Electronic Health Record Systems Certification: the European Perspective

presented by

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AGENDA

1. The EuroRec Institute
2. EHR-systems Certification: the QRec Project
3. Rationale for EHRs Certification
4. The EuroRec Repository:Methodology and Tools
5. The EuroRec Resources and Services for Interoperability
6. Forthcoming Events
7. Questions and Answers

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EuroRec (http://www.eurorec.org)

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

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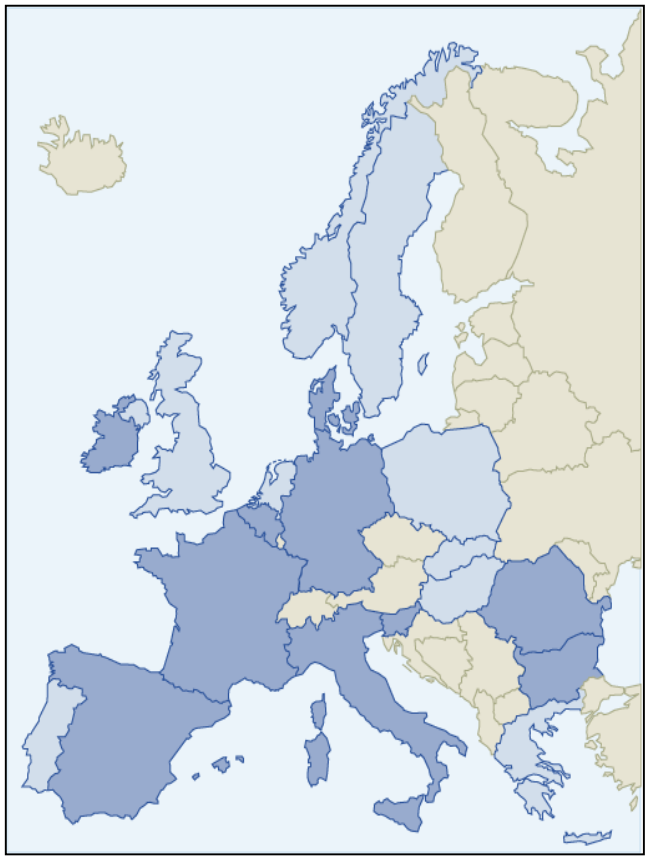
ProRec Centers



Centres	Applicants
Belgium	Norway
Bulgaria	Greece
Denmark	Hungary
France	Portugal
Italy	Poland
Germany	Sweden
Ireland	The Netherlands
Romania	Slovakia
Slovenia	United Kingdom
Spain	

" Differences in languages, cultures and HC-delivery/funding systems "

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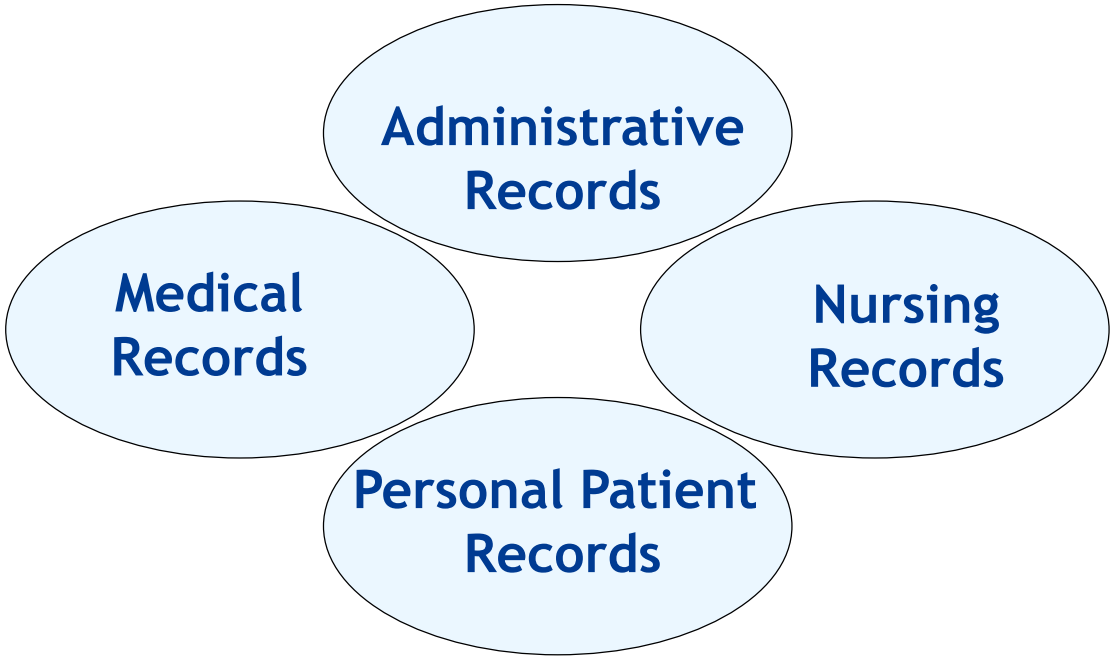
EHRs: TRENDS

