GLOBAL HEALTH INFORMATION TECHNOLOGY SDO HARMONIZATION

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APAMI

AGENDA

- Background

- Structure

- Work Process

- Current status

- Issues and future

- Conclusion

EMERGING BUSINESS PARADIGM

EVOLUTION OF BUSINESS STRATEGY

- Innovation on product, process, service and business model is essential to business success.
- Supply chains are becoming more global, more exclusive, and more competitive.
- Technology advances will continue to be both incremental and disruptive. Adoption rates at smaller firms still lag those of larger ones.
- Sustainability is rapidly becoming the overarching business driver for industry. Whether it is simply a response to rising energy and resource costs or as a corporate growth strategy, sustainability is a struggle to balance economic, environmental, and societal challenges and opportunities.

[NIST MEP, Dec. 2008]

APPROACH TO SUSTAINABLE BUSINESS

- Support for energy efficient production
- Support for production of alternative energy

Providing:

- Process improvements (lean and clean, energy efficiency, and supply chain)
- Waste minimization (green design, cradle to cradle, waste to profit, and packaging and distribution)
- Growth (new technologies, modifying existing capability to meet emerging needs, and increasing manufacturing capacity in US)
- MEP has manufacturing clients working in fuel cells, solar, wind turbines, composite

[NIST MEP, Dec. 2008]

EVOLUTION OF GLOBAL STANDARDIZATION

- Standardization is "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 (ISO/IEC Guide 2:2004)."

- The standardization, historically had been used by the rulers to control the nation. Today, standards have been part of the human lives.

EVOLUTION OF GLOBAL STANDARDIZATION (2)

- WTO/TBT(Technical Barrier of Trade Agreement) influences world trades as such that 80% of global trade today is affected by international standards (OECD Report 1999) and domains of those trades have been expanded to cover manufacturing products, systems, services, material managements, transportation, finance, environment, labor, education, and healthcare.

- The international standards are becoming essential tool to expand global market share of business; and many countries invest heavily and competitively in SDO activities.

GLOBAL INTEROPERABLE EHRS DEVELOPMENT

"Interoperability"

HIT STANDARDS ENABLE
HEALTHCARE INDUSTRY BUSINESS SUSTAINABILITY

BUSINESS EFFICIENCY
ENERGY EFFICIENCY
GREEN ENVIRONMENT
(BY MAKING PAPERLESS)

HL7,CEN/TC251 AND CDISC STANDARDS IN

ISO/TC 215 TO BE INTERNATIONAL STANDARDS

'Single set of standard for a single set of clinical business and single test'

BACKGROUND

- 2nd GHITSS was held in Geneva on October 8 (Sun), 2006 – with HIT Industry Reps.

- 1st GHITSS was held in Hamamatsu, Japan on September 19 (Sun), 2005 – with HIT Nat'l Coordinators and Industry Reps.

  "HIT standards are not sufficient to develop and deploy EHR, but there are duplications"

  "Need of collaboration among HIT SDOs"
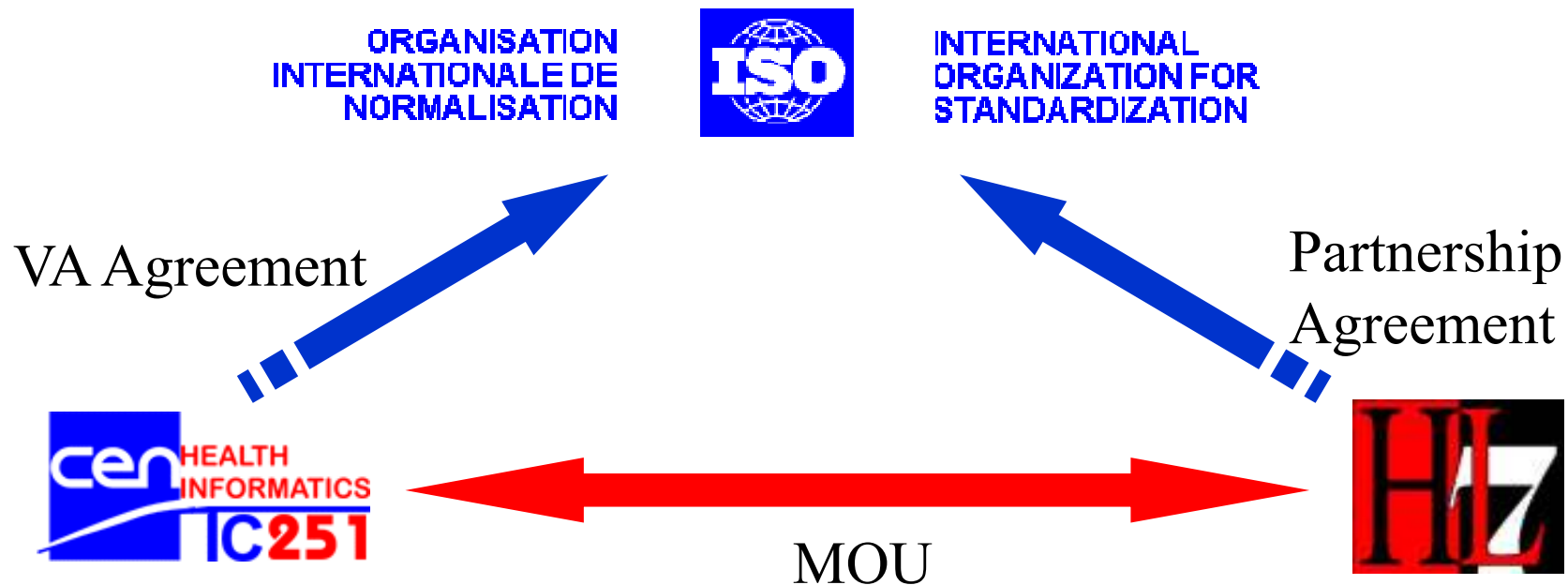
CURRENT PROBLEMS OF STANDARDS

