Quality Label and Certification Processes

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Betere zorg door betere informatie Nictiz

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cen Health Informatics TC251

IVZ INŠTITUT ZA VAROVANJE ZDRAVJA REPUBLIKE SLOVENIJE

HL7 INTERNATIONAL

Instytut Logistyki i Magazynowania

EN 13606 ASSOCIATION

SEVENTH FRAMEWORK PROGRAMME

Antilope Validation Partners

MEDIQ	Denmark, Norway, Sweden Finland, Iceland, Estonia, Lithuania, Latvia
NÁRODNÉ CENTRUM ZDRAVOTNÍCKYCH INFORMÁCIÍ	Poland, Czech Republic, Slovakia, Hungary
IHE UK Integrating the Healthcare Enterprise	Ireland, United Kingdom
PROREC-BE	Belgium, The Netherlands, Luxemburg
Interop Santé	France, Switzerland,
FACHHOCHSCHULE TECHNIKUM WIEN	Germany, Austria
PROREC-SI	Slovenia, Croatia, Serbia, Bosnia, FYE Macedonia, Montenegro
assinteritalia	Italy, Malta
TicSalut	Portugal, Spain
HL HELLAS	Romania, Bulgaria, Greece, Cyprus, Turkey

Policy Context

The challenge

eHealth Deployment in Europe

The environment

Directive 2002/21/EC Common Framework on communication networks

Directive 2007/47/EC on medical devices

Directive 2011/24/EU on Patients' rights in Cross Border Healthcare

MoU on eHealth between EC and US

Requirement

Consensus on a common Interoperability Framework
For an harmonized implementation across Europe

Testing and Certification Objectives

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 harmlonized 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

HITCH Roadmap

ChP1

Get ready 2012-2013 ***Operationalize 2013-2014*** ***Deploy 2015-20XX***

European Strategic Milestones

eEIF

Ehealth Interoperability Framework

Evaluation of Testing & LabelCert.

Pilot Testing & LabelCert.

EuropeanTesting & LabelCert. Operational

Testing & Certification Processes

European-Level QMS V1.0

Proposed European-Level Testing Process

Proposed European-Level LabelCert. Process

European-Level QMS V2.0

European-Level Testing Process

European-Level LabelCert Process

Support of Project-Level Testing & LabelCert Process

Testing Tools

Testing Management Platform V1.0

Test Methodology

Interop/functional Linkage

Test Management Platform V2.0

Test Cases V1.0

Test Tools V1.0

Test Cases V2.0

Test Tools V2.0

Support of Project-Level Testing Tools

Slide 6

ChP1 Milan had many comments on the english for the slide notes. I applied those and polished the text.
Parisot, Charles (GE Healthcare), 06/11/2013

Key Recommendations

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

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

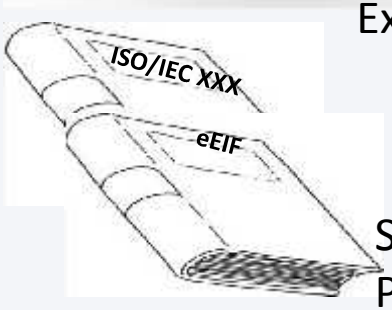
1	Apply generic criteria of quality to the initiatives (independence, openness, impartiality, transparency and confidentiality)
2	Involve stakeholders to the definition of the priorities in defining feasible goals
3	Structure the Quality label and Certification processes in line with ISO standards

ANTILOPE Methodology

Methodologies

INPUTS from

Experts



Standards and SDOs

Project

Questionnaires

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☑

RECOMMENDATIONS

- Definition of an Interoperability testing strategy in Europe
- Key points to be taken into account:
  - Comprehensive test plan, test cases, tools and test data
  - Definition of exhaustive/mandatory/ realistic Use cases/ test cases
  - Risk assessments
  - End-users actively involved