EHRs start to become:

- transmural, virtual
- multidisciplinary and interactive
- longitudinal and intelligent



! Integration with other eHealth applications ...!

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Current EuroRec EU-funded 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)

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QREC's Objective

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

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EuroRec Institute is coordinating partner
QREC has 12 partners and 2 subcontractors
Project duration is 30 months (1/1/2006-30/6/2008)

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QREC: ORIGIN

Several EU-member states (Belgium, Denmark, UK, Ireland, …) have already proceeded since years with (EHRs-) quality labelling and/or certification (more often in primary care) ***but these differ*** in scope, in **legal** framework under which they operate, in policies and **organisation**, and perhaps most importantly in the quality and **conformance criteria** used for benchmarking …

These differences represent a richness but also a risk: ***harmonization efforts should help to avoid further market fragmentation in Europe***

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Central Repository

EuroRec will act as a central repository of **validated quality criteria** and other relevant materials that can be used to harmonise European testing, quality labelling and procurement specification of EHR systems.

*It will **not impose particular certification models** or specific criteria on any member country but will foster, via ProRec centres and other channels, the progressive adoption of consistent and comparable approaches to EHR system quality labelling.*

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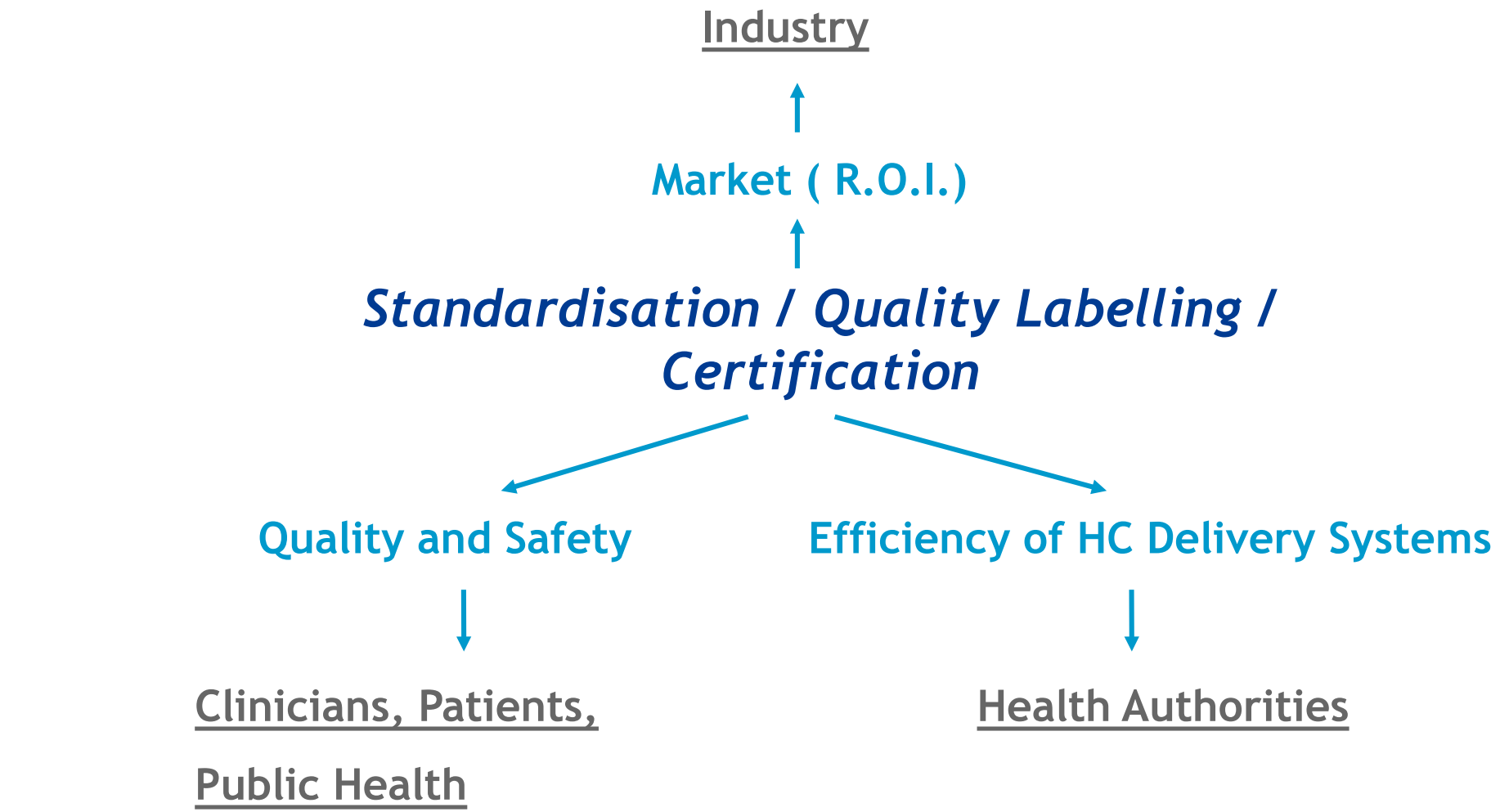
Benefits for the Stakeholders



