openNCP is available at https://openncp.atlassian.net/wiki/dashboard.action?updatesSelectedTab=popularThe testing strategy focuses on cross border exchanges including the NCP (National Contact Point) to NCP, end to end functional testing, semantic and documentation validation, audit trail and security aspects.

The profiles and services that are described and tested are

- epSOS security - secure node
- epSOS security - Time Client
- epSOS security - Audit record repository
- epSOS Authentication
- epSOS identification service
- epSOS Patient Service
- epSOS Order Service
- epSOS Dospensation Service
- epSOS Patient Summary document
- epSOS Consent document
- epSOS ePrescription document

The testing strategy is based on the following phases related to the maturity of the system under test:

- Pre-Projectathon (Pre-Pat) where the participants test their systems against test validators and simulators;
- Projectathon where participants test their system during a face to face event in order to perform conformance and interoperability testing. The systems under testing (SUTs) could be a simulation of the national environment or the national system itself ;
- Projectathon on line: On line sessions based on Gazelle tests, to allow PNs to get approval to go to the PPT. It is also called Pre PPT
- Pre-Pilot Testing (PPT) for testing conformity and interoperability of real environments but with virtual data.

IHE Europe, as an epSOS Beneficiary, was assigned the task to define and develop the testing tools and simulators, given that the majority of profiles to be tested are existing IHE profiles
A clear process is available for a Nation who wants to join the community and to test their own environment.
Note: all the information is not publicly available. See the website: http://www.epSOS.eu

Certification Scheme

a/ type of certification

- *certification with a certified third party*
- *certification with third party*
- *quality assurance*
- *other*

Explain the roles of the organisations involved, their qualifications (accredited, certified,…), level of trust of the seal,…

The type of certification is based on quality assurance with a third party. epSOS project describes all the steps of the quality assurance procedure and plays the role of the scheme owner and delegates to IHE-Europe the role of the testing laboratory.
The level of trust is based on the quality of the specifications defined by epSOS and the tests including test plan and test tools realized by the IHE-Europe. Several lessons were learned during the project in term of quality improvement such as the stability of the specifications, their organizations and their impact on the testing process.

In epSOS WP3.9, WP3.10, WP4.3 in epSOS Phase 1 and WP3.C, KT1.4.10, WP4.C in Phase 2 (see www.epsos.eu) have defined several technical / semantic detailed participation criteria for the epSOS test phases. These are also known as Conformance Gates. There are three Conformance Gates, and they are incremental; i.e. each one is built upon the previous one, and further extends the previous. A participant has to pass Conformance Gate 0 (CG0) to be allowed to participate to a pre-PAT and PAT. CG0 criteria are as depicted in D.3.C.1. A participant has to pass Conformance Gate 1 (CG1) to be allowed to participate to a PPT-slot. CG1 criteria are also presented in D.3.C.1. A participant has to pass Conformance Gate 2 (CG2) to be allowed to enter into operation.

As noted in D.3.C.1, epSOS reuses concepts from ISO/IEC 9126 for product quality verification. The ISO/IEC 9126 Software engineering - Product Quality standard identifies three main viewpoints over which the evaluation should be performed, enabling a layered approach for quality improvement.

1. IQ verification and validation (V&V) “Internal quality” is technical and verifies the internal functional and non-functional aspect of the system.

2. EQ V&V "External Quality" is mostly technical, verifying functional and non-functional aspects of a system with a view to its external interfaces.

3. QI V&V "Quality in use" gives a non-technical, functional end-user perspective verifying business and end-to-end processes.

b/ Describe the certification process in place

The procedure is the following: (see D.3.9.2 and D.3.C.1)

Below, we briefly go over the test phases that are within the scope of epSOS:

- **Pre-Projectathon (pre-PAT):** Conformance testing to be allowed to go to the Projectathon, performed from the participant systems towards the simulators and validators provided by IHE-Europe. It is initiated by registration to Gazelle® Management tool for PAT, and continues until the PAT. IHE-Europe checks and validates pre-PAT tests latest 2 weeks before the PAT.
- **Projectathon (PAT):** IHE Connectathon like face-to-face event to perform conformance and interoperability testing. It also includes end-to-end functional testing involving health professionals (HPs). PAT allows to enter in the Pre-Pilot Testing.
    - **PAT Grace Period:** Immediately after the PAT, when they are back home the participants are allowed to complete unfinished test cases and provide logs remotely for 1 or 2 weeks.
- **Pre-Pilot Testing (PPT):** Conformance, interoperability and end-to-end functional testing with real national infrastructure and virtual data (Representative and Critical Test Data). Its goal is to ensure that there are no problems or issues with the setup and configuration of the pilot environment of a PN. The initiation of the PPT environment should immediately start after passing a PAT. PPT is a continuous process and the PNs need to operate their testing environments even after starting real operation.
    - **pre-PPT-slot:** For participation in a PPT-slot, the PNs have to provide evidence that they are ready for the PPT-slot through links to validation results in the test simulators and validators provided by Gazelle. Furthermore, they have to exchange PS and/or eP/eD documents with all possible counterpart PNs available in the PPT environment and the other PNs who will participate to the same PPT-slot.
    - **PPT-slot:** According to the needs and statuses of the PNs, two weeks long PPT-slots are organized a few times in a year for repeating all tests within the scope of pre-PAT and PAT (i.e. conformance, interoperability and end-to-end functional testing) with real national infrastructure and virtual data. PPT-slot is a conformance gate to go into real operation. It is a remote testing activity managed through Gazelle by IHE-Europe. Registration through Gazelle® Management tool is necessary as in the case of PAT.

It should be noted that, testing by the Participating Nations (PNs) is not be limited to these test phases. In addition to Component Unit Test (CUT), Component System Test (CST) and Component Integration Test (CIT) phases that are advised to the PNs, they are encouraged to use the simulators and validation services of IHE-Europe even during their development process. These simulators and validators are used normally during pre-PAT and PPT, but they are in fact available online almost 7/24.

The interactions among the epSOS test phases is depicted in the following figure.

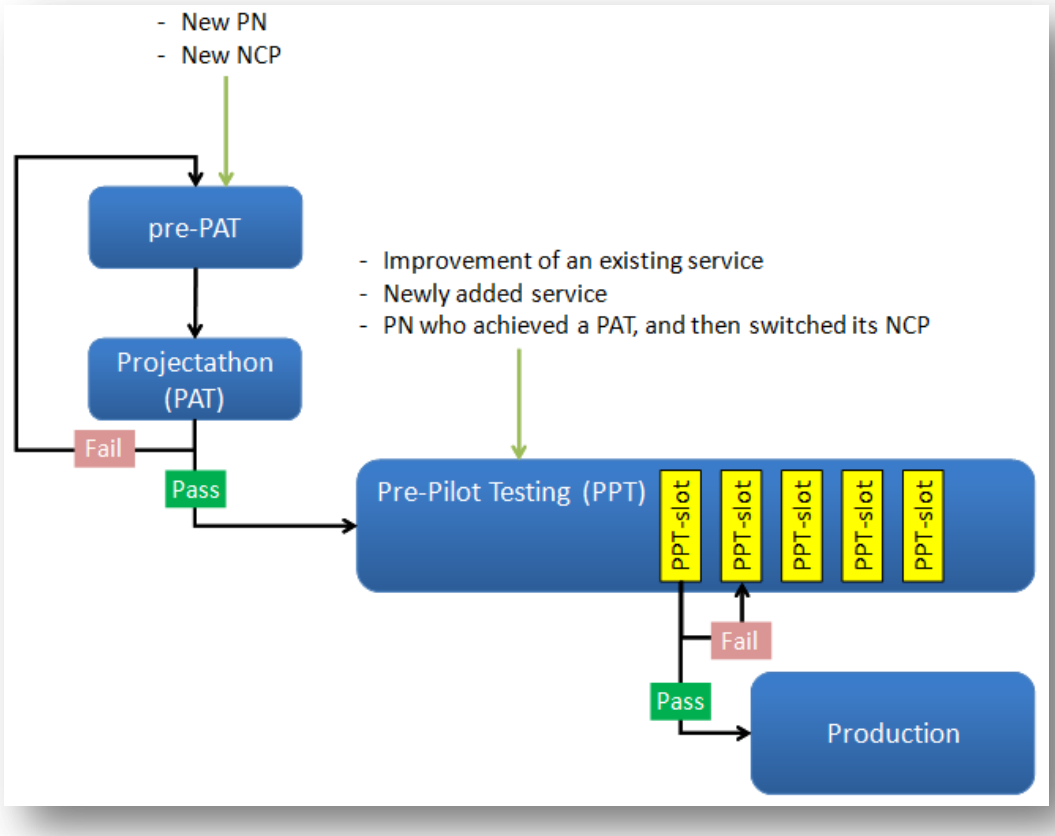

Figure 12: epSOS testing strategy

Pre pilot testing (or sometime noted as LSP testing) is key in epSOS to enter into operation. This is depicted below.