- Conflicting standards

- Conflicting versions

- Conflicting implementations of same standard

- Lack of specific standards

- Duplication of standards

- A premature market for HIT standards

- Political barriers: different health systems and often low support for standardization

CURRENT PROBLEMS OF STANDARDS(2)

- SDO barriers: seeking returns from an expensive standardization process

- Company barriers: seeking returns from own standardization

- ICT user barriers: seeking to prevent costs of using standards

- Lack of certification

MOU AMONG SDOs

"CEN/TC 251 and HL7 agree to collaborate in the spirit of mutual appreciation, respect and openness to seek pragmatic solutions to obtain unification of their set of standards for healthcare communication and to make the results globally available to ISO"

CEN, ISO, HL7 AGREEMENT

CEN/TC 251, ISO/TC 215, HL7 Agreement on Collaboration and Cooperation and Coordination

Signed by Chairs on October 11, 2006 in Geneva

"One context one standard and one test"

CEN, ISO, HL7 CHARTER

Joint Initiative on SDO Global Health Informatics Standardization

CHARTER

Final Draft(v7)-March 30, 2007
Approved by all SDOs-August 27, 2007

CEN/TC251, ISO/TC215, HL7 CHARTER

- Follow-up of the Agreement

- Detailed working processes

- Purpose: The **Joint Initiative on SDO Global Health Informatics Standardization** is formed to enable common, timely health informatics standards by addressing and resolving issues of gaps, overlaps, and counter-productive standardization efforts through…

- Governance:

