

Quality Labelling and Certification of Electronic Health Record systems (EHR s)

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EUROREC

Definition

Electronic Health Record (EHR)

Repository of information regarding the health status of a subject of care, in computer processable form.

(ISO TR 20514:2004)

The EHR is the primary source of data and information in Health Information Networks (HINs)

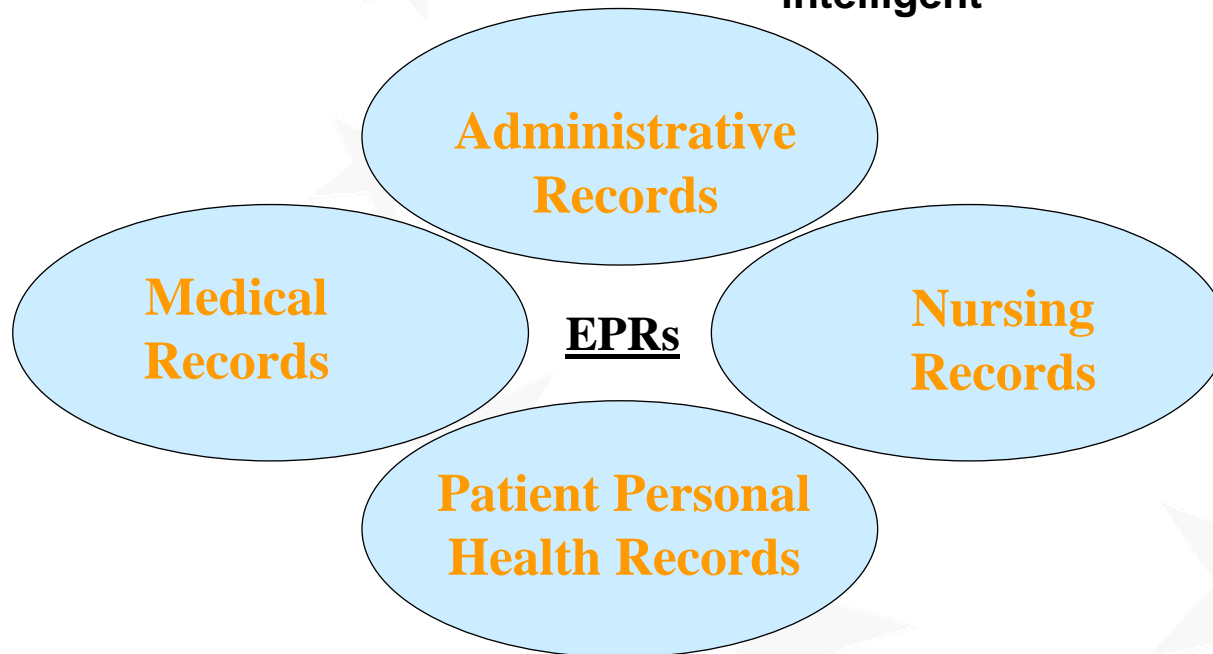
Primary Goals:

- Supporting continuing, efficient and high quality integrated healthcare**
- Enabling to share patient health information between authorized users**

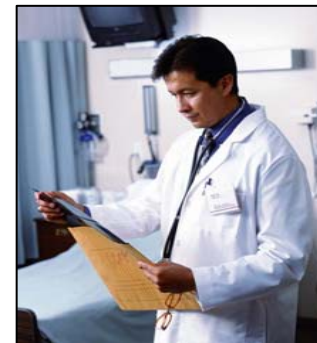
TRENDS in EHRs (1)

EHRs become

- transmural / virtual
- multidisciplinary and patient centered
- intelligent



! Integration with other health care software applications ...!



TRENDS in EHRs (2)

-Medical and Bio-Medical data

“The PHENOMES will meet the GENOMES in the EHRs of the Future”

-Security: Privacy Enhancing Techniques

-Semantic Interoperability: Ontology based Approaches

-Added value of EHRs: eg. Decision Support Systems

-Grid Technology (?): HealthGrid



- The « **European Institute for Health Records** »
- A **not-for-profit** organization, established April 16, 2003
- **Mission: the promotion of high quality Electronic Health Record systems (EHRs) in Europe**
- **Federation of all the national ProRec centres in Europe**

EUROREC: ORGANIZATION (2)

