European Standardization of Health Informatics

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Content

- Perspectives on the benefits of standards for health on-line
- Overview of CEN/TC 251 work
- Collaborating international bodies

A business which also takes care of people

Knowledge

Patient history

Treatment plans

Outcomes

Information management is central to modern healthcare

Laboratory

Staff

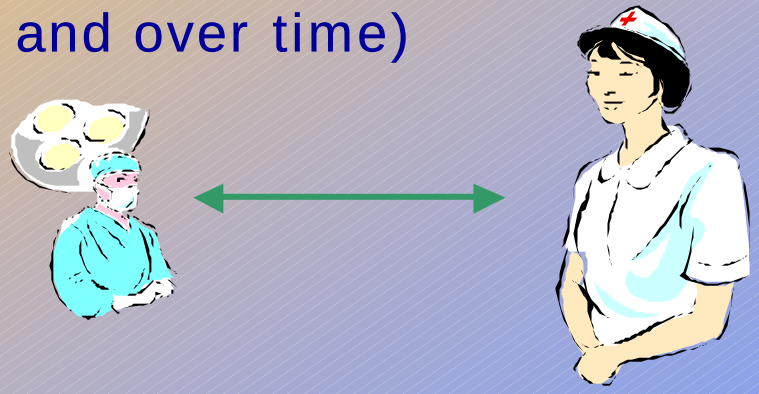
Financial

Referrals

Supplies

Managing information is largely about communicating

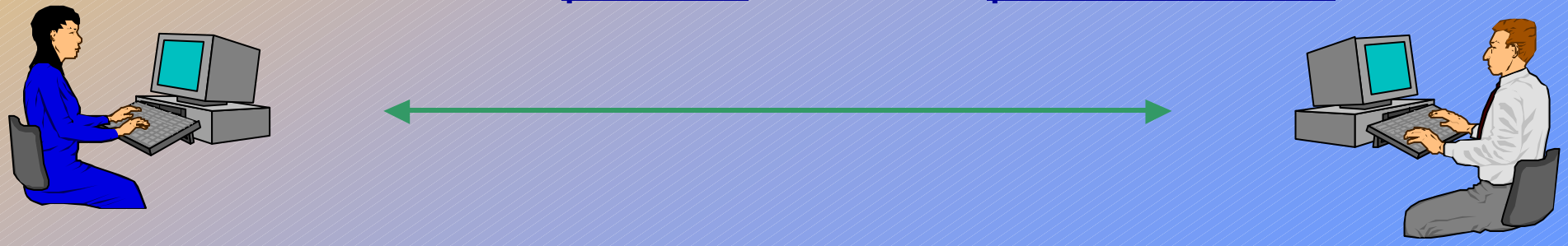
- between different staff members within a unit
  (multiprofessional teams and over time)



- between units

GP ⟷ Hospital

- between the patient and the professionals



A Communicating Health System

- All health information is made available for continous care
- Knowledge based systems are interacting with patient data
- Effective co-operation between professionals
- Active patients are a part
- All patient cases can be used to generate new knowledge

Standards are Essential for enabling Health on-line

- Improve Efficiency by enabling Professional Co-operation in new ways
- Facilitate Integration of modular systems from different suppliers
- Lower costs and facilitate procurement
- Support Quality Management and Research with aggregated data

