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# EHR Certification in Belgium

## A success story

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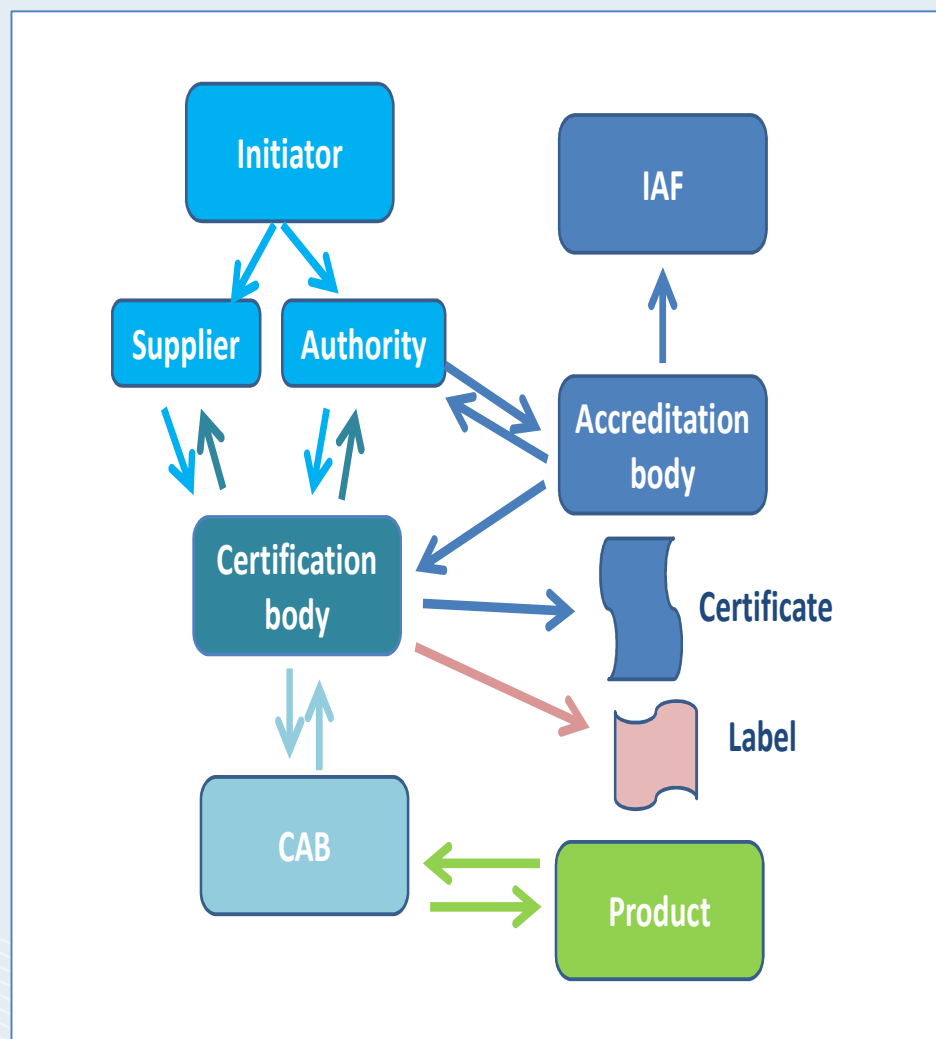
Pascal Coorevits, EuroRec and Ghent University