President	: Georges De Moor	(Belgium)
Secretary General	: François Mennerat	(France)
Vice-President (1)	: Rolf Engelbrecht	(Germany)
Vice-President (2)	: Kieran Hickey	(Ireland)
Treasurer	: Louis Schilders	(Belgium)
Deputy-Treasurer	: Knut Bernstein	(Denmark)

ProRec CENTRES



Centres

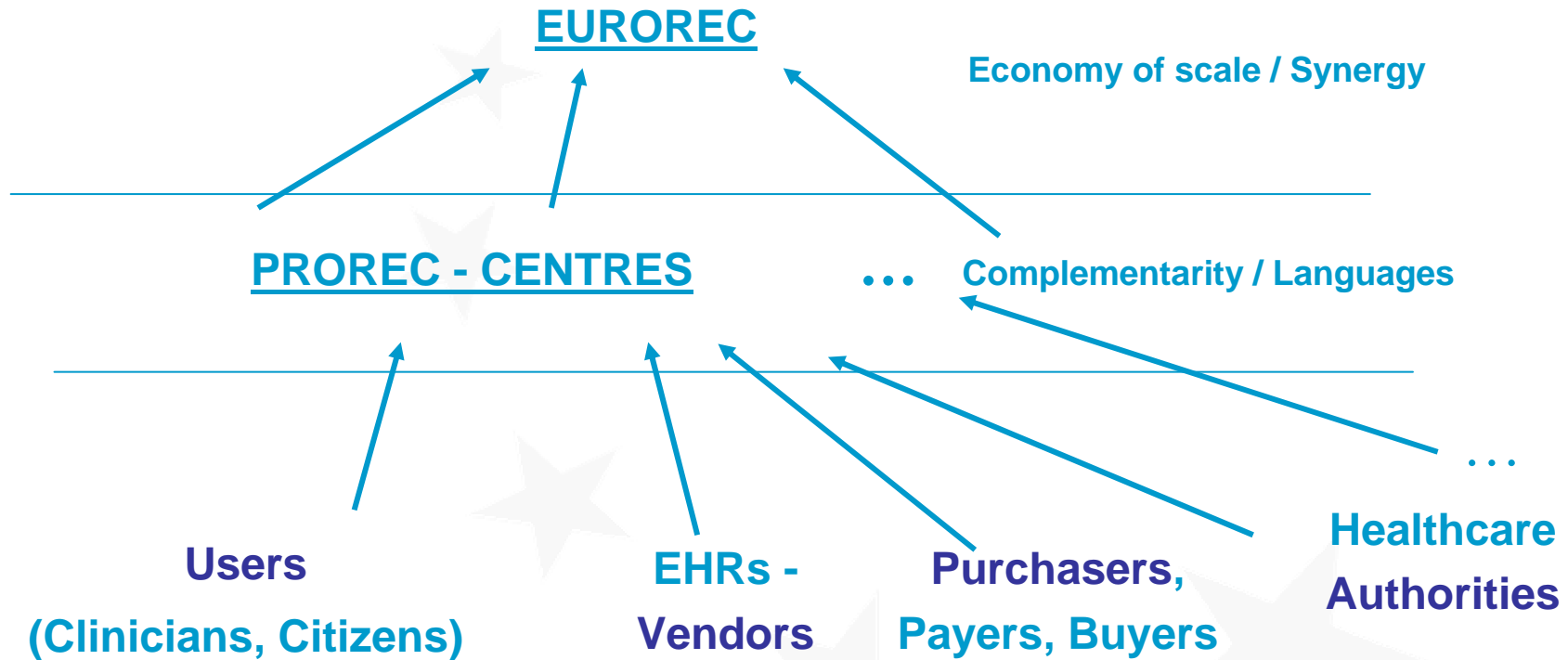
**Belgium
Bulgaria
Denmark
France
Italy
Germany
Ireland
Romania
Slovenia
Spain**

Applicants

**Norway
Greece
Hungary
Portugal
Poland
Sweden
The Netherlands
Slovakia
United Kingdom**

“ Differences in languages, cultures and HC-delivery systems ”

EUROREC: Organisation



EUROREC: GOALS



- Support **ProRec** centres
- Inform **users** of current trends in EHRs and express their needs
- Help **public authorities** to define and implement strategies
- Defend the **EHRs-industry** (ROI)
- Promote **research, education** and development in EHRs
- Foster **international co-operation** (with US, Canada, Japan, Australia...)