Testing, Quality labelling and certification processes

Functional Model

Quality Label and Certification processes - Definitions

QL & C processes

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

Conformity assessment

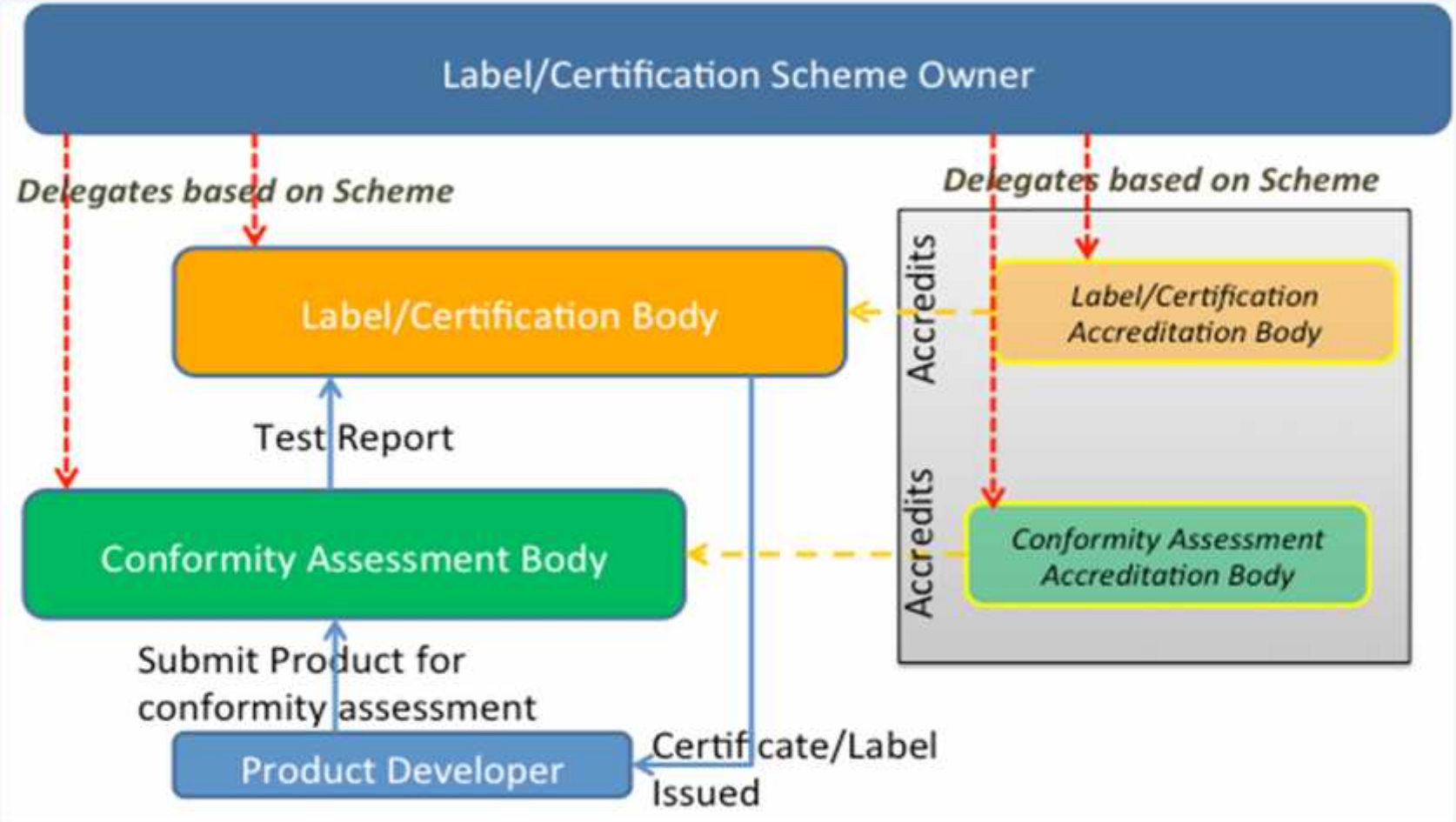
- demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (ISO/IEC 17000)