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Q-REC Rationale –Certification is Essential

To assure the quality of EHR systems, e.g., patient safety may be at risk due to:

- system design, specification and functional inadequacies,
- poor or confusing presentation of clinical relevant information.

Sharing of information requires a quality assessment of EHR products with a view to ensuring interoperability with other systems because:

- healthcare information, in particular clinical information, is often scattered over a number of informatics systems
- the structures of these EHRs may significantly differ from one system to the other, depending on the creator and the purpose.
- more and more incentives are being given to share patients' medical data to support high quality care and "continuity of care" in a seamless way.

Certification of EHRs is essential for purchasers and suppliers

- to ensure that EHR systems are robust enough to deliver the anticipated benefits as EHR systems and related product quality (data portability and interoperability are difficult to judge).
- To reduce the risk for purchasers and therefore accelerate the adoption of high quality and more interoperable EHRs.

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The EuroRec Repository: Introduction

- The Q-Rec repository will comprise several kinds of artefact relating to the quality labelling and benchmarking of EHR systems:
  - **EHR system requirements**
  - **EHR system conformance criteria**
  - EHR system test plan items
  - An inventory of quality labelled (certified) EHR systems
  - An inventory of EHR related standards
  - An inventory of terminology and coding schemes
  - A directory of certified EHR archetype repositories
  - A directory of reviewed open source specifications and components