HISTORY of EU-PROJECTS (1)

PROREC : Promotion Strategy for the European HC Record
(CEU, FP4, HC 1110, 1996-1998)



WIDENET : Offering World-Wide Services through an
International Network of Health Record
centres (CEU, FP5, IST-14203, 2000-2003)



QREC : Quality Labelling and Certification of
Electronic Health Record systems in
Europe (CEU, FP6, IST-27360, 2005-2008)

HISTORY of EU-PROJECTS (2)



European Conferences on Electronic Health Records



Current EuroRec Projects

- RIDE-project** on **Semantic Interoperability**
- EHR-Implement project** on **political, social and economical aspects when implementing national EHRs systems**
- QREC-project** on « **Quality Labelling and Certification of EHR systems in Europe** » is a **Specific Support Action (SSA)**
(with EUR 1.3 million in EU funding)

QREC: Main Objectives

To develop formal methods and to create a mechanism for the quality labelling and **certification of EHR systems** in Europe, in primary- and in acute hospital-care settings

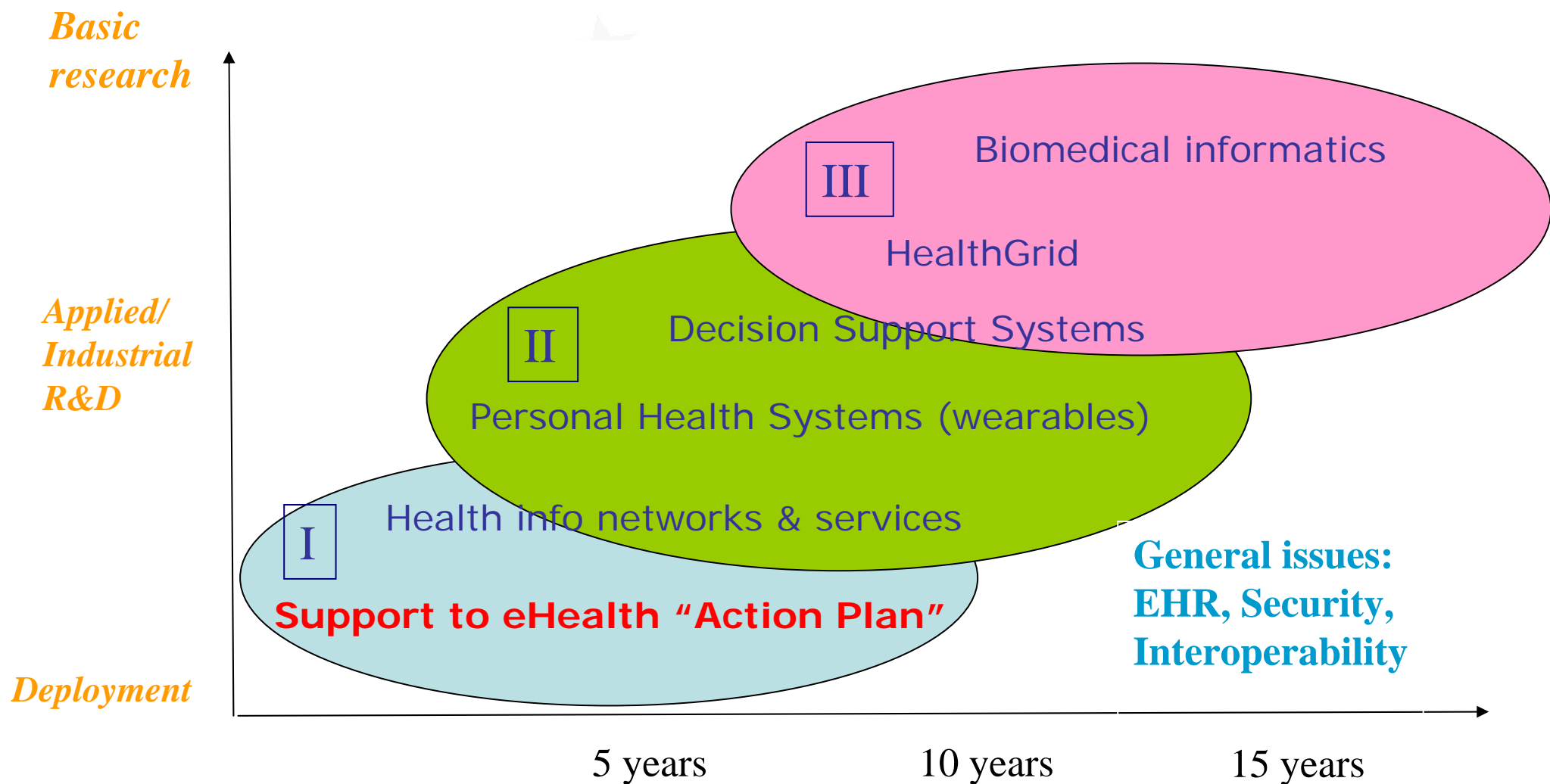


EuroRec Institute is coordinating partner
QREC has 12 partners and 2 subcontractors
(project duration is 30 months from 1 Jan. 2006 on)

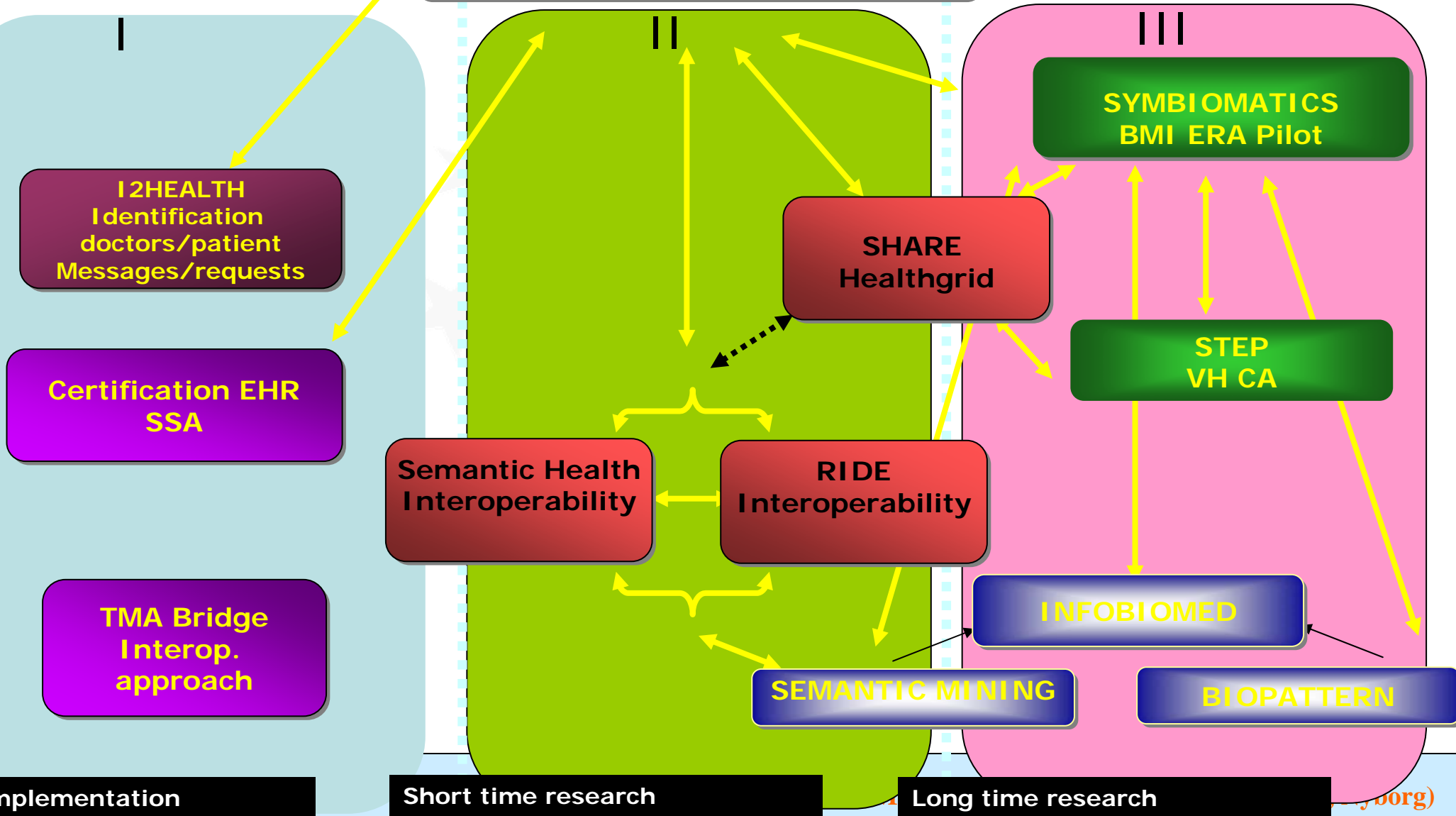
QREC: Coordination with Health Authorities