    1. Joint Initiative Council
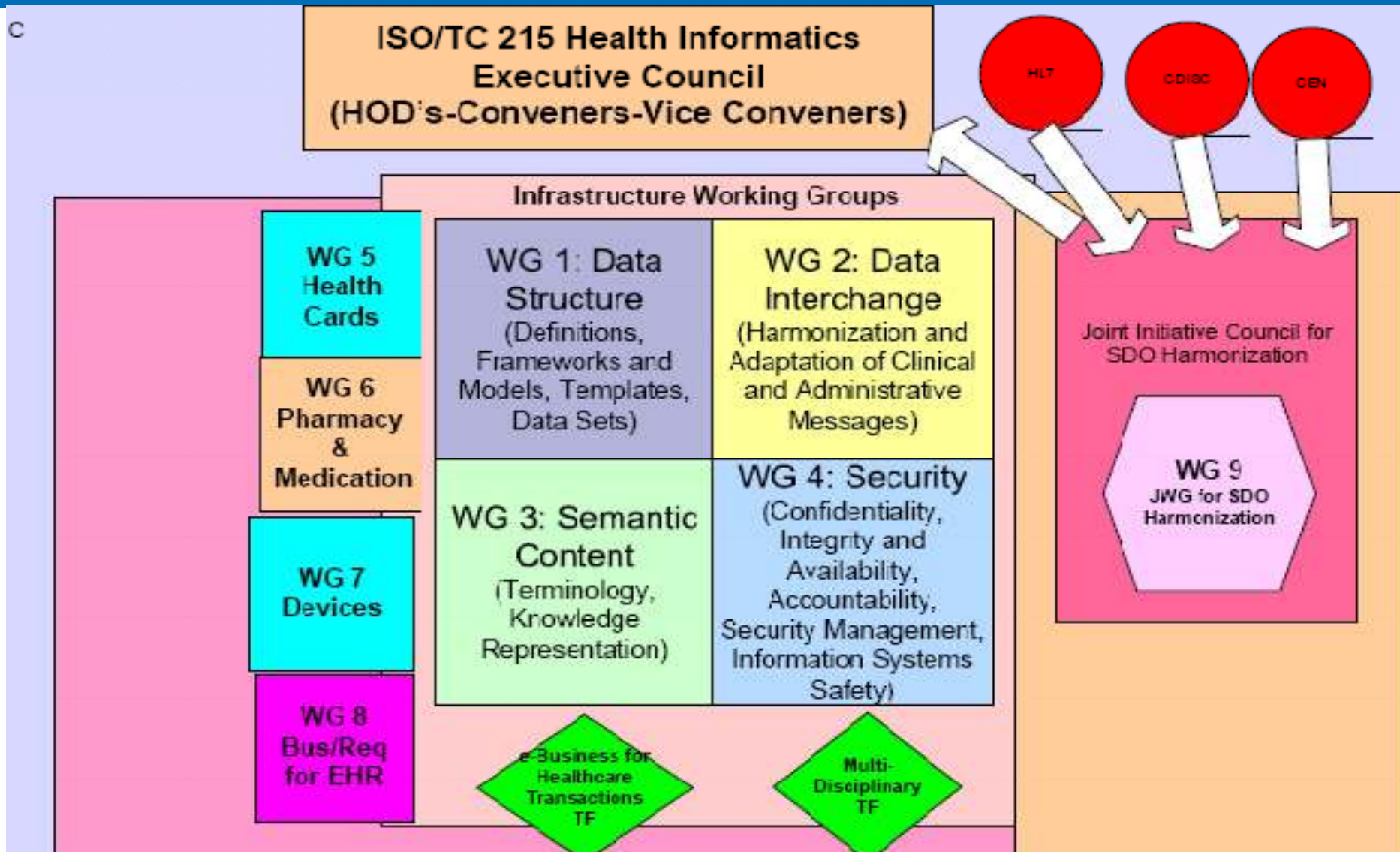
    2. Joint Working Group

JIC MEMBER SDO

[As of February 2009]

GLOBAL SDO HARMONIZATION

SDO HARMONISATION ORG.

- JIC (Joint Initiative Council)

    Chair: Ed Hammond, PhD (HL7)

    Secretary: Audrey Dickerson (ISO/TC215)

- JWG (Joint Working Group)

    Co-chairs: Melvin Raynolds (CEN/TC251)

    Don Newsham (ISO/TC215)

    Charles Jaffe, MD (HL7)

    Secretary: Australia (ISO/TC215)

FUNCTIONS

- JIC sets work processes, directions and policies

- JWG compiles existing standards and identify gaps with work items

- ISO/TC215 WGs engage in standards development

WORK PROCESS

WTO* Stage / status → Body ↓	Preliminary / preparation			Non-normative		Normative
CEN CENELEC	New work item (NW)	Working draft (WD) then Committee draft (CD)	Public draft for Enquiry (prEN) Draft Workshop Agreement on web for comment (CWA	Technical Report (TR)	Workshop Agreement (CWA)	European Standard (EN) Technical Specification (TS) Workshop Agreement (CWA)
ISO IEC	New work item (NW)	Working draft (WD) then Committee draft (CD)	Public draft for international ballot (DIS/FDIS)	Technical report (TR)	Technical specification (TS)	International Standard (IS)
HL7	Proposal	Committee draft	Draft for Membership Ballot	Implementation guidance	Draft standard for trial use (DTSU)	Standard

WHAT HAPPENS WITH STANDARD ?

- Each SDO follows own process for balloting

- IP is retained by SDOs

- The same standard published by SDOs

- IS gives advantage in international trade by meeting WTO "TBT."

CURRENT STATUS OF JIC WORKS

- ISO 13606-1:2008 Health informatics - Electronic health record communication - Part 1: Reference model (CEN published)

- ISO 13606-2 Health informatics - Electronic health record communication - Part 2: Archetype interchange specification (CEN published) (in press)

- ISO/FDIS 13606-3 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists (CEN published)

- ISO TS 13606-4 Health informatics - Electronic health record communication - Part 4: Security (CEN published)(in press)

CURRENT STATUS OF JIC WORKS(2)

- ISO/FDIS 13606-5 Health informatics - Electronic health record communication - Part 5: Interface specification (CEN prEN)

- ISO/HL7 27931 Health informatics - HL7 