The year 1 priority

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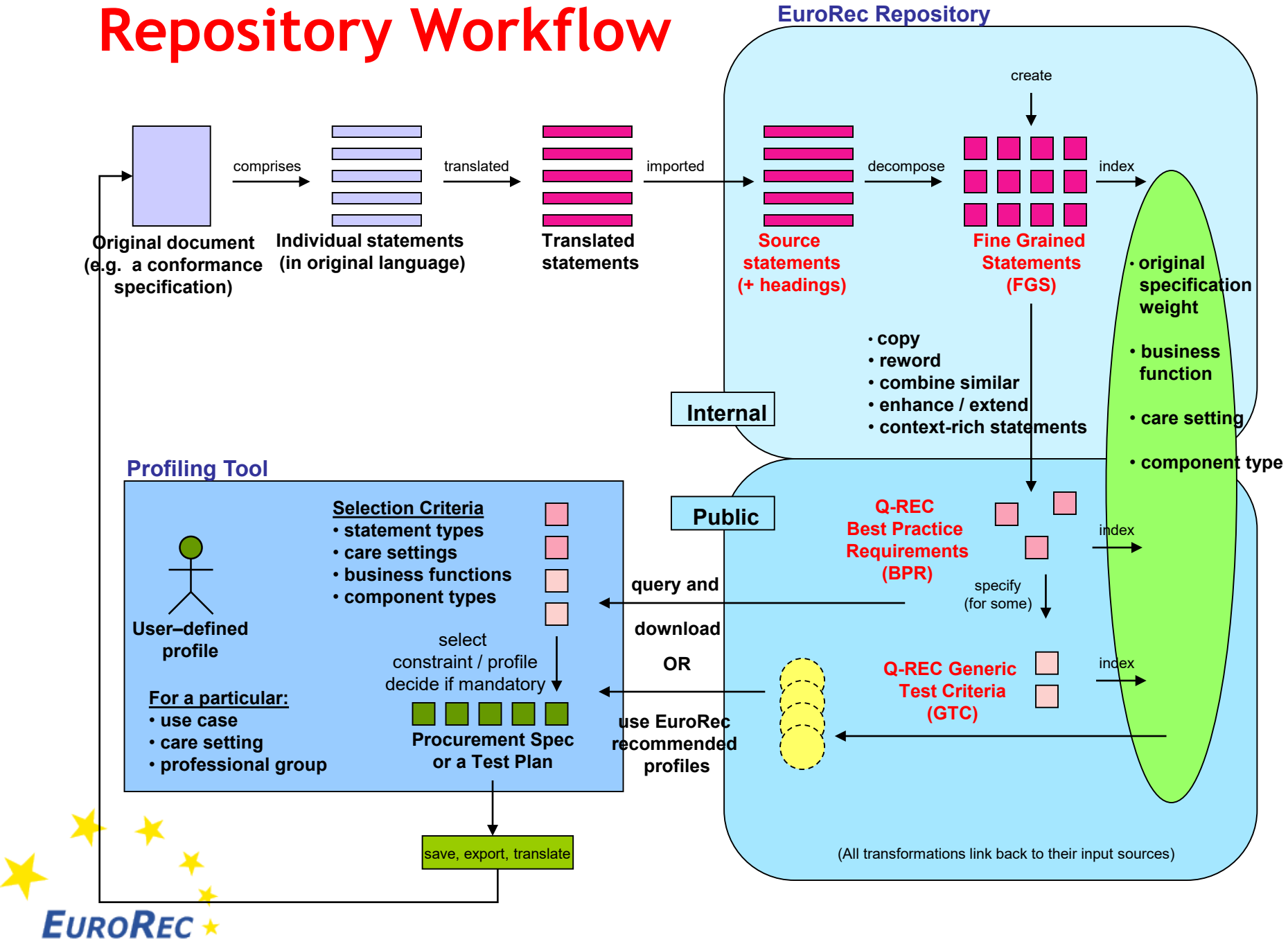
Repository Workflow



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EHRs Criteria: Business Cases

- A **purchaser** wishing to procure an EHR system module
- An **e-Health programme** wishing to ensure consistent EHR system functionality nationally
- A **vendor** wishing to (re-)develop an EHR system module
- Developers wishing to interface to a given EHR system module across multi-vendor systems
- All may be:
  - seeking design guidance
  - wishing to obtain quality labelling certification
  - searching for trustworthy products

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Example Use Cases for the Repository

- For a given **EHR system module**, to
  - browse the functional criteria
  - query for specific requirements or criteria
  - extract (download) the full set of criteria for the module
    - to put into a procurement specification
    - to use in order to develop a local test plan
- For a given **care setting**
  - identify which modules are relevant
  - choose which requirements are of greatest local relevance
  - find certified suppliers that meet these

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Other Repository Requirements…

(Obtained from stakeholder interviews and events)

- Focus primarily on **pragmatic** (de facto) requirements
- Keep **aspirational** (best practice) ones separate
- Do **strip out** very particular **national** phrases
- **Reference** the statements to their original sources
- **Cross-index** them against all likely usage scenarios
  - i.e. be inclusive when indexing
- An **English language** only version will initially be fine