The coordination with healthcare authorities will be done through the collaboration with the eHealth ERA consortium and its European Health Care Authorities (HCA) Ministries Group that is co-ordinating with several national e-Health roadmap activities within the EU-Framework Programme.

Both platforms (EuroRec and eHealth ERA) will follow the necessary **bottom-up and top-down approaches** for the adequate assessment of needs and for the optimal choice of methods for *EHRs certification in Europe*.



eHealth ERA



QREC: ORIGIN

Several EU-member states (Belgium, Denmark, UK, Germany, ...) have already proceeded with (EHRs-) quality labelling and certification schemes, **but they differ** in scope, in **legal** framework under which they operate, in policies, in **organization**, in the choice of quality **conformance criteria** for benchmarking and testing...

*These differences represent a richness but also a risk of further market fragmentation: **harmonization efforts should help us to avoid this!***

EHRs Certification: the case of Belgium

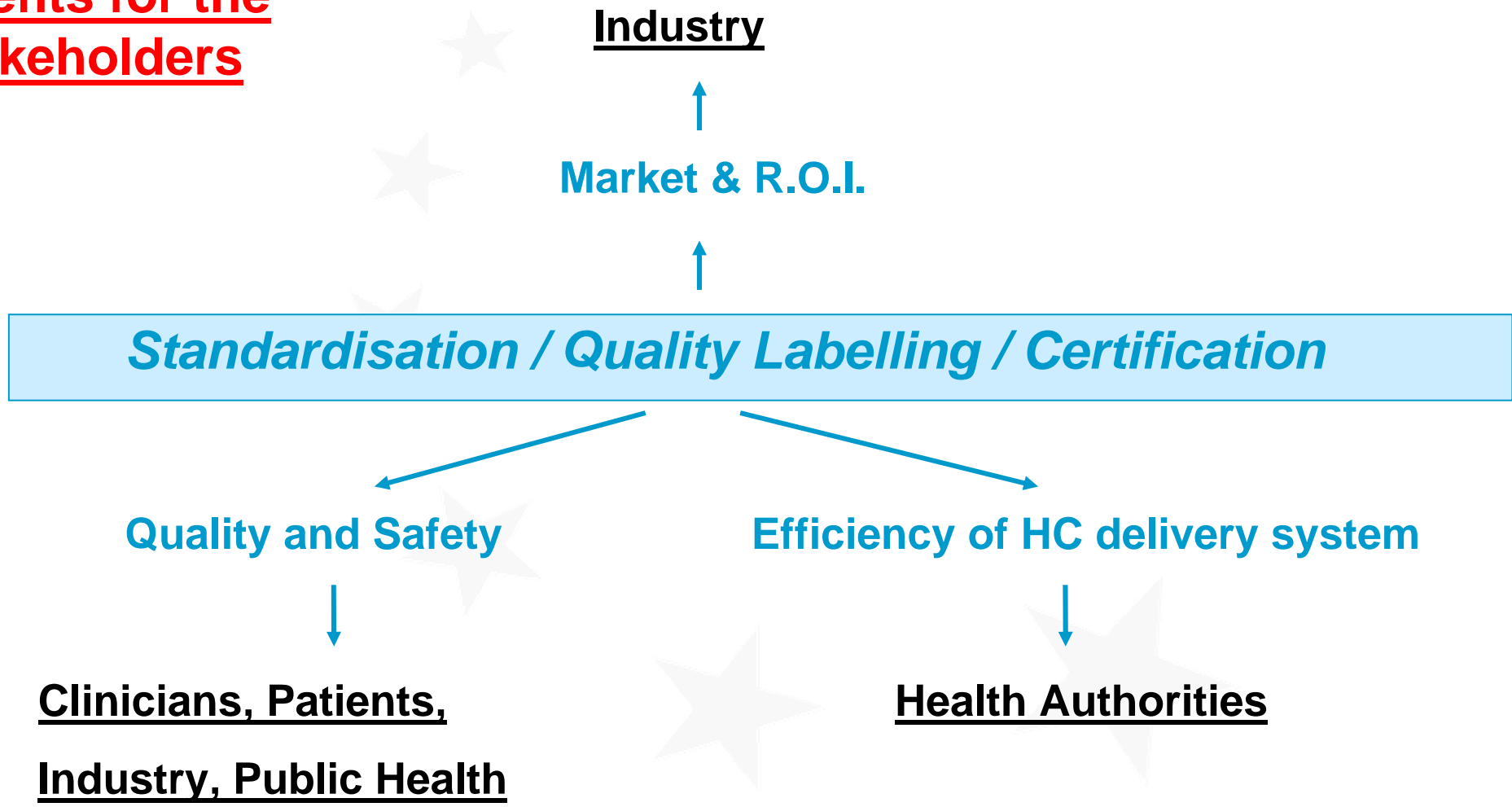
- Early 1998: PROREC Belgium develops a quality labelling system for EHRs in the ambulatory setting (**333** Quality Criteria defined)
- Belgian Ministry of Public Health and Social Affairs establishes a national Health Telematics Committee and implements the EHRs certification process in Belgium (May 3,1999):
 - the conformance criteria list is now reduced in size (about **100**)
 - the certification is a **voluntary one**, but is **incentivized** by legislation and budgets: GPs are actually paid when using certified systems (+/-**750 EURO/phys. /year**)
- The conformance testing (initially organized on a yearly basis) is now being conducted (since 2005) on a **permanent basis**



