Antilope

Advancing eHealth Interoperability

Labelling and certification in Europe

London Summit

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Presented by Jos Devlies, EuroRec

cip competitiveness and innovation framework programme 2007–2013

EUROREC

SEVENTH FRAMEWORK PROGRAMME

What do we want ?
What do we need?

- As **patient**, we want the best possible care.
- As **physician** (and care giver), we want to provide that best possible care.
- As **community** we want to enable / to enforce that best possible care.
- We need therefore resources and tools, eHealth is one of these tools.
- eHealth tools need to be of appropriate quality and used adequately
- **How do we know eHealth facilities to be of appropriate quality?**

Another dimension of quality

- ANTILOPE
  - Focuses on interoperability / data exchange
  - More precisely on the quality of the quality assessment
  - Addressing:
    - Quality issues related to the organisations involved in quality assessment
    - The use case based approach
    - The tools used during the quality assessment process
    - The quality issues related to the quality assessment processes
- ANTILOPE MISSION

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

Quality Assessing eHealth applications / functions

- Two Thematic Network projects studied the possibilities
  - HITCH (Healthcare Interoperability Testing and Conformance Harmonisation)
  - EHR-Q^{TN} (Electronic Healthcare Record Quality)
- They addressed different / complementary domains
  - Interoperability between systems (starting with exchange)
  - Functionality of the applications at both end (sender / receiver)
- They identified two tracks and two methods
  - Public / accredited versus private market driven
  - Third party versus self-assessment

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

UK and all EC health communities

1	Recognise that each health care system is different
2	Build upon local status, developments and initiatives
3	Antilope aims to foster collaboration not impose an EC wide standard

HITCH Roadmap

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

Testing, Quality labelling and Certification processes

Functional Model

Quality Label and Certification processes - Definitions

QL & C processes

- Requirements, activities and tasks to support high quality interoperability assurance or certification

Conformity assessment

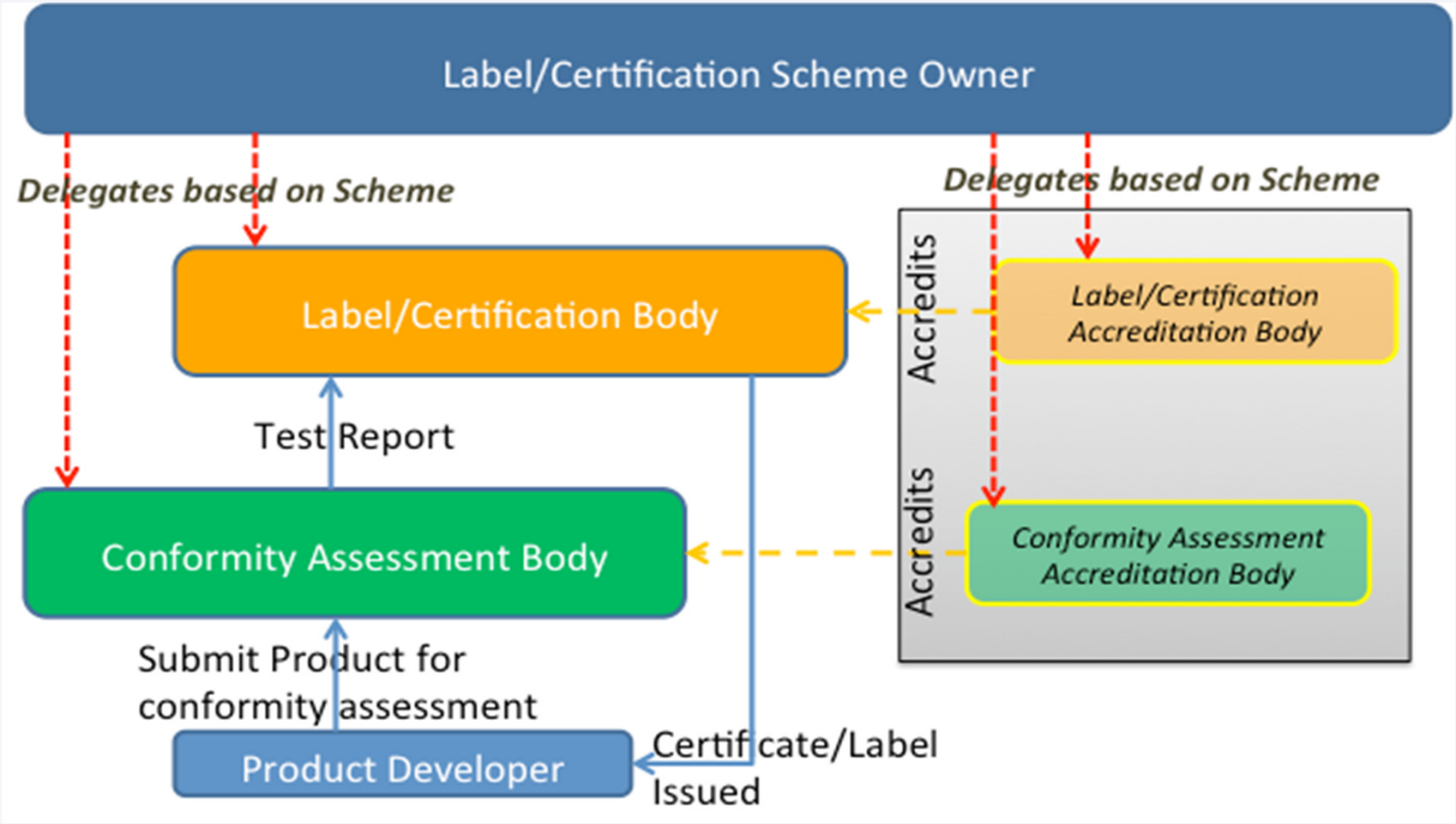
- demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (ISO/IEC 17000)