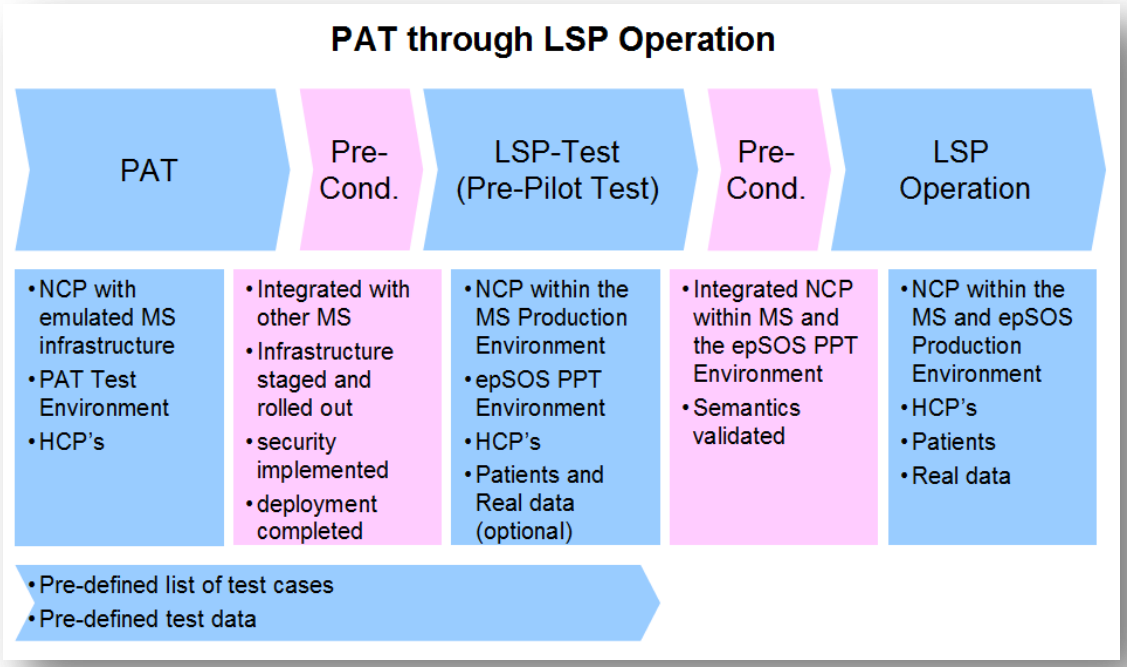

Figure 13: Projectathon and Pilots

While progressing from the end of Projectathon to PPT, it is necessary to ensure that selected tests executed during the Projectathon are repeated as a regression test to ensure that there have been no changes to the NCP (A & B) during the switch from the emulated national infrastructure to the real national infrastructure, and that the configuration is correct before allowing it to actively join the epSOS Infrastructure. For this reason, a PPT-slot is composed of all the test steps that are involved in pre-Projectathon and Projectathon.

In addition to the regression tests, other tests are required that focus on the clinical risk to patients. The goal of the tests are to verify that the medical information received by a HP in country B is semantically correct in relation to the information sent from country A, and presents no risk to the patient. This is known as **end-to-end functional testing**, and it is carried out with participation of HPs and/or semantic experts from the participating PNs. After doing several patient data exchanges, these experts are asked to fill in electronic questionnaires[3] that are prepared by epSOS and hosted by IHE-Europe. Then, these questionnaires are evaluated by the semantic experts of epSOS. end-to-end functional testing is done during both PAT and PPT. The details of end-to-end functional testing is presented in D3.10.1 Appendix 8 - epSOS end-to-end Functional Testing for Projectathon and Pre Pilot Testing: Guidelines for HPs and PNs.

All terminology epSOS is using is taken from the "ISTQB Glossary of Software Testing Terms" (http://www.istqb.org/downloads/glossary.html). Other standards mentioned in epSOS documentation are IEEE Std. 829-2008 Standard for Software and System Test Documentation and IEEE Std. 1012-2004 Standard for Software Verification and Validation.