UK's NHS Connecting for Health proposal for GP system choice

- A multi-step accreditation process as to reach a minimum bar that will be progressively raised over time
- Funding from the national programme 
- New priorities and services being rolled out:
 1. Electronic Prescribing
 2. GP to GP record transfers
 3. Choose and Book services
 4. ...

Benefits for the Stakeholders



EHRs Certification: Expected Impacts

- to reduce EHRs investment risk for buyers/purchasers
- to open the European EHR market
- to guarantee better return on investment (ROI) for vendors
- to induce cost savings in healthcare
- to improve the quality of care and safety of patients
- to encourage patients to play a greater role in managing their own health information
- to provide valuable population health and research information
- to foster availability, accessibility, inter-operability and portability of the patient records no matter where the patients are located or are travelling...

QREC: Core Tasks (1)

1. Study of current EHRs « Quality Labelling and Certification » -systems: (State-of-the-Art Report)
2. Assay of the requirements amongst all stakeholders across Europe, covering both current and planned EHRs certification activities (Survey)
3. In-depth analysis of the ways to classify and profile EHR systems (Profiling and Indexing)
4. Comparison of various possible EHR certification systems (Methods)

QREC: Core Tasks (2)

5. Definition of a model (a common European **Template**) with harmonized guidelines and procedures for EHRs quality labelling and certification
6. Benchmarking process Manual for EHRs certification
7. **Business Plan**

QREC's short term strategy

1. Collect **criteria** from existing systems
2. Choose from the collected criteria a reasonable set of **high priority** ones (not the « lowest common denominator »-approach)
3. **Indexing** the criteria
4. Analyze how everything could interact within possible certification schemes
5. Warehouse the agreed guidelines and criteria
6. Streamline and automate the certification procedure
7. Validate the whole system through pilots

QREC: Concrete Results

The Quality Labelling system will act as a **filter**, enabling:

Potential buyers to express their **Needs** and requirements (including **Contexts of Use, EHRs modules,...**) and to find **Test Plans** with **Appropriate Scenarios and Criteria** against which a number of existing **EHRs** could be tested;

Vendors to check their own systems in order to get a quality label or certification and to plan **Further Development**.

QREC: Concrete Results (2)

The **buyers** and the **vendors** will thus become the main “clients” for the certification related services

The **end users** will be helped by clearing house activities of EuroRec (registries, inventories and other services...)

