Quality Label and Certification Processes
Education Material
on eHealth Interoperability

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To design a European quality label or certification process that supports eHealth interoperability in Europe.

These processes shall operate in harmony with country specific quality label or certification processes

Main benefits:

For Healthcare providers

– A harmonized European market for the eHealth solutions
– Better integration between solutions
– Ability to exchange electronically medical data between Regions and Nations

For Industry

– One recognized quality label or certification process in Europe
– Avoid duplication between the national and regional testing processes
– Factor and mutualize specifications elements and corresponding testing tools
Stimulate the creation of European market based on the evolving European eHealth Interoperability Framework associated with a modular European Conformance Assessment Program

Harmonize the quality label and certification processes in Europe and among countries and regions

Propose a European interoperability quality label and certification process that allows for flexible national or regional approaches
Recommendations from previous projects

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**HITCH**

*(Healthcare Interoperability Testing and Conformance Harmonisation)*

**EHR-Q^{TN}**

*(EHR Quality Labelling)*
HITCH Project Recommendations

1. Develop an European ecosystem by promoting recognized profiles, test plans and test tools

2. Define flexible testing processes

3. Provide a European Interoperability Assessment Scheme
EHR-Q^{TN} Project Recommendations

1. Apply generic criteria of quality to the initiatives
   (independence, openness, impartiality, transparency and confidentiality)

2. Involve stakeholders to the definition of the priorities in defining feasible goals

3. Structure the Quality label and Certification processes in line with ISO standards
Testing, Quality labelling and certification processes

Functional Model
QL & C processes

• Requirements, activities and tasks to support an entity in organizing high quality interoperability assurance or certification

Conformity assessment

• demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (ISO/IEC 17000)
A certification or quality label process requires:

- **A Certification/Label Scheme Owner**: a party that sets the Certification or a quality label program or system;
- **A label/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 (often called a testing laboratory).
Quality label and Certification Functional Model
Implementation: Model 1
Labeling by eHealth project using accredited testing lab(s)
Implementation: Model 2

Labeling & testing by eHealth project (no third party accreditation)
Case Studies
Case study-1 : DMP in France

• Objective :
  – DMP is the national PHR/EHR in France
  – The process called “homologation” is described in detail in the annex II. The goal of the « homologation » is to validate that the healthcare software connected to the DMP (French National PHR) are conform with the DMP specifications.

• Specifications defined by ASIP Santé (national agency) based on IHE profiles, HL7 and DICOM
  – Access to the DMP
  – INS (National Identification of the Patient)
  – Creation and management of the DMP
  – Registration of medical documents in the DMP
  – Consultation of the DMP
  – Other services

• Label/Certification scheme defined by ASIP Santé
Case study – 1 : DMP in France

Step 1
Registration of the Vendor to the process (ASIP Santé)
Registration and published candidates for DMP compatibility

Step 2
Access to the test environment
Access to the support
Pre-Homologation: upload files and validation of the tests

Step 3
Homologation and testing validation
Update and bugs resolution
Final decision by the committee and publication of the results

Label (Homologation) Process

Mapping Services/Standards and Profiles

24/09/2014
Case study – 2: epSOS project

eEIF
UC1, UC2a UC2b

<table>
<thead>
<tr>
<th>Nr</th>
<th>Level</th>
<th>Use case</th>
<th>Profiles</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Cross-border</td>
<td>epSOS project - e-Prescription and e-Dispensation for cross-border information sharing for citizens travelling in Europe</td>
<td>• IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA*</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Pharmacy: PRE*, DIS*</td>
</tr>
<tr>
<td>2a</td>
<td>Cross-border</td>
<td>epSOS project - patient summaries for cross-border information sharing for citizens travelling in Europe</td>
<td>• IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA*</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Patient Care Coordination: XPHR*</td>
</tr>
<tr>
<td>2b</td>
<td>Cross-border</td>
<td>epSOS project - patient having access to his or her patient summary</td>
<td>• IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA*</td>
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<td></td>
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<td>• Patient Care Coordination: XPHR*</td>
</tr>
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epSOS Specifications

IHE Profiles

epSOS Testing Process

Test Plans
Testing Tools

Antilope
Harmonisation of the quality label or certification processes in Europe
International profiles, guidelines, standards, test tools

International → Selection → Testing Methodology

Use cases
Recognized Profiles and standards
eELIF, other

International testing schemes:
- Certification by an accredited (e.g. ISO 17065) third party
- Certification by a non
- Accredited third party testing by an accredited (e.g. ISO 17025) test laboratory
- Quality assurance
- Other

Europe → Selection

Project Specifications
Use cases
Specific
Selected Profiles and Standards
Specific

Project Testing
Test Plans
Specific
Test Tools
Specific

National/Regional
In Europe: Three key steps

1. Define the Interoperability Conformance Assessment Scheme closely related with the eEIF
2. Promote creation of accredited Conformance Assessment Bodies in Europe
3. Develop Suitable Organisation for the QL&C process
At the National and Regional levels