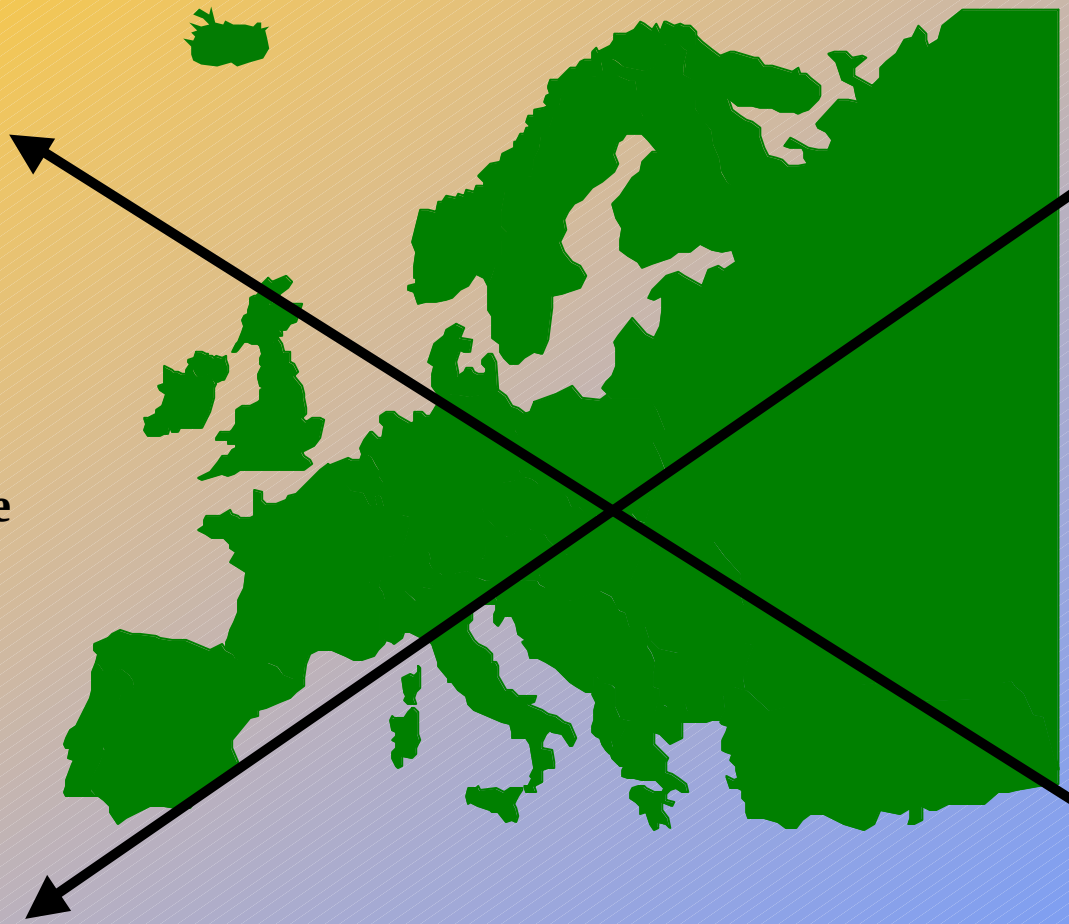
eEurope -

An Information Society For All

The Action Plan of the European Commission includes Health on-line as one of the key areas:

> **" To develop an infrastructure of interoperable systems for medical care, disease prevention and health education through national and regional networks which connect citizens, practitioners and authorities on-line."**

Standards
a Key to Interoperability



Primary care

Secondary care

Community care

Pharmacies

Laboratories

Insurance bodies

National/regional planning for public health

Research

Patients

Standards should exist, be validated, well-known and implemented by major actors to enable:

- The transfer of most types of patient centered information between all European healthcare organisations including complete health records, medicine prescriptions, referrals and results of all types of investigations performed.
- Support of multimedia communication for the above purposes and including direct videoconferencing
- The safe integration of also wireless medical devices of all types capable of information provision or in need of computer control from external health systems.

Standards requirements continued:

- The integration of various knowledge sources available cross-border in multilingual form with the patient centered health information systems
- To meet the security requirements for confidentiality, integrity (including electronic signatures added to various document parts), availability and accountability.

Standards requirements continued:

- To allow interoperability and where appropriate, policy bridging to ensure that security, including access control between healthcare organisations also cross-borders with pan-European recognition of digital certificates of professional qualifications and registration.
- This should also allow the patient in his home using internet and appropriate security techniques to be directly accessing health professionals and data pertaining to the patient.
- The build up of appropriate quality control measures with in certain cases appropriate third party testing and certification of the health information systems to protect patient safety and to ensure interoperabilty of products

Different reasons to want standards for different actors

- Healthcare providers (Hospitals, doctors and other professionals)
  - Enable interoperability between different units and systems to increase efficiency of care
  - Lower costs for buying systems by having a large competitive (international) market
- Systems suppliers (software companies)
  - Enable the provision of modular systems where one product can tie into the total needs of the customers
  - Large market for their ”standard” product – less maintenance problems than with customer specific special solutions

Standards and authorities

- Public health authorities in many countries sees standards as an important way of increasing the efficiency of the sector
  - Leading to better quality with minimum resources. In many western countries healthcare expenditures are not increasing anymore
- Standards enable the collection of statistical information for surveillance and planning purposes
- Standards for Informatics may help the authorities to excert quality control of health care information systems and medical devices. We are moving towards certification of software.