QREC: Main WorkPackages

**WP 1: Consortium Management, Project Co-ordination
and Quality Assurance**

**WP 2 : EHR systems Quality Labelling and Certification
Development**

WP 3 : Resources for EHR Interoperability

WP 4 : Benchmarking Services

WP 5 : Communication and Dissemination Activities

QREC: WP 3

WP 3 : Resources for EHR Interoperability

- T3.1 Register of **Conformance Criteria** and Guidance Documents
- T3.2 Inventory and Register of **EHR Archetypes** and Guidelines for their Use
- T3.3 Register of Health **Coding Systems** in Use in Europe
- T3.4 Inventory of Relevant **Standards** for EHR systems
- T3.5 Register of **XML Schemas** and Open Source Components for EHR systems

Interoperability: types

- **Technical interoperability**
 - **Organisational interoperability**
 - **Functional interoperability**
 - **Syntactic interoperability**
 - **Semantic interoperability**
 - **Political interoperability**
 - **Legal interoperability**
 - **Social interoperability**
 - **Inter-standard interoperability**
-
- **Many references (IDABC/EIF 2004, CEN/ISSS 2005, NAHIT 2005, TMA 2004, Miller 2000, ETSI 2005:3, LISI ...)**

Definition

Archetype (in eHealth):

An *EHR archetype* is an agreed, formal and interoperable specification of the data and their inter-relationships that must or may be logically persisted within an electronic health record for documenting a particular clinical observation, evaluation, instruction or action.

A uniquely identified, reusable and formal **expression of a specific health concept**,

expressed by means of an Archetype Definition Language and composed of descriptive data, constraint rules and ontological definitions.

Archetypes can be specialisations of other archetypes.

- *(It is not the goal of Q-REC to develop archetypes)*
- The goals are:
 - to identify high quality archetypes which will have been developed elsewhere and to make them available to a broader community
 - to develop formal methods of validating the design and content of archetypes
 - to develop a formal process of verification and certification for archetypes
 - to develop, in collaboration with the *openEHR* Clinical Review Board, an archetype repository

QREC: WP 3/ T3.3

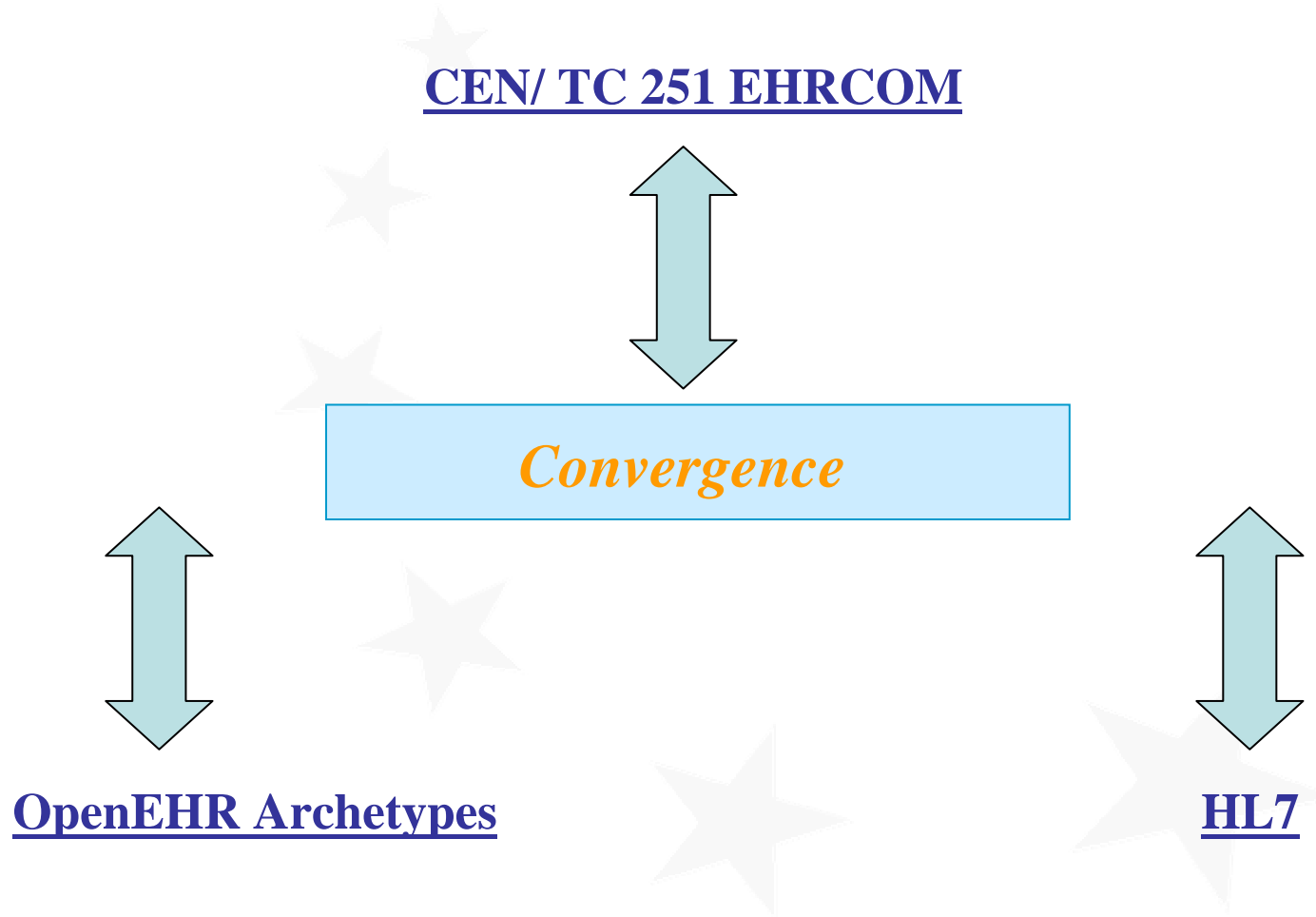
T3.3 Registration of Health Coding Systems in Use in Europe