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Methodology for the Repository Design

1. Typology of EHR system statements
2. Generic information model for the repository
3. Design of indices (ontology)
4. Planning of the repository management workflow
5. Design of the web-based user interface requirements

- Review of other relevant work of this kind
  - e.g. HL7, CCHIT, ISO TC/215, academic work
- Learning from early iterations of statement classification
- Testing of the pilot repository

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Typology of EHR System Statements

- Source Statements
  - faithfully extracted from original EHR system specifications and test plans
  - translated if necessary
- Fine Grained Statements (FGS)
  - usually derived from source statements
  - made more generic, decomposed, reworded, corrected
- Best Practice Requirements (BPR)
  - recomposed from FGS into the more common useful building blocks
  - may enhance or extend the scope of FGS: “push the boat out a bit”
- Generic Test Criteria
  - derived from FGS and/or BPR
  - formally worded as testable functions

The system calculates a date for the delivery on the basis of the date of the last menstruation

- Too specific, and complementary requirements were not found in the source materials
- Need to meet the clinical requirements

- The system must be able to calculate the expected date of delivery on the basis of the date of the last menstrual period
- The system must be able to document the expected date of delivery on the basis of one or more sources of evidence
- The system must be able to note which source of evidence for the expected date of delivery is considered to be the most trusted in a given patient for clinical management purposes

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The system offers the possibility to group medical data in SOAPT headings, in order to facilitate their display

- Need to expand SOAPT to Subjective, Objective, ... for clarity
- This requirement can only be enforced for display if the data are captured or mapped to these headings

- The EHR system must offer the option for authors to enter data under standard clinical headings: "Subjective, Objective, Analysis, Plan, Treatment", or their equivalent
- The EHR system must provide the ability to display data under the standard clinical headings: "Subjective, Objective, Analysis, Plan, Treatment", or their equivalent, if the EHR data is represented under, or can be mapped to, such headings

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The system should list of generic medication sorted by the cheapest product first

- **Change a national mandatory stipulation into a more generic feature option**

- The EHR system should *enable a* list of generic medication *to be* sorted by the cheapest product first

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Indexing the statements (1)

- **Multiple indexing of each statement**
  - to maximise the likelihood of finding all relevant statements when searching via the indices

1. **Business Function** (50 in 8 subcategories)
2. **Care Setting** (18 in 3 subcategories)
3. **Component Type** (18 in 4 subcategories)

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Indexing the statements (2)

- **Indexing the source artefact**
  - so that users know the "strength" and jurisdictional acceptance of each original criterion

1. **Specification weight** (11)
2. **Specification function** (17)

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Repository Information Model Requirements

- Version management
  - identifiers, time-stamping, ratification status, versioning
- Attribution
  - authorship, review, comments
- Traceability
  - backward references to source materials
  - cross-references between statement types
  - reference to publication organisations and country
- Translation
  - ability to link translated versions of statements

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User Interface Requirements

- For Q-REC repository managers
  - Manage users and authorisations
  - Enter or importing statements
  - Maintain indices
  - Manage cross-references
- For Q-REC classifiers
  - Search for statements using multiple index terms
  - Index statements
  - Cross-reference similar statements
  - Compose new FGS or BPR based on existing statements
- For end users (not yet implemented)
  - Browse statements through EuroRec Profiles
  - Search for statements using multiple index terms
  - Export query results
  - Save personal profiles and searches

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List of Fine Grained Statements

Select a Fine Grained Statement by:

Detailed search down: password AND AND

View all

Drill down via the indices:

Business Functional Indices: No selection **OR** Care setting Indices: No selection

Search

	ID	Fine Grained statement
select	2201	The system enables variable **password** strength according to length and type of characters
select	2206	The system enables to reset or change a **password**
select	2207	when a **password** has been reset, the user shall change the **password** at the next logon before being able to continue
select	2211	The system enables a user to change his **password**
select	2212	**Password**s to log into the system are case-sensitive
select	2213	**Password**s are case sensitive
select	2214	**password**s are not stored in readable format
select	2215	The system enables to enforce the security policy statements relating to re-use of **password**s
select	2216	Security Policies contain rules for **password** life cycles
select	2224	**Password**s are never communicated in plain text
select	2225	**Password**s are not displayed during entry