Standardization

Activity of establishing, with regard to actual or potential problems, **provisions for common and repeated use**, aimed at the achievement of the optimum degree of order **in a given context**

Definition from ISO/IEC Guide 2

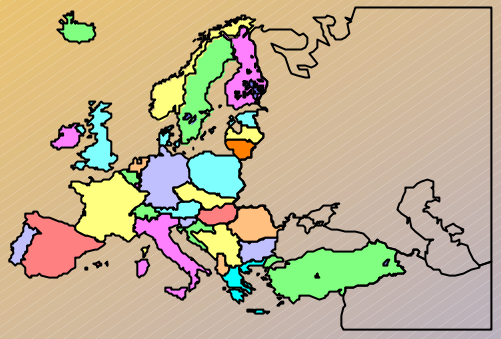
The context

- Karolinska Hospital
- Stockholm region
- Sweden
- Europe
- The World

In Europe we decided in 1990 that many of the issues that needed standards for health infor[illegible] would best be solved on a European scale rather than national

There was no international work and it was felt that there was a need to support **one internal market** for IT products in all of the European Union.
There is also a large number of citizens moving between these countries for work, studies and vacation.
Interoperability of health information systems was desired

Standardization of Health Informatics in Europe



CEN = Comité Européen de Normalisation
European Committee for Standardization

22 EU and EFTA countries are members + candidate observers

CEN / TC 251

Technical Committee on Health Informatics

Secretariat is managed by SIS - Swedish standards institute

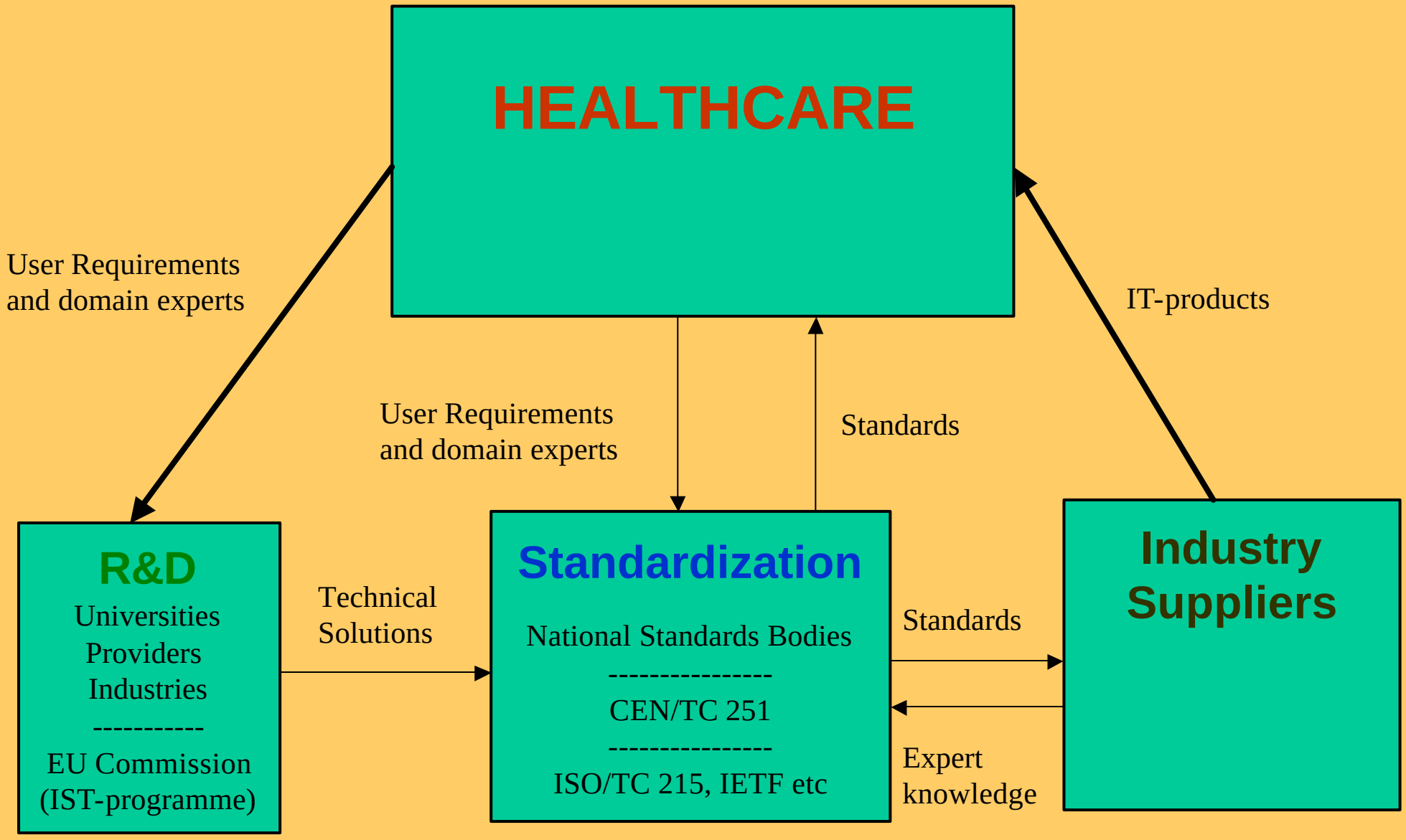
www.centc251.org

A political mandate

and financial support from EU and EFTA

- EU and EFTA policies have given CEN a mandate to produce standards for Healthcare Informatics in Europe
- A small funding from CEC mainly for co-financing of project teams and central co-ordination. 1998-2001, 500 kEUR/year
- European funding has been extremely important in speeding up the process

Development of standardized IT solutions



CEN / TC 251
working groups and convenors

- I: Information models
  - Gerard Freriks, Netherlands
- II: Terminology and knowledge bases
  - Göran Holmberg, Sweden
- III: Security, Safety and Quality
  - Gilles Trouessin, France
- IV: Technology for interoperability
  - Melvin Reynolds, UK

Working Group I: Information Models

- Electronic Health Records
- General Purpose Information Components
- Messages for various purposes including e-prescriptions
- Service architecture for health information interchange
- Patient Data Cards

ENV 13606: 1999

- **Health informatics - Electronic healthcare record communication**
  - **Part 1: Extended Architecture**
  - **Part 2: Domain Termlist**
  - **Part 3: Distribution Rules**
  - **Part 4: Messages for the Exchange of Information**