Implementation of the European Standard EN 1068

EuroRec has been appointed as the Registration Authority and has been mandated by CEN/BT and /TC 251



Harmonization Efforts



QREC and Standards

- Although **standards** could be considered as the « DNA » of health records,
- the **QREC certification** will **not** be restricted to (technical) conformance testing against existing standards (which only are intermediary instruments to reach higher goals , i.e. optimal management of health)
- but QREC's approach will therefore be **pragmatic**, focusing on **functional criteria** directly related to the quality, safety, security, equity and efficiency of health(care) services

EUROREC: Communication and Dissemination (1)

Fostering a harmonised implementation of high quality EHRs will require promotion, awareness and organisation of educational events, hence :

- EuroRec Website and associated *services based on trustworthy resources* (to help purchasers, vendors and end-users)
- Tutorials on EHRs and Certification
- Workshops and Annual Conferences
- Liaison (with US, Canada, Japan, Australia...)

EUROREC's wish to liaise (example: with the US)

– Standards :

- **ANSI-HISB (Healthcare Informatics Standards Board)**
- **HL7 (CDA / Care Record Summaries)**
- **ASTM E31.28 Electronic Health Record SC (Continuity of Care Record)**

- Certification :

- **CCHIT (Certification Commission for Healthcare Information Technology)**
- **NAHIT (National Alliance for Healthcare Information Technology)**
- **AHIC (American Health Information Community)**

« Should we go Global? »: Questions

- Are the **business cases** for EuroRec, CCHIT, and others similar? What should be their **corporate goals**? (...to raise EHRs quality? ...not just to earn money?)
- Are the **EHRs markets** in the different regions of the world comparable? In Europe the EHRs market is highly regulated, fragmented (differences in languages, HC delivery systems, majority of companies are SMEs...)
- Is the **power** in the different regions at the same side? (vendors/US) (purchasers/Europe); how to strike the balance?
- What should be the procedure? Should certification be **required or only recommended** and thus organized on a voluntary basis?
- How to ensure credibility/authority: how **independent** should certification bodies be?

Preliminary conclusions?

- EHR systems Certification **bridges a gap** between the current marketplace and expectations from end users, from standards makers etc.
- Certification is challenging and should be a **gradual exercise**: it puts the bar for EHR systems higher and higher and thus pressure on vendors; they should therefore be involved to keep e.g. the chosen criteria at a realistic level
- Certification systems are not only about conformance criteria, but also about **processes** which should be very carefully **managed**
- We **can we learn from differences** (we must learn from each other)
- We should avoid unefficiency and overlaps in efforts; by joining forces at the global level we also will gain even more credibility amongst stakeholders...
- and is better **Health & its management** (ultimate goal) not a **global affair** ?

Thanks for listening!



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