Result of the search on “password”

A0 - EHR data (record) management															
A00 - EHR Data Entry															
QREC-ID	FGS	A0	A00	A01	A02	A03	A04	A05	A09	A1	A10	A11	A12	A13	A14
		DATA	entry	analysis	content	struct.	display	export	generic att	CL. FUNCT	medication	statements	assessment / measur.	care plan.	shared care
GS001549.01	The system enables to enter medication items.		A00		A02						A10				
GS001551.01	The system records prescribing medication.		A00		A02						A10				
GS001552.01	Prescibing medicinal products results in recording or updating a medication item.		A00		A02						A10				
GS001560.01	A medication item can be entered by an authorised user other than the prescriber.		A00								A10				
GS001577.01	The system provides a coded list of medicinal products.		A00								A10				
GS001648.01	The system accepts and integrates medication items from an external source.		A00								A10				A14
GS001665.01	The system enables to set required fields to enforce generation of a complete prescription.		A00					A05			A10				A14
GS001683.01	The system enables to reorder a prior prescription without re-entering previous prescription data.		A00								A10				
GS001697.01	The system enables the use of fractional amounts of medicinal product units in an dosing scheme.		A00		A02						A10				
GS001867.01	The system stores renewals notifications provided by the pharmacy.		A00		A02						A10				
GS001868.01	The system stores inquiries done by the pharmacy.		A00		A02						A10				
GS001869.01	The system stores fill notifications done by the pharmacy.		A00		A02						A10				
GS002101.01	The system enables to reply to a request for a refill from a pharmacy		A00					A05			A10			A13	A14

Management-Tools (Excel Table)

Q-REC Services

1. An Inventory of Certification Criteria for EHR Systems

- Introduction

- Preliminary list of EHR certification criteria
- The EuroRec/Q-REC repository of certification criteria **(under construction!)**

2. An Inventory of Standards relevant for EHR Systems

- The role of standards
- Why does EuroRec publish this inventory of standards relevant for EHR systems?

- List of EHR standards
- List of standardisation bodies
- Q-REC-Eurorec overview on EHR standards 01 (.doc)

3. EHR Archetypes

- Background

- White paper: Archetype paradigm: an ICT revolution is needed (.pdf)

4. EHR Tutorials

- About the Q-REC EHR tutorials

- The tutorials

5. Open Source Components and XML Schemata

- Background

- View the forms

6. Register of Health Coding Systems in use in Europe

- Background
- Motivation
- A European standard for the registration of coding systems
- Disclaimer

- View the forms

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Definition

Archetype (in eHealth):

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 specializations of other archetypes.

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Upcoming Events 2007

- Archetypes, A Two Days Course (Leiden) 29-30 March, 2007
- EHR Com EN 13606 Hands on (Brussels) 4 April, 2007
- **eHealth Conference 2007 "From Strategies to Applications" (Berlin) 17-19 April, 2007**
- EHTEL Conference 2007 "3C Challenges and Opportunities" (Rome) 24-25 May, 2007
- RIDE Workshop "Roadmap to Interoperability" (Istanbul) 6-7 June, 2007
- International Council for Medical Care Compunetics ICMCC (Amsterdam) 8-10 June, 2007
- International Conference on Computers in Medical Activity (Lodz) 19-21 September, 2007
- **World of Health IT (WHIT/HIMSS) (EuroRec Annual conference) (Vienna) 22-25 October, 2007**
- AMIA Conference 2007 (Chicago) 10-14 November, 2007

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LIAISON (example with the US)

Certification:

CCHIT (Certification Commission for Healthcare Information Technology)

Policy:

US Health and Human Services Department

(! EU-US Policy Workshop,May 10,2007)

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Questions

- Are the **business cases** for EuroRec, CCHIT,and others similar? What are their corporate goals ?
- 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 **decision 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 organised on a voluntary basis?
- How to **ensure credibility/authority**: how independent should the bodies implementing certification be?

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Thank you for your attention!

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