Electronic Health Record Standards Development

- EN 13606 Task force is working under the leadership of Dipak Kalra
- The prestandard is developed based on existing experiences and the new ideas on a dual model approach
  - A reference information model
  - A template / archetype for specific uses
- Collaboration with the Open Electronic Health Record Foundation

Health informatics - General Purpose Information Components

Part 1: Overview

Part 2: Non-clinical information

Part 3: Clinical information

These use: **Health informatics – Data types**

- This is an essential core for all future information models in CEN for Messaging, Records and HISA.
- This is a result of the harmonisation with HL7
- GPICs has been submitted to ISO

- Service request and report messages – Part 1: Basic Services including referral and discharge Now RFC

EN 12967-1

- **Health informatics – Service architecture**

  Part 1: Enterprise viewpoint
  Part 2: Information viewpoint
  Part 3: Computational viewpoint

- **The revision is based on the existing ENV (HISA) and the Short strategic study Health Information Infrastructure. The model is using ISO / IEC 10746 Open distributed processing – reference model as a basis for the description.**

Working Group II:
Terminology and Knowledge bases

- Semantic organisation of information and knowledge
- Terms, concepts and interrelationships of concepts
- Guidelines for the production of coding systems and knowledge bases
- Systematisation of the semantic structure behind the names of compositions and headed sections of the health care record

Working Group III:
Security, Safety and Quality

- Guidelines for management of security for health
- Detailed protocols for various core security services based on inter-sector standards.
- Data protection in the context of the EU data protection directive, particularly for communication outside of Europe.
- Access control policy bridging and systems for Anonymisation.

Working Group IV: Technology for interoperability

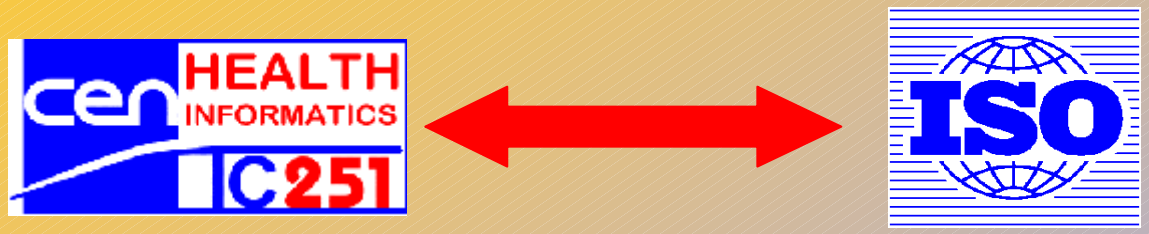
- **Intercommunication of data between devices and information systems**
  - **including clinical analysers, medical imaging and Intensive Care Unit equipment**
- **Integration of data for multimedia representation**
- **WG IV has an important collaboration with IEEE and ISO/TC 215 for Point-of-Care Medical Devices and with DICOM for imaging**