[3] http://gazelle.ihe.net/content/epsos-cda-evaluation-form

c /Content/requirements

Use cases/Services/Profiles that are part or included in the eEIF
Level of coverage
Specific use cases/Services/Profiles

The services that are defined are (http://gazelle.ihe.net/node/135)

- epSOS security - secure node
- epSOS security - Time Client
- epSOS security - Audit record repository
- epSOS Authentication
- epSOS identification service
- epSOS Patient Service
- epSOS Order Service
- epSOS Consent Service
- epSOS Dispensation Service
- epSOS Patient Summary document
- epSOS Consent document
- epSOS ePrescription document
-

The services are based on several IHE profiles: IHE-XCA, IHE-XCPD, IHE-XDR, IHE-ATNA, IHE-CT… and HL7 V3 CDA and the security specifications use.
Coding systems are also used such as LOINC and its translations in European languages, SNOMED CT.
The table below presents the mapping between epSOS services and standards and profiles and the list of test tools that were used.

Table 6: epSOS services

epSOS Services	Standards/profiles	Test tools
epSOS security - secure node	VPN - IPSec (RFC 4301), TLS v1 (RFC 2246)	
Message format	WS- I basic Profile WS-I Basic security Profile WSDL 1.1 HTPP 1.1 SOAP 1.2 HTPP	(see below)
epSOS security - Time Client	IHE-CT (RFC1305)	
epSOS security - Audit record repository	IHE-ATNA	Audit Message content validation tool
epSOS Authentication	SAML v2	SAML assertion validation tool
epSOS identification service	IHE-XCPD	XCPD Initiating Gateway XCPD Responding Gateway

epSOS Patient Service	IHE-XCA	XCA Initiating Gateway XCA Responding Gateway
epSOS Order Service	IHE-XCA	XCA Initiating Gateway XCA Responding Gateway
epSOS Consent Service	IHE-BPPC	XDR simulator XDS tools
epSOS Dispensation Service	IHE-XDR	XDR simulator XDS tools
epSOS documents	CDA v3	EVS - Validator

d/ Methodology, tools, test criteria

The test environment is available on line. The PN registers directly the system to be tested and defines the configuration by describing the epSOS services that the system is able to support. After registration of the systems for a specific testing phase, The Gazelle Management tool prepares the worklist for each system by combining actors of different systems according the test plan.
The PN is now able to follow one of the phases described in the testing strategy by following the instructions of the test plan.
Testing tools and documentation are available publicly. Anyone who wants to test his product against the epSOS testing tool can manage it virtually.

Test criteria were defined during the epSOS specifications phase and were validated by the epSOS team. IHE-Europe uses these criteria to proceed the test validation and report to the epSOS project. The results are analysed and the final decision of the success of the tests is under the control of the project.

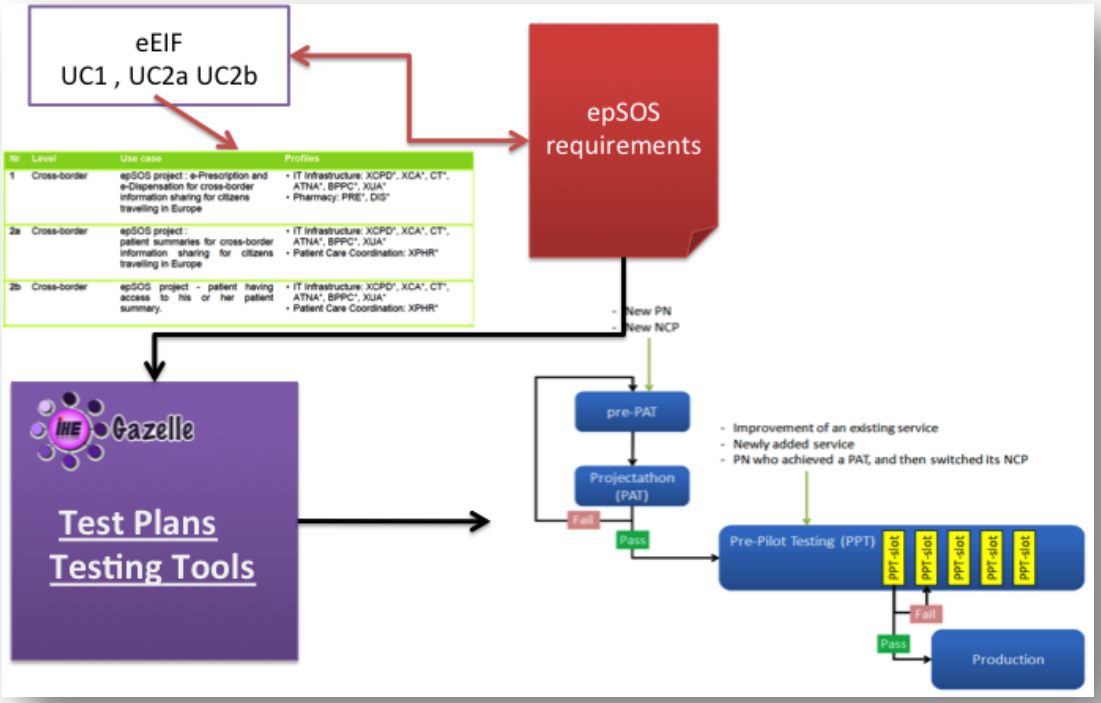

Figure 14: Test methodology

Four types of tools have been selected:

