Quality Labelling and Certification of Service Provider Platforms

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Introduction

- Certification is the process of issuing the written assurance ("the certificate") that an independent accredited external body has audited and verified that a product or software conforms to specified requirements (based on ISO definitions)

- Certificate is a document issued by a certification authority attesting that a person or product meets a set of requirements or criteria
Actors

Certification body

Accreditation body

Certificate

Label

Conformity Assessment Body

Product/Service
i~HD objectives

- EHR4CR platform governance, quality criteria and certification of clinical research platform services
- Access portal to quality labelled interoperability assets, with guidance on their adoption
- Set-up a formal collaboration between organisations regarding quality labelling and certification
Aims of the Quality Labelling and Certification Program

• Confirmation and recognition of the competence of an organisation

• Indication that the service provider is operating in accordance to specified i~HD criteria

• Ensure trust in the service provider
Four phases

1. Setting-up the framework
2. Application & pre-assessment
3. Assessment
4. Evaluation & Issuance
Categories

• General
• Service provisioning (e.g. extracting and reporting of data, security aspects, …)
• IT platform (data entry and processing, transferring of data, data quality checks, …)
• IT infrastructure (security, data storage, backups, …)
i~HD criteria

BSI

ECRIN

eCF

EuroRec
Sources

• eClinical Forum
  – eSource Readiness Assessment (eSRA): assessment of eSource (EHR) systems used for storing source data during clinical trials

• European Clinical Research Infrastructures Network (ECRIN)
  – Requirements for Certification of ECRIN Data Centres

• Federal Office for Information Security (BSI)
  – Security recommendations for cloud computing providers

• The European Institute for Health Records (EuroRec)
The European Institute for Health Records

• Not-for-profit organisation

• Main mission is to promote the use of high quality Electronic Health Record systems (EHRs) in Europe

• Expertise in Quality Labelling and Certification of EHRs
Repository of Quality Criteria

- +1700 Quality Criteria
- Indexed (+14000 total links indices)
- Validated (25 European Member States)
- Translated (20 languages)
EuroRec Seals

• Validation service against cross-border subsets of quality criteria
  – Seal 1: 20 criteria, minimal set of quality criteria
  – Seal 2: 50 criteria, addressing various essential EHR functions

• EHRCR profile contains research-specific quality criteria in order to certify EHR systems as suitable for use in clinical research

• Creation of new Seals for EHR4CR, EURECA, interoperability assets, service provider platforms, …
EuroRec’s Quality Labelling and Certification Tools

**Composer**
Selecting quality criteria from repository of 1700+ items

**Certifier**
Creating certificate sets of selected quality criteria

**Scripter**
Writing test scripts and developing test scenarios

**Testing**
Conducting conformance tests and evaluations
Scenario based testing

Scenario

Script 1

Crit x

Crit y

Crit z

Script 2

Script ...

Crit ...

...
Test Script Example

Generate discharge report for patient X

- The software generates the discharge report
- Automatic and manual selection of administrative and clinical data is possible
- Reports can be validated before they are sent
- Validated reports cannot be changed afterwards
EuroRec tools – Composer & Certifier

- Composing “basket” of quality criteria from the repository
- Creating of “certification sets” from a “basket”
### EuroRec tools - Scripter

- Writing scripts and assigning them to criteria

```plaintext
Report

Script content:
Generate discharge report for patient Y

Default view

1. (13) The software distinguishes at least the following roles: administrator, administrative user and clinical user.  
   - Mandatory 1
2. (30) The software can read the eID card to retrieve the patient’s NISS.  
   - Mandatory 1
3. (47d) The software generates the following documents imposed: the nursing termination report (see documentation)  
   - Mandatory 1
4. (126) The model documents provide automatic and manual selection of administrative and nursing data from the file possible. These data are automatically integrated in the production of the document actually. The completed model documents  
   - Mandatory 1
5. (128) The documents created based on models in which the data is integrated automatically, can be adapted and validated before they can be printed or forwarded.  
   - Mandatory 1
6. (128bis) The documents prepared are saved per patient and can not be changed after validation. However, it is possible to create new versions.  
   - Mandatory 1
```
EuroRec tools – Building the scenario

**Open patient record**

**Description:**
Log in as user X. Open patient record of patient Y with eID card

**Selected statements:**
1. The software distinguishes at least the following roles: administrator, administrative user and clinical user.
2. The software can read the eID card to retrieve the patient’s NISS.

**Report**

**Description:**
Generate discharge report for patient Y

**Selected statements:**
1. The software generates the following documents imposed: the nursing termination report (see documentation).
2. The model documents provide automatic and manual selection of administrative and nursing data from the file possible. These data are automatically integrated in the production of the document actually. The completed model documents
3. The documents created based on models in which the data is integrated automatically, can be adapted and validated before they can be printed or forwarded.
4. The documents prepared are saved per patient and can not be changed after validation. However, it is possible to create new versions.
**Generate discharge report for patient Y**

**Statements:**

1. **(47d)** The software generates the following documents imposed: the nursing termination report (see documentation).  

2. **(126)** The model documents provide automatic and manual selection of administrative and nursing data from the file possible. These data are automatically integrated in the production of the document actually. The completed model documents.

3. **(128)** The documents created based on models in which the data is integrated automatically, can be adapted and validated before they can be printed or forwarded.

4. **(128bis)** The documents prepared are saved per patient and cannot be changed after validation. However, it is possible to create new versions.

**Comment testee:**


**News**

**SAVE the Date 1st eStandards Conference**
Next steps for standardization in health information sharingBerlin 21st April 2016 in conjunction with conHIT 2016. ... [more](#)
26/04/2016

**STC2016 Transforming Healthcare with the Internet of Things**
The European Federation for Medical Informatics (EFMI) and the French Association for Medical Informatics (AIM) invite you to participate to the Special Topic Conference (STC) "Transforming Healthcare ... [more](#)
23/12/2015

**1HD Inaugural Conference programme published**
We are pleased to announce the agenda of the Inaugural Conference of the European Institute for Innovation through Health Data (I~HD) that will be held in Paris on March 10, 2016. ... [more](#)
22/12/2015

[www.eurorec.org](http://www.eurorec.org)
Thank you!

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