ISO - collaboration with CEN

ISO/TC 215 Health informatics was established in 1999 proposed by the US but with strong support from Europe

Vienna agreement between CEN and ISO

- There are many examples with thousands of standards processed in collaboration between CEN and ISO.
- The Vienna agreement intends to
  - Avoid duplication of effort and divergence
  - Allow parallel voting process where feasible
- In health informatics a number of European prestandards ENVs have been the starting point for ISO/TC 215 work items
  - Vienna agreement allows the improved ISO documents to be processed in parallel as full European standards.



- CEN/TC 251
  Health Informatics

  - WG I Information Models
  - WG IV Technology for Interoperability
  - WGII Terminology and Knowledge Bases
  - WG III Security, Safety and Quality
  - Task Force Cards

- ISO/TC 215
  Health Informatics

  - WG 1 Health Records and Modelling Co-ordination
  - WG 2 Messaging and Communication
  - WG 3 Health Concept Representation
  - WG 4 Security
  - WG 5 Health Cards

ISO - CEN joint work programme

Collaboration with IEEE

Point-of-Care medical device communication – Framework and overview

Point-of-Care medical device communication – Transport profile - cable connected

Point-of-Care medical device communication – Physical layer - Cable connected

Point-of-Care medical device communication - Transport profile - IrDA based protocol

Point-of-Care medical device communication - Nomenclature for vital signs devices

Point-of-Care medical device communication – Domain information model for generalised virtual medical devices

Point-of-care medical device communication - Device specialization - Framework and overview

Point-of-care medical device communication - Device specialization - Vital signs monitor

Point-of-care medical device communication - Device specialization - Pulse oximeter

Point-of-care medical device communication - Device specialization – Defribrillator

Point-of-care medical device communication - Device specialization – ECG

Point-of-care medical device communication - Device specialization - Blood pressure

Point-of-care medical device communication - Device specialization - Temperature

Point-of-care medical device communication - Application profiles - MIB elements

ISO - CEN joint work programme

Health informatics - Guidance on data protection in applications involving transfer of personal health data in across national borders

Health informatics - Clinical analyser interfaces to laboratory information systems

Health informatics – Integration of a reference terminology model for nursing

Health informatics - Vocabulary for terminological systems

Health informatics – Data types

Health informatics –General purpose information information components – Part 1: Overview

Health informatics –General purpose information information components – Part 2: Non-clinical

Health informatics –General purpose information information components – Part 3: Clinical

ISO - CEN work programme

ISO/TC215 WORK ITEM	CEN/TC251 WORK ITEM
Health informatics - Patient healthcard data - Part 1: General structure Part 2: Common objects Part 3: Limited clinical data Part 7: Electronic prescription	Revision of published ENV 12018 Now as an EN renamed: Health informatics - Patient healthcard data - Part 1: General structure Part 2: Common objects Part 3: Limited clinical data Part 4: Extended clinical data Part 5: Identification data Part 6: Administrative data Part 7: Electronic prescription Part 8: Linkage and reference data
Machine readable cards- Healthcare applications - Cards: General characteristics	EN 1387: Machine readable cards- Healthcare applications - Cards: General characteristics
Machine readable cards- Healthcare applications - Numbering system and registration procedure for issuer identifiers	EN 1867: Machine readable cards- Healthcare applications - Numbering system and registration procedure for issuer identifiers

ISO/TC 215 still only in the beginning of something very important

- Many core areas dealing with information for specific messages or record structures have not been even started in ISO.
  With a few exceptions in the PoC and Pki area there are no ISO standards available that can be used for implementations yet.

- There is a continued need for work in some areas on a European scale and not the least nationally (e.g. to produce implementation guides of EN and IS)
- ISO/TC 215 is an important vehicle for establishing international consensus

Global standardization of health informatics is welcomed by Europe because:

- Joint work of the best experts of the world improves the quality of our standards
- The market for industrial products (soft and particularly hard) should be more and more global although it must be recognized that for different reasons many systems are developed for national markets only
- There is an emerging requirements for cross-border communication of health information which we want to support
  - BUT this need is still almost non-existent globally and small even within Europe