# 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 involved in certification

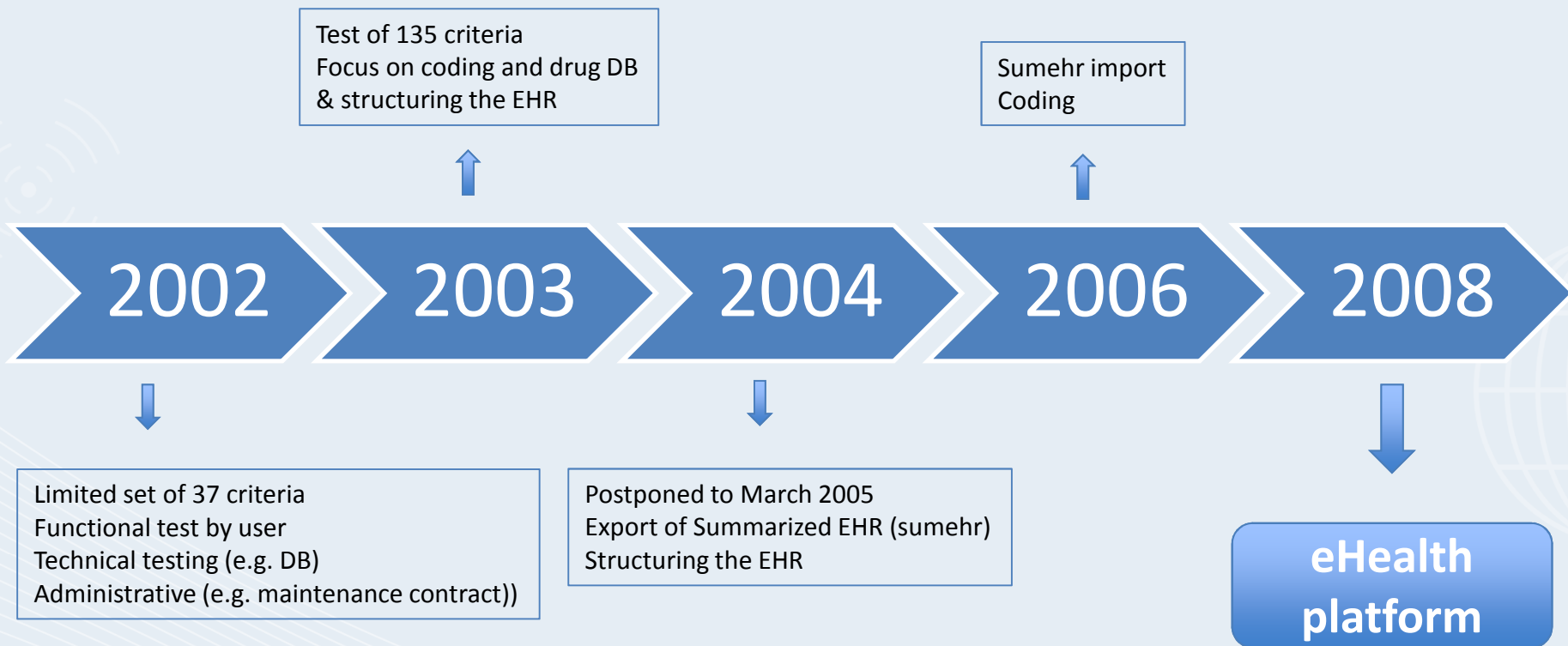




# EHR Certification in Belgium

- Declaration of Minister of Health ('97) → defining main EHR functions
- ProRec-BE: translation into technical implementation requirements ('97-'98)
- Law of January 25<sup>th</sup> 1999: *“His Majesty may define minimal criteria to be met by software applications managing the electronic medical and electronic nursing records in order to be homologated by the Minister of Health”*

# History of EHR Certification sessions



# Impact of EHR Certification

- Before certification...
  - Very fragmented EHR market
  - No interoperability, no standards used to exchange patient data
  - Issues with vendor liability
- After some years of certification...
  - EHR market consolidation
  - Vendors recognise positive impact
  - Improvement in interoperability

# Recent certification sessions

- Session 2010-2011
  - General practitioners
- Session 2013-2014
  - General practitioners
  - Physiotherapists
  - Home care nurses



# Four phases of EHR Certification

- Setting up the certification framework
- Pre-assessment phase
- Assessment or testing phase
- Granting/maintaining the certificate

**EHR-Q<sup>TN</sup>**

# Pre-assessment phase

- Selection of functions to be assessed
- Defining the criteria
- Negotiate feasibility with suppliers and users
- Create appropriate documentation



# Defining criteria

Gridlines

☒ View
 ☒ View
 ☐ Print
 ☐ Print

Headings

☐ Bring Forward
 ☐ Send Backward
 ☐ Selection Pane
 ☐ Align
 ☐ Group
 ☐ Rotate

Sheet Options

Arrange

waarvan het percentage dossiers met een INSZ kan worden bepaald voor de patiënten

E	F	G	H	I
	AE	N	7	Het systeem neemt geen verwijderde gezondheids gegevens op bij de productie of export van gegevens, maar bewaart ze wel in de originele gegevensbank.