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



Case Studies

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
ACCÈS SÉCURISÉ AU DOSSIER		
TD0.1	Authentification sur le DMP	SAML / TLS
	n DMP et vérification de l'autorisation	HL7-V3
	orisation	(ws)
	utorisés	(ws)
	extuel	--
	NISTRATIVE DU DOSSIER D'UN PATIENT	
TD1.1	Création d'un DMP	HL7-V3
	DMP	
	tives d'un DMP	
	P	
	atient	(ws)
	és/bloqués sur un DMP	(ws)
	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)

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*, BPPC*, 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*, BPPC*, 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*, BPPC*, XUA* • Patient Care Coordination: XPHR*

IHE Profiles

epSOS Specifications

Gazelle

Test Plans

Testing Tools

epSOS Testing Process

- New PN
- New NCP

pre-PAT

Projectathon (PAT)

Fail

Pass

- Improvement of an existing service
- Newly added service
- PN who achieved a PAT, and then switched its NCP

Pre-Pilot Testing (PPT)

PPT-slot PPT-slot PPT-slot PPT-slot PPT-slot

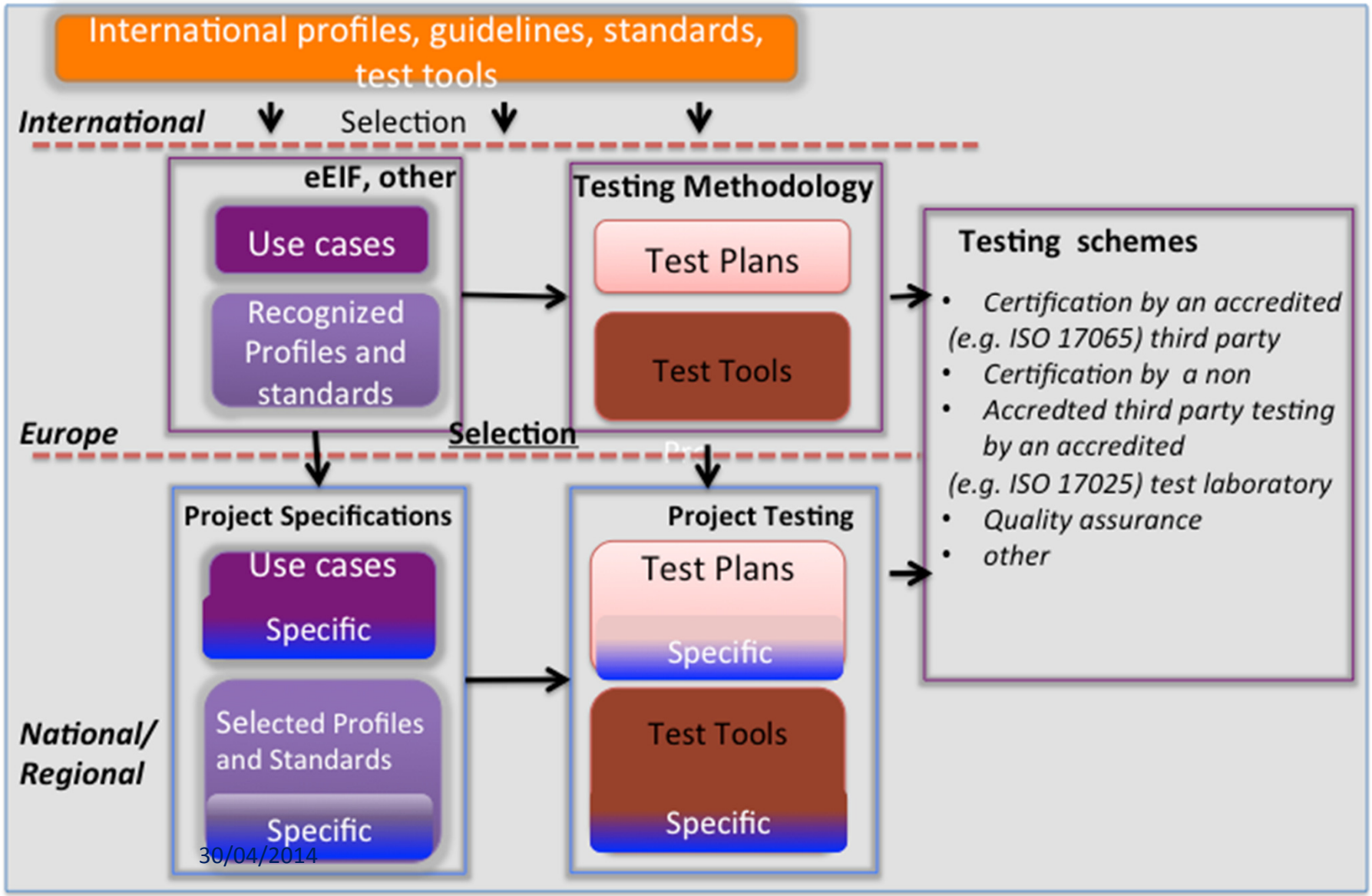
Fail

Pass

Production

Harmonisation of the quality label or certification processes in Europe

The Quality Label and Certification processes (1/2)



Guidelines and recommendations

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

Scenarios of implementation

- An ANTILOPE cross-border model, focusing on
  - Interoperability
  - Use case implementation
  - Considering eEIF
- A (complementary) model, focusing on
  - Functionality
  - Primarily national requirements

For more information,

please refer to document D*4*.1.

available on the Antilope website

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

Next steps for the project

- **Next steps:**
  - Collecting all the feedbacks from the summits and other conferences: January to June 2014
  - New version to be submitted to the SEPs (experts)
  - Validation by the Core Group in November
  - Final drafts of the deliverables on January 2015
- Few feedbacks received due to the complexity of the topic where expertise is needed
- Benefit:
  - Align with ISO standards
  - Mutualisation and harmonisation in Europe
  - One QL&C processes at the EU level where derivation is described