Functions

A certification or quality label process requires:

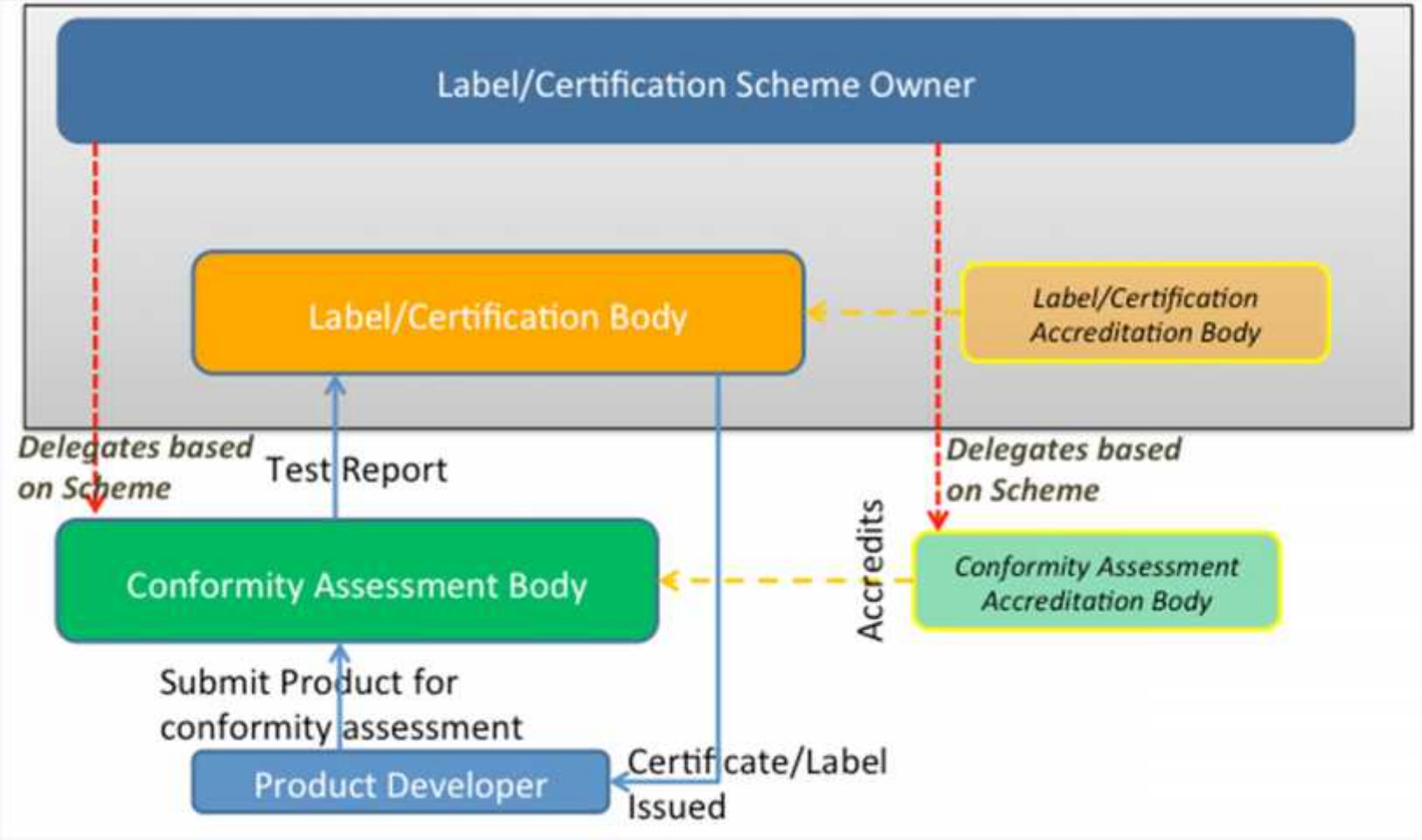
- A *Certification/Label Scheme Owner*: a party that sets the Certification or a quality label program or system;
- A *label/Certification Body*: a party that issues the quality label or certificate on the basis of the conformity assessment performed by a conformity assessment body;
- A *Conformity Assessment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