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

The Gazelle® Management Tool is already used for the IHE-Europe Connectathon. A specific instance of Gazelle® will be created for epSOS in order to manage the necessary testing processes and results. Its major functionalities include:

- Participant registration
- User management (participants and testers)
- SUT management

- Test management
- Simulator management
- Test engine
- Configuration management
- Samples sharing management
- Pre Projectathon test management (including the test grading)
- Connectathon test management (including the test grading)

For more information see: http://gazelle.ihe.net/GazelleMasterModel/. To access the Gazelle® Management Tool a login is required. It is possible over the following link to register oneself and obtain a login: http://gazelle.ihe.net/GMM/users/login/login.seam. Click on the hyperlink "Create an account" and complete the required fields selecting epSOS as the Company name.

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

Table 7: Simulators

Simulators	Purpose	Responsible Organisation
eDispensation Service	actors from IHE-XDR profile extended to be simulated	IHE
Patient Service	actors from IHE-XCA profile extended to be simulated	IHE
Identification Service	actors from IHE-XCPD profile extended to be simulated	IHE
Consent Service[4]	actors from IHE-XDR profile extended to be simulated	IHE

Simulators are accessible via URL's. The following example URL allows the user to access the XCPDINIT Simulator:

http://gazelle.ihe.net/XCPDINITSimulator/home.seam

[4] Is based on the BPPC Profile.

Table 8: External validation services

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

External Validators are accessible via URL's. The following example URL allows the user to access the CDA Validation:

http://gazelle.ihe.net/EVSClient/cda/validator.seam

Schematrons check both syntax and codes of the documents, verifying the adoption of the epSOS Coding Systems. The currently used Master Value Set Catalogue (MVC) can be accessed at URL:

http://gazelle.ihe.net/epSOS/codes/epSOS-pivot.xml

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

- Demographic data service will provide demographic data from each European country to the SUT's. The demographic data service is accessible via the following URL:
  http://gazelle.ihe.net/DDS/home.seam
- PKI server will provide certificate, CRL, and other services linked to a PKI environment. The PKI service is accessible via the following URL:
  http://sumo.irisa.fr/cgi-bin/pki/pub/pki?cmd=getStaticPage&name=homePage

Target

Which products and services are the target of the certification scheme ? Explain if the certification can be

recognized at the European level. How ?
What need to be improved in order to achieve the two level certification model
Benefit for the target

The target is the national contact point (NCP) and its link with the national infrastructure of each country. When the country passes all the test phases, the PN is able to exchange medical data with another country.

The epSOS use cases are described in the eEIF and the list of standards and profiles that support the use cases are also part of the eEIF. The testing process and its phases that were experimented demonstrates that the process is sustainable. It depends of maintenance of the epSOS specifications and the testing tools. Permanent organization is expected.

The process of quality assurance should be change on a certification process (see the schema). It will give a strong impact to the development of the eEIF in Europe.