Label:

- C: to be evaluated
- AE: auto evaluation
- N: new
- P: previous
- L: later

# EHR Certification criteria 2010-2011

Criterion	Criterion
8: Identification user	59b: prevention cervical cancer
9: Access to patient records	59c: prevention colon cancer
13: User access	65: care elements
19: Patient identification (INSS)	86c: sumehr export
20: eID and SIS	86e: sumehr preview
21: check double patient records	91: export partial patient data
26: Global Medical Record	97: GP software migration format
43: ICPC2 and ICD10 coding	108: yearly contact group
45: ATC and CNK coding	120: CEBAM
47: Cheap medicines	121: encryption/decryption

# Providing documentation

For each of the criteria to be tested:

- Description
- Q&A from suppliers
- Interpretation
- (non-exhaustive) list of testing/validation options





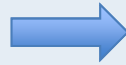
# Assessment phase

- Logistics (inscription, financial aspects, ...)
- Defining test populations and test scenarios
- Testing the applications
- Documentation of (non)conformity



# Criterion – script – scenario

Example: Criterion 26 “The software shows the presence or absence of a Global Medical Record and shows the date of signature and the GMR-holder (RIZIV number)”



Script:

Open the record of patient X  
Add date of signature: June 5th 2010  
Add GMR-holder: user Y

Scenario		
Script 1 <ul style="list-style-type: none"><li>• Crit. x</li><li>• Crit. y</li><li>• Crit. z</li></ul>	Script 2 <ul style="list-style-type: none"><li>• Crit. a</li><li>• Crit. b</li></ul>	Script 3 <ul style="list-style-type: none"><li>• Crit. c</li></ul>

# Assessment phase - testing

- Testing “on site”
- Delegation consisting of representatives of supplier, eHealth platform and CAB
- Supplier executes the scenario
- Functional & technical testing
- Lots of screen captures
- Documentation in scenario

# Functional evaluation

Jean Dale 31/03/1954 (ID:70214101)

Préc./Suivant Nouveau patient Effacer patient Nouveau formulaire Nouveau rapport iCal Introduire les codes Prescrire EID Impr.Etiq Imprimer Rechercher

Dossiers patients (4346) autre

Jean Dale  
Age: 56 ans

Résumé Patient  
Médecins  
Fichiers  
Planning  
Vaccines  
Prescription  
INBOX  
NEW MESSAGES  
Labo. Taktik [BIOFRS:C] (10/01/09)\*  
NEW PROTOCOLS  
Clinique Saint-Pierre CHIORT [10397007  
Etat général/Vaccination/Médication  
Suivi général  
Consultation (03/08/06)  
Consultation (22/03/09)  
Consultation (16/04/09)  
Consultation (01/06/09)  
Consultation (16/07/09)  
Consultation (22/07/09)  
Consultation (15/09/09)  
Consultation (03/10/09)  
Consultation (08/11/09)  
Dossier médical  
Dossier Médical (12/01/10)  
Pression sanguine élevée

Nom: Dale Prénom: J

Informations générales

Date nais.: 31/03/1954 Sexe: M L. de nais: Statut: Conjoint: Niv.étude: Profession: Nationalité: Langue: D. décès: L. décès:

Assurances

Assurance: Mutualité Saint-Michel(135000) NISS: 54033148729 Matric.: 8673530218 Titular: DMG: 12/06/2010 Ass. empl.: Aucune sélection

Tél. & Email

Tél.: 005384696 Fax:

Adresse principale

Adresse: Rues des Moisseurs Code post: 1040 Ville: Brussel (Etterbeek) Pays: BELGIUM

Contact

Nom: Tél.: Adresse: Code post: Ville: Pays:

Données complémentaires

Attributs

Statut du patient

☒ Activé

Planning échu

Des événements planifiés ont atteint leur date d'échéance.

Plannings

Date	Patient	Détail
07/01/11	Georges Orwell	Dépistage cancer colo-rectal
04/01/11	Jean Dale	recherche de sang occulte
04/01/11	Nathalie Junkers	Frottis du col
04/01/11	Nathalie Junkers	Recherche de sang occulte dans les selles
07/01/11	Nathalie Junkers	Dépistage cancer colo-rectal
07/01/11	Nathalie Junkers	Dépistage cancer du col de l'utérus
04/01/11	Rachel Matos Candido	vaccin contre la grippe
04/01/11	Véronique Ilma	Frottis du col
04/01/11	Véronique Ilma	Rappel Tétanos

à éch. dans 90 jours

# Technical evaluation

```
<item>
  <id S="ID-KMEHR" SV="1.0">10</id>
  <id SV="1.1" S="LOCAL" SL="ProRec SW">10028</id>
  <id S="LOCAL" SV="1.0" SL="GPSMF-ID">0029</id>
  <cd S="CD-ITEM" SV="1.3">diagnostic</cd>
  <content>
    <cd S="CD-CLINICAL" SV="1.0" DN="eenmalige episode van lichte depressie">10093303</cd>
    <cd S="ICPC" SV="2">P76</cd>
    <cd S="ICD" SV="10">F32.0</cd>
  </content>
  <content>
    <text L="nl">lichte depressie</text>
  </content>
  <beginmoment>
    <date>2001-07-04</date>
  </beginmoment>
  <lifecycle>
    <cd S="CD-LIFECYCLE" SV="1.0">active</cd>
  </lifecycle>
  <isrelevant>true</isrelevant>
  <recorddatetime>2001-07-04T15:05:05</recorddatetime>
</item>
```



# Documenting



## Scenario 3

Supplier :

Software:



Label 2010

<CR26>

### Action

#### Command

Open the record of patient G1.