Quality label and Certification Functional Model



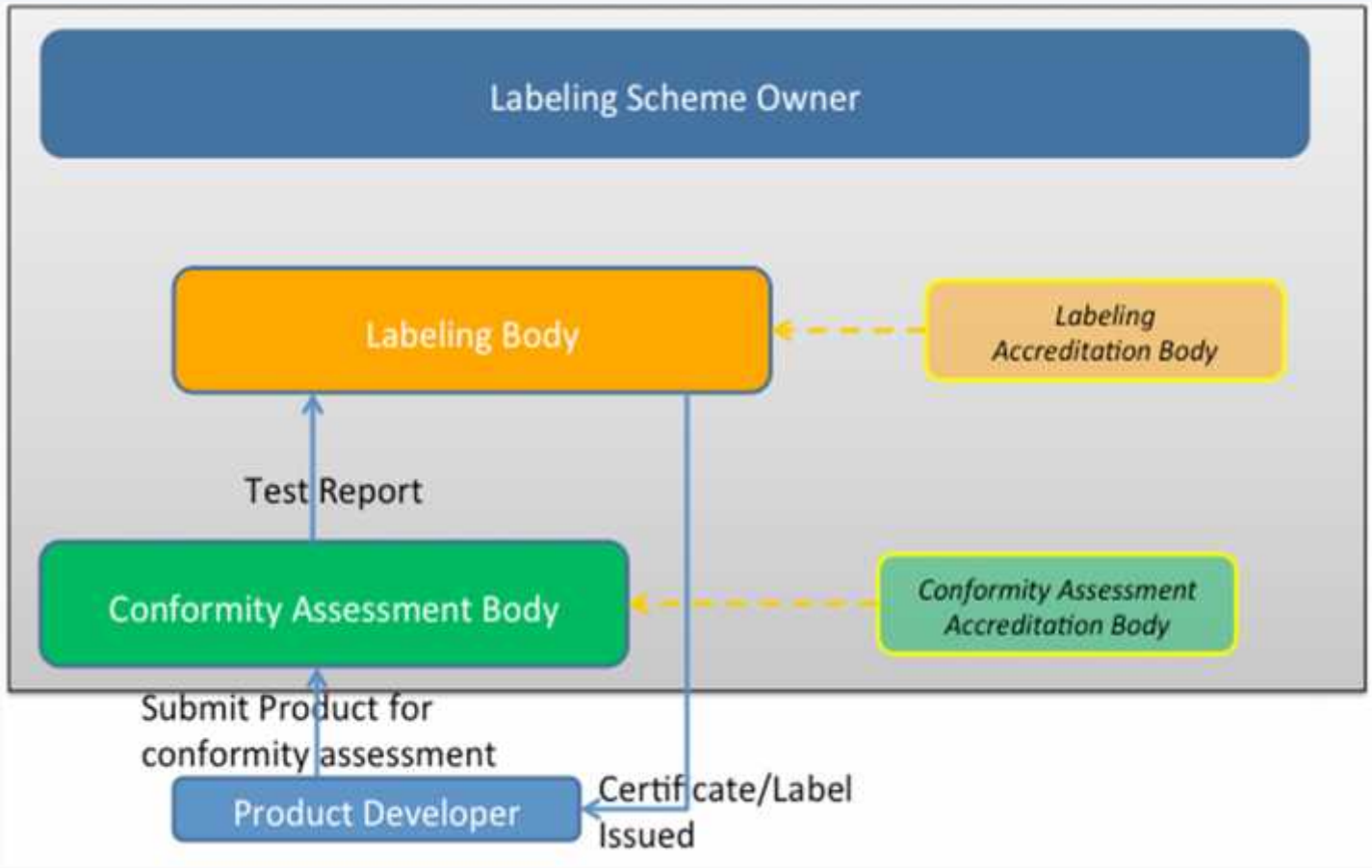
Implementation: Model 1

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

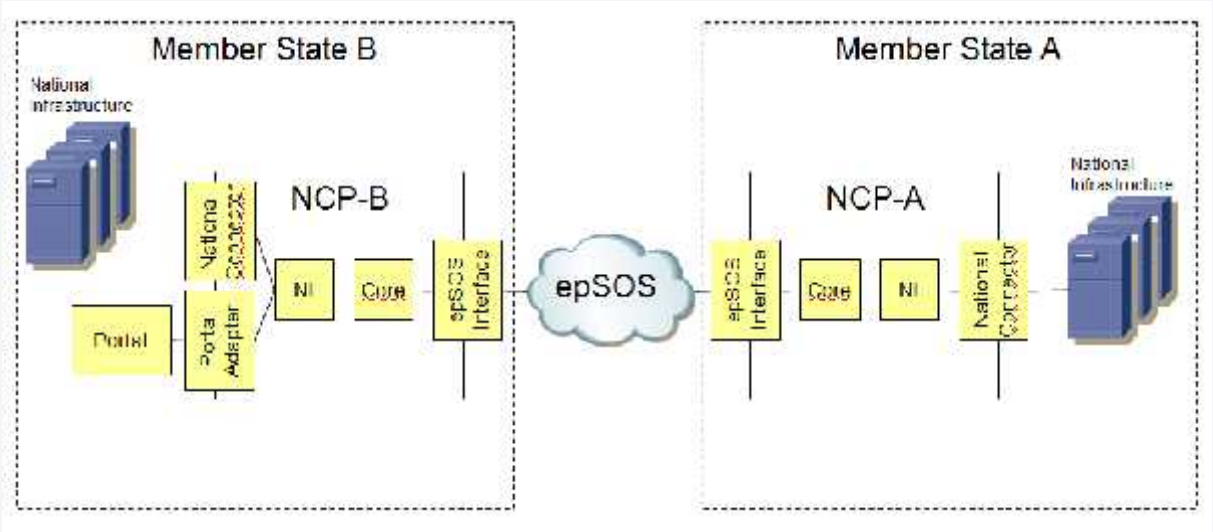
Label (Homologation) Process

Mapping Services/Standards and Profiles

Transactions DMP pour LPS		Technique Standards ou protocole utilisés
TD0.1	Authentification sur le DMP	SAML / TLS
	DMP et vérification de l'autorisation	HL7-V3
	risation	(ws)
	torisés	(ws)
	xtuel	--
	ISTRATIVE DU DOSSIER D'UN PATIENT	
	Création d'un DMP	HL7-V3
	DMP	
	tives d'un DMP	
	P	
	tient	(ws)
	s/bloqués sur un DMP	(ws)
	ocuments 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)

Case study 2 - epSOS

- Objective: 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 documents for a patient travelling in Europe.



