



ISO and HL7

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International Standard Makers

- ISO TC 215 – Health Informatics
- Europe's CEN TC 251
- HL7 International
- DICOM International
- IEEE International
- CDISC
- International Healthcare Terminology SDO



Why do it?

Benefits of Cooperation

- Reduction of redundant/overlapping standards
- Dealing with limited experts and resources
- Better use of existing resources
- More cohesive integration of domain experts with basic technology
- Easier integration of standards due to consistency based on common data model



Why Do it?

Benefits of Cooperation

- Create standards faster from concept to delivery
- More complete requirements specifications because of different perspectives
- Share common tools for standards creation and implementation
- Starting global is easier, technically and politically



Barriers to collaboration

- Creating standards is inherently competitive
- Volunteer-driven with biased views on what is needed or willing to work on
- Protection of status quo and existing investments
- More organizations mean more leadership positions
- Nationalistic views



Barriers to collaboration

- Differences in balloting, work processes, publication model
- Pressures of single stakeholder community
- Fear of loss of control in what standards are produced
- Differences in priorities and what is important
- Intellectual property issues; copyright issues; sales of standards issues



Early approaches to cooperation

- SDO to SDO agreements
 - Vienna Agreement: CEN and ISO
 - Partner Standards Development Organization: IEEE and ISO
 - Pilot Project: HL7 and ISO
- DICOM has Liaison D status with ISO and participates through ISO Working Group 2
- MOU between and among most SDOs



HL7 to ISO: Pilot Project

- Methodology Development Framework
- Reference Information Model
- Clinical Terminology Services, R1
- V2.5 Messaging Standard
- Clinical Document Architecture R2
- EHR-Functional Model
- Clinical Genomics - Pedigree



What did not work

- Individual Case Safety Report
- Structured Product Labeling
- Annotated ECG
- Electronic Submission of Stability Data



CEN-ICH-HL7 Regulatory Standards

ICH

Electronic Common Technical Document

Product Information Management Data Exchange

Individual Case Safety Report

Medicinal Product Specification

Medicinal Vocabulary Message

Application Form

HL7 ANSI

Regulated Product Submission

Structured Product Labeling

Individual Case Safety Report

Structured Product Labeling

Work underway – trial set, not balloted

Regulated Product Submission



CEN to ISO

- CEN 13606, parts 1-5: Electronic Health Record Communications
 - Reference model
 - Archetype interchange
 - Reference archetypes and term lists
 - Security
 - Exchange models
- Health Informatics Service Architecture



Joint Initiative Council

- Environment in which standards are developed jointly among participating SDOs
- Goal is one standard for one business case
- One SDO acts as host with project lead; participating SDOs provide co-chair
- Work may be done in multiple settings
- Resulting work is balloted across each group simultaneously; comments dealt with collectively
- Publication of standards will identify all participating SDOs and will be available from each SDO.
- JIC restricted to chairs of each SDO plus two alternate representatives



Joint Initiative Council

- Charter Members
 - CEN TC 251
 - HL7
 - ISO TC 215
- Later members
 - CDISC
 - IHTSDO (probationary)
- Potential Members
 - LOINC
 - IEEE



Projects for joint work

- Data types – in publication
- Individual Case Safety Report – in ballot
- 13606-1/HL7 v3 Implementation Guide
- Glossary Project
- BRIDG
- Identification of Medicinal Products (IDMP)
- Clinical Trial Registration and Result – CTRR (proposed)



Process to submit work

- Template for proposing JIC project
 - Available from any participating SDO
- Includes definition of scope (very important)
 - What is not covered as well as what is covered
- Justification and global interest
- Participating SDOs
 - Identify project identity in each SDO
 - Level of commitment
- Identify Host SDO, each SDO leads
- Identify deliverables, time line



Future

- Global acceptance of HL7 RIM as THE Reference Information Model
- International: all global standards done as JIC projects
- U.S.: Use HL7 CDA as technical document or container. Other SDOs become domain experts and define content and IG for CDA. SDOs retain identity, membership. Result is a single coordinated set of alike standards meeting needs of each domain.
- The future looks brighter!