Control the presence of a GMR<sup>19</sup>. (\*26\_1/2)

Show the start date and the name / social security number of the responsible healthcare professional for the GMR. (\*26\_2/2)

#### Comments testers

#### Comments supplier

<CR97>

<CR121>

### Action

#### Command

Export all the data for this patient as a 'GP software migration format' file.

Decrypt external file 1 with the key of the CAB.

Integrate the content of the file in the record of patient G1.

#### Comments testers

#### Comments supplier

# Evaluation report

21	Check double patient records	Unacceptable
26	Global Medical Patient Record	Good to very good
43	ICPC2 and ICD10 coding	Good to very good
45	ATC and CNK coding	Good to very good
47	Generic medicines	Acceptable
59b	Prevention cervical cancer	Good to very good
59c	Prevention colon cancer	Acceptable
65	Care elements	Acceptable
86c	Sumehr export	Acceptable
86e	Sumehr preview	Acceptable
91	Export partial patient data	Acceptable
97	GP Software Migration Format	To be evaluated

**Good to very good**

- Only minor aspects can be enhanced
- Criterium correctly implemented (also contentwise)

**Acceptable**


- Minor deficits

**To be evaluated**

- Major deficits

**Unacceptable**

- Essential aspects of criterium not or not correctly implemented



# Evaluation

## CRITERIUM 21

*“The software discovers possible double patient records during the creation of the patient record, based either on the last name, first name, sex, date of birth, or based on the INSS number, and prohibits the creation of multiple records with the same INSS number.”*

Good to very good

Acceptable

To be evaluated

Unacceptable

## COMMENTS

- The same INSS number can appear in different patient records
- The same patient can have two patient records (one with and one without INSS)
- No unique identification

# Granting the certificate

- Health Insurance Institute grants certificates and ensures that users are entitle to receive financial incentive
- Certificate is granted for a defined version and is valid until next certification
- Appeal procedure / retesting sessions
- Contractual commitment to distribute certified EHR within three months
- Minimal support & maintenance by supplier



# Certified EHR software 2012-2013

Naam van het softwarepakket	Naam van de firma	Geteste versie
HealthOne	Health Data Management Partners SA/NV	Health One v7.2.0
Epicure	MedicalSoft Sprl	Epicuresoft v15
MediDoc	Corilus Vlaanderen	MediDoc 7.2
OmniWin	Corilus Vlaanderen	Omniwin 19.3.0
MedSoft	Corilus Vlaanderen	MedSoft 3.0
Accrimed	Corilus Vlaanderen	Accrimed 6.7.3
SoSoeme	Corilus Vlaanderen	SoSoeMe v11.3
Medigest	Corilus Vlaanderen	Medigest 2011.2.1
Le généraliste	PC Sol	Le Généraliste 5.5070
OmniPro	MIMS	OmniPro 2.16.0.d
Medinote	The Virtuous Circle	MediNote 3.6
Pricare	FIGAC Asbl	Pricare 5.3
Prodoc	VZW Pro_doc gebruikers	Pro_Doc 4.1
iCure	Taktik	iCure 3.5.0
MediWin	Infodef	MediWin 4.37
Socrate	Socratem	Socrate Medical v9
Windoc	CompuGroup Medical Belgium bvba	WinDoc 8.8.



# Current certification session

	GPs	Physiotherapists	Nurses
Documentation	April 2013	May 2013	June 2013
Test population	May 2013	June 2013	July 2013
Demo test scenario	May 2013	June 2013	July 2013
First tests	September 2013	October 2013	December 2013
Second tests	December 2013	February 2014	April 2014

# Sources

- EuroRec website <http://www.eurorec.org>
- EHR-Q<sup>TN</sup> website <http://www.eurorec.org/RD/EHR-Q-TN.cfm>
  - D5.2 “Roadmap towards Sustainable Pan-European Certification of EHR systems”
  - D6.2 “State of the Art of EHR Quality Labeling and Certification Procedures & Scenarios”
- HITCH website <http://www.hitch-project.eu>
- Belgian eHealth platform  
<https://www.ehealth.fgov.be/nl/registratie-van-de-medische-softwarepakketten>

# Thank you!



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