Case study – 2 : epSOS project

eEIF

UC1 , UC2a UC2b

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

IHE Profiles

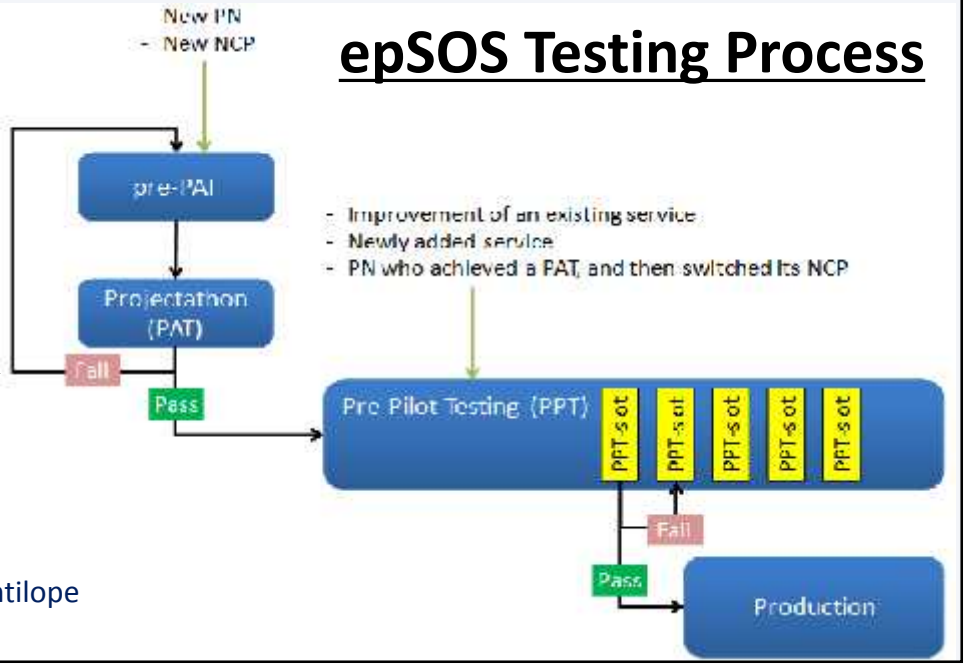
epSOS Specifications

IHE Gazelle

Test Plans

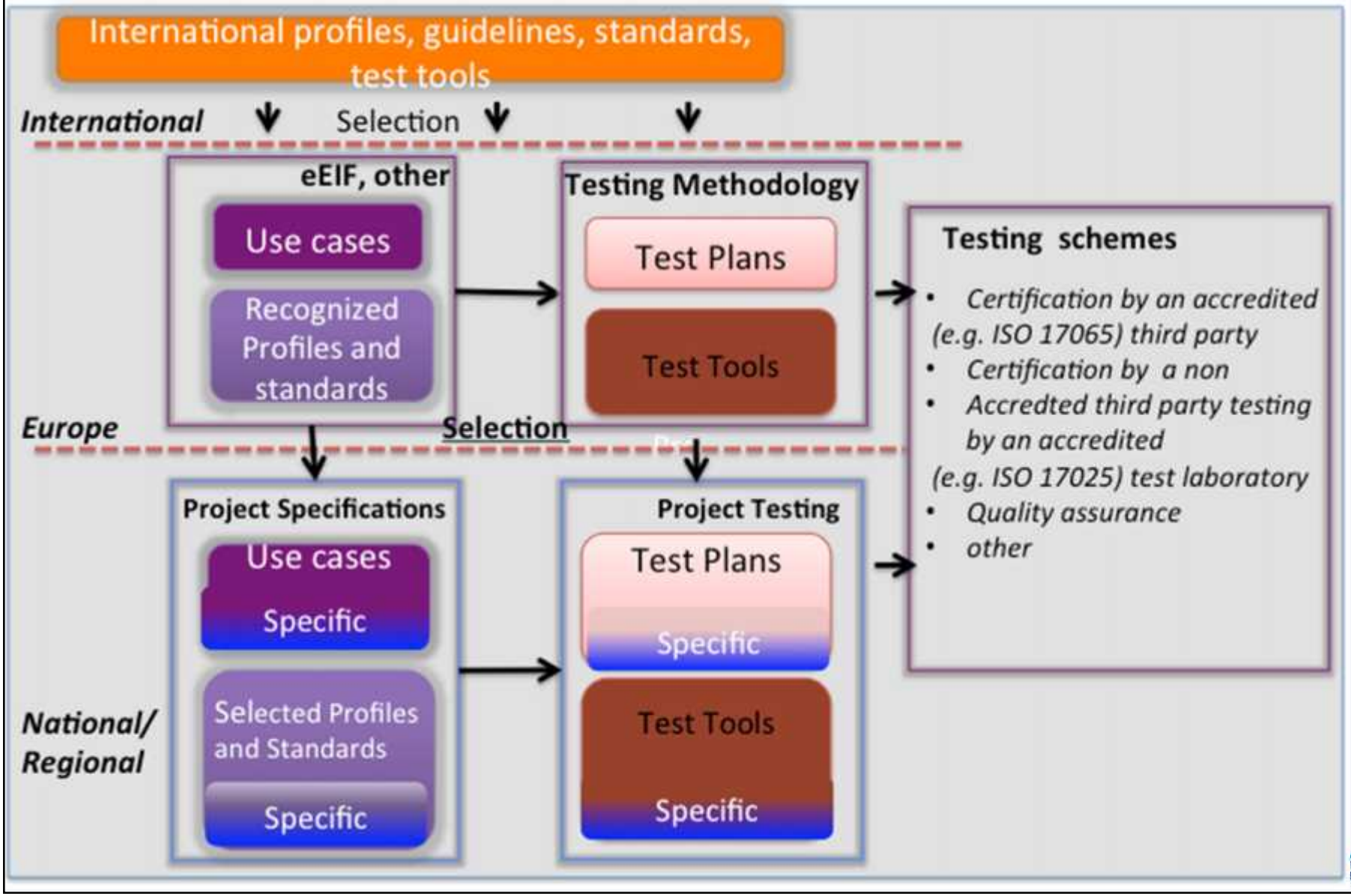
Testing Tools

epSOS Testing Process



Harmonisation of the quality label or certification processes in Europe

The Quality Label and Certification processes (1/2)



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

Governance

Governance

European ehealth Governance Group

(Stakeholders: Authorities, Competence Centers, User and Vendor Associations)

Interop. Framework Governance (eEIF)

IOP Framework Coordination

Interop. Quality Label or Certification Governance

QL&C Coordination

SDOs and Profiling Organisations

EU Terminology Value Set Mgt Body

Cross-Border projects (e.g. epSOS specifications)

Conformance Body Assessment

IHE Projectathon Connectathon

Other

EU project

National or Regional ehealth

Governance

- 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 ?

4 STEPS

Step 1 Define your needs

Step 2 Setting up

Step 3 Execute and report

Step 4 Assess and Communicate

Step 1: Define your needs on Quality Label or Certification

- **Input**
  - National/regional project using use cases, standards and profiles desscribed 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 plan*

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*