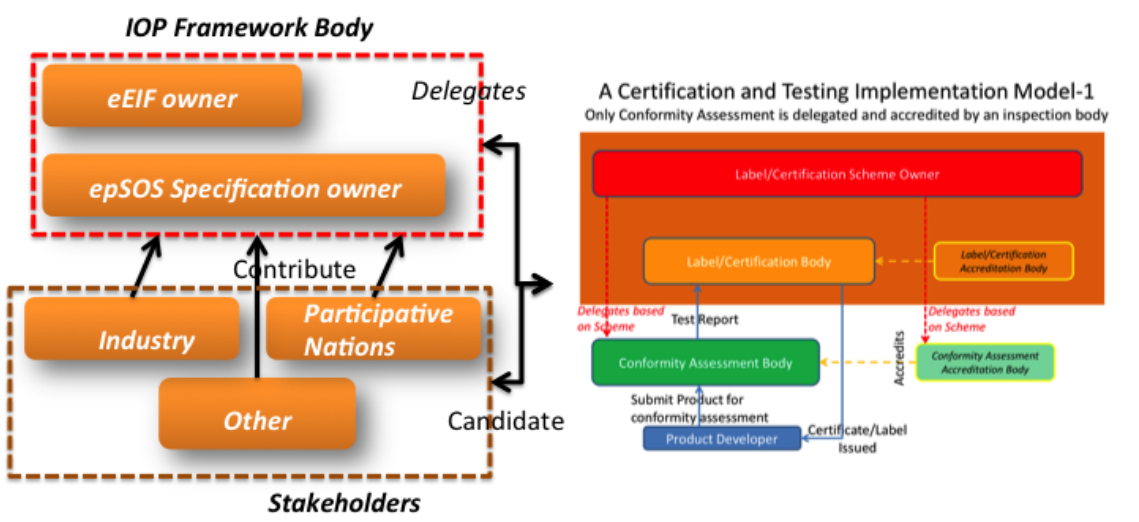

Figure 15 Governance and QL or C processes

The benefits for the PN are

- Recognition of their certification success
- Standard Harmonization between European countries
- less expenses by pooling testing effort
- Better quality and robustness of the specifications
- Open and standardized healthcare environment

Appendix B : French QL or C processes: DMP

Objective of the "homologation" scheme

The goal of the « DMP-compatible homologation » is to validate the capability of the software to interact consistently with the DMP, in conformance with the technical specification of the DMP interfaces..
The specification describes the external interfaces of the DMP system to be used by any software (http://esante.gouv.fr/sites/default/files/DMP1_LPS_TEC_DSFT_des_interfaces_LPS_20120724_v1.0.zip). The testing conformance is extended to the validation of the mandatory data and their values vis a vis the specifications.

Several services are described:

- Access to the patient record
- INS (National Patient Identifier)
- Creation and management of the Patient record
- Feed a patient record with new or optional content
- Query and retrieve content from the patient record
- Manage the visibility and/or status of content in a patient record
- Other services

These services are combined into three profiles:

- Create ("Creation")
- Write ("Alimentation")
- Read ("Consultation")

A "homologation" scheme is defined by ASIP santé (www.esante.gouv.fr) which is the national eHealth agency in France. The testing validation procedure called homologation is also under the supervision of the agency.

The list of vendors/software that pass the testing session is published at http://www.dmp.gouv.fr/dmp-compatibilite. Profiles and the type of authentication that are implemented are also listed for the software. As of February 2014, 126 distinct software are registered and labeled as "DMP-compatible".

Certification Scheme

a/ type of certification

- *certification with a certified third party*
- *certification with third party*
- *quality assurance*
- *other*

Explain the roles of the organisations involved, their qualifications (accredited, certified,…), level of trust of the seal,…

The type is a quality label process. All the steps of the QL procedure are carried by the national agency ASIP Santé: Asip Santé provides the specifications, registration, the « homologation » procedure, test methods, testing tools, support and test session.

The procedure is an institutional and mandatory procedure for exchanging medical data between

the DMP and the software. The level of trust is based on the quality of the specifications and the tests realized by the national agency. No third party is involved on the procedures and ASIP Santé did not have their own processes audited by an external auditor at the time (although ASIP santé is currently applying for an ISO 9001 certification for a part of its activities).

b/ Describe the certification process in place

The procedure is the following:

- **step 1:** the vendor sends the signed contract to the Asip santé. The output is that the vendor is registered in the diffusion list of the "DMP Compatibilité"
- **Step 2:** the test environment is open to the vendor and a dedicated test environment is allocated to the vendor. A "pre-homologation activity is set up : testing transactions are sent.
- **Step 2b:** technical support is available to allow the vendor to finalize his own tests.
- **Step 3:** homologation. The vendor sends his results to the Asip Santé for analysis. The output is the validation of the tests and the publication of the results in the Asip santé website.

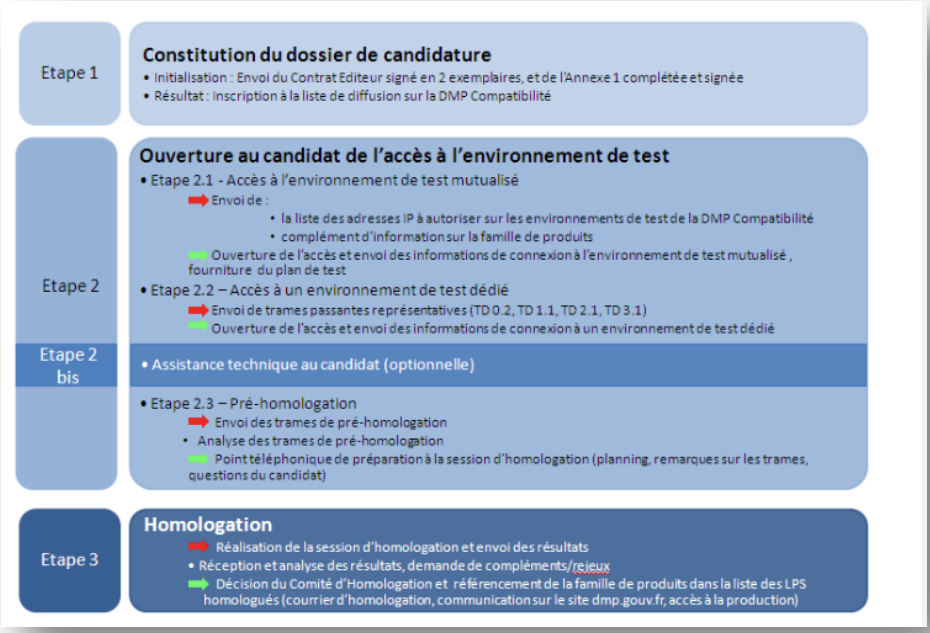

Figure 16: DMP homologation process

c/Content/requirements

Use cases/Services/Profiles that are part or included in the eEIF
Level of coverage
Specific use cases/Services/Profiles

The main use case is the connection of the healthcare software to the national PHR for four services:

- Secured access to the DMP
- Creation and management of the DMP

- Feed the DMP with medical documents
- Consultation of the DMP.

The DMP system leverages the national interoperability framework which selects and further constrains (through the process of national extension) these profiles: XDS, PDQ, DSG, ATNA, CT, XD-LAB,APSR, and the PCC content profile . The specification also provides a set of HL7 messages for the administrative management of the patient record.
(http://esante.gouv.fr/services/referentiels/referentiels-d-interoperabilite/referentiels-d-interoperabilite). Coding systems are also used such as LOINC and its translation, SNOMED V3.5VF.

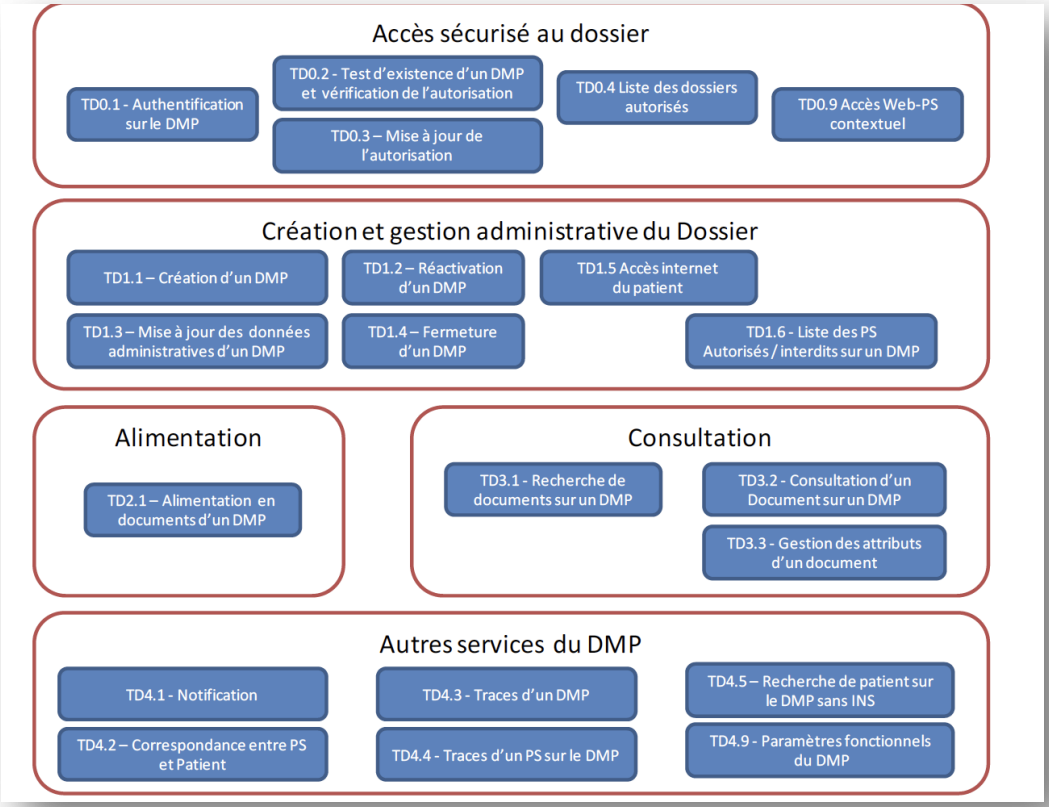

Figure 17: DMP services

In the following schema, the relationship between DMP transactions and profiles/standards at the technical level is presented:

			Technique
Transactions DMP pour LPS			**Standards ou protocole utilisés**
ACCES SECURISE AU DOSSIER			
TD0.1	Authentification sur le DMP		SAML / TLS
TD0.2	Test d'existence d'un DMP et vérification de l'autorisation		HL7-V3
TD0.3	Mise à jour de l'autorisation		(ws)
TD0.4	Liste des dossiers autorisés		(ws)
TD0.9	Accès Web-PS contextuel		--
CREATION et GESTION ADMINISTRATIVE DU DOSSIER D'UN PATIENT			
TD1.1	Création d'un DMP		HL7-V3
TD1.2	Réactivation d'un DMP		
TD1.3	Données administratives d'un DMP		
TD1.4	Fermeture d'un DMP		
TD1.5	Accès internet du patient		(ws)
TD1.6	Liste des PS autorisés/bloqués sur un DMP		(ws)
ALIMENTATION			
TD2.1	Alimentation en documents d'un DMP		IHE XDS-b
CONSULTATION			
TD3.1	Recherche de documents sur un DMP		
TD3.2	Consultation d'un document sur un DMP		
TD3.3	Gestion des attributs d'un document		
AUTRES SERVICES DU DMP			
TD4.1	Notifications		(ws)
TD4.2	Correspondance entre PS et Patient		(ws)
TD4.3	Traces d'un DMP		(ws)
TD4.4	Traces d'un PS sur le DMP		(ws)
TD4.5	Recherche de patient sur le DMP sans INS		IHE-PDQ
TD4.9	Paramètres fonctionnels du SI-DMP		(ws)

Figure 18: List of services and standards

ws represents web services that are specific to the project. Any standard is used.
For the audit traces, IHE-ATNA can be used but it is not required.

d/ Methodology, tools, test criteria

The test environment is available on line. The vendor after registration to the "homologation" procedures (he signed the contract) receives its login/password to access to the server where he uploads the CPS API library and information on the integration of these APIs to his healthcare software. He also received CPS smartcards (that are generally used by the Healthcare professionals for authentication to the DMP application) and certificates. The certification authority used for the DMP is the CA-class4 of the PKI CPS.
Four educational environments are available to simulate healthcare applications in interaction with the DMP system.

Tools and Test criteria are not available publicly. The tools were developed by ASIP Santé and are proprietary.

Target

Which products and services are the target of the certification scheme ? Explain if the certification can be recognized at the European level. How ?
What need to be improved in order to achieve the two level certification model
Benefit for the target

The target is the Products that are designed for the connection to the DMP.
To be recognized at the European level, ASIP Santé has to separate the specification activities, the testing validation activities and to assign the latter to an accredited laboratory. Further analysis is required to analyze the articulation between the specific and the profiles included in the European Interoperability framework in order to refine the two levels certification process.

For example, the DMP specifications are based on IHE-XDS.b. This profile is tested with the coding systems defined for the DMP (in the French context). The validation of the profile with specific coding systems is acceptable for the European level if the requirements are the same as the generic profile. Differences have to be published. The DMP XDS transactions do rely on the ATNA profile: those transactions are pursued between mutually authenticated nodes. In full conformance with the "NA" part of the ATNA profile. However, ASIP Santé does not require the "DMP-compatible" software to be capable of exporting their audit trails to a central audit trail repository per the "AT" part of the ATNA profile.. The profile IHE-XDS is coupled with IHE-ATNA. In the case where the healthcare software did not pass the test criteria related to this requirement, it will not be considered as passed at the European level but the software can be certified in France.
Anyway the feasibility of the implementation can be easily proved.

The benefits for the vendor are

- Recognition of their certification success
- More References from one country to another in Europe
- Less expenses
-

The benefits for the Healthcare providers are

- Better quality and robustness of the products
- Products are less expensive
- Open and standardized healthcare environment