1. National and Regional Project leverage profiles recognized by eEIF and use flexibility with needed national extensions

2. Ensure that the European level certification may be used as an entry criteria at the national level

3. Organise acceptance and the recognition of profiles candidates in the eEIF based on local use cases
• European eHealth Governance group
  – All categories of stakeholders
  – Take decision and validates Interoperability framework and Conformance Assessment Program Scheme

• Interoperability Framework coordination
  – Refines, selects Use cases and profiles and maintains the eEIF
  – Analyses and prepares all the items in order to reach the consensus before validation by the eHealth Governance Group

• Conformance Assessment Scheme coordination
  – Specifies the Conformance Assessment Program scheme
  – Delegates the testing validation to the CABs
Guidelines and recommendations
How to deploy QL & C processes in your organisation, region, or nation?

Step 1: Define your needs on Quality Label or Certification

- **Input**
  - National/regional project using use cases, standards and profiles described in the eEuropean Interoperability Framework (eEIF - Antilope WP1) or other needs
  - List of existing Test tools and test plans (Antilope WP3)

- **Activities**
  - Analyse the gaps between the eEIF and the needs
  - Specify the needs of QL or C regarding the specifications and requirements
  - Specify the Conformance Assessment Program scheme for the project

- **Output**
  - Conformance Assessment Program scheme (CAPS)
  - Specifications of the tooling needs

Step 2: Setting up the QL or C context

- **Input**
  - step 1 output

- **Activities**
  - Select existing test tools and test plans and describe what are missing
  - Specify the tender for the development of the new test tools by following the recommendations of Antilope WP3 (open source recommended)
  - Define the organisation: Is scheme owner, QL or C body the same organisation or two organisations and what are their level of recognition?
  - Specify the testing process and procedures (WP2 QMS, ISO standards)
  - Select the Conformance Assessment Bodies and their QL or C level

- **Output**
  - Organisation in place
  - Selection of CABs
  - Selection of organisations or companies that will develop new test tools and test plans

Step 3: Execute and Report

- **Input** from the previous steps

- **Activities**
  - Recruit candidates for the QL or C
  - Check whether the candidates have their EU label or certificate
  - Execute the test process
  - Validate and report the results
  - Publish the results

- **Output**
  - Validation report, passed candidates

Step 4: Assess and Communicate

- **Input** from all the previous steps

- **Activities**
  - Evaluate the entire process (including the selection of specific profiles, test tools and test plan that can be shared at the European or International level)
  - Communicate on the existence of new use cases, profiles, test plans and test tools and add them in the inventory database
  - Communicate on the results of the QL or C process

- **Output**
  - Communication plan
  - Assessment Report

Antilope 24/09/2014
**QL & Certification “in action”**

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**4 STEPS**
QL & Certification “in action”

4 STEPS

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- **Output**
  - Communication plan
  - Assessment Report
  - Interoperability Framework to be communicated
Antilope roadmap

**Get ready 2012-2013** | **Build 2013-2014** | **Operationalize 2014-2015** | **Deploy and Maintain 2016-20XX**

**Antilope roadmap**

- **European Strategic Milestones**
  - eEIF
  - Refined Ehealth Interoperability Framework
  - European-Level QMS V1.0
  - European-Level QMS V2.0
  - Proposed European-Level Testing Process
  - Proposed European-Level Quality LabelCert. Process

- **Testing & Certification Processes**
  - Antilope
  - Advancing eHealth Interoperability
  - Quality LabelCert Processes V1.0
  - European-Level QMS V1.0
  - Evaluation of Testing & LabelCert.
  - European-Level QMS V2.1
  - European Conformance Assessment Program Scheme v1.0
  - European Conformance Assessment Program
  - Quality LabelCert Processes V1.1
  - Projects
  - Education

- **Test Tools**
  - List of Test Tools V2.0
  - Test Management Platform V1.0
  - Test Cases V1.0
  - Test Tools V1.0
  - Test Management Platform V2.0
  - Test Cases V2.0
  - Test Tools V2.0
  - Test Tools V2.0

- **List of Test Tools**
  - List of Test Tools V1.0
  - Testing Management Platform V1.0
  - Test Cases V1.0
  - Testing Management Platform V2.0

- **Support of Project-Level Testing**
  - Support of Project-Level Testing Tools

- **Definition of the EU governance**
  - Organisation and rules in place
  - Pilot Testing & LabelCert.
  - Testing & Quality LabelCert. Operational

- **Pilot Testing & LabelCert.**
  - Evaluation of Testing & LabelCert.

- **Operational Support of Project-Level Testing & LabelCert Process**
  - Support of Project-Level Testing Tools

- **Maintenance of all assets**
  - Maintenance of all assets

**24/09/2014**

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For more information, please refer to document D4.1. available on the Antilope website

http://www.antilope-project.eu/