  - *Interoperability Framework to be communicated*

SEVENTH FRAMEWORK PROGRAMME

Roadmap

Key messages

Antilope roadmap

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

European Strategic Milestones

Ehealth Interoperability Framework

eEIF

Definition of the EU governance

Refined Ehealth Interoperability Framework

Organisation and rules in place

Pilot Testing & LabelCert.

Testing & Quality LabelCert. Operational

Testing & Certification Processes

European-Level QMS V1.0

Proposed European-Level Testing Process

Proposed European-Level Quality LabelCert. Process

European-Level QMS V2.0

Quality LabelCert Processes V1.0

Antilope Advancing eHealth Interoperability

European-Level QMS V2.1

Evaluation of Testing & LabelCert.

European Conformance Assessment Program Scheme v1.0

Quality LabelCert Processes V1.1

Projects

Education

Support of Project-Level Testing & LabelCert Process

Testing Tools

HITCH

Test Methodology

List of Test Tools V1.0

Testing Management Platform V1.0

Test Cases V1.0

Test Tools V1.0

List of Test Tools V2.0

Test Management Platform V2.0

Test Cases V2.0

Test Tools V2.0

Maintenance of all assets

Support of Project-Level Testing Tools

Key Recommendations

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

For more information,

please refer to document D*4*.1.

available on the Antilope website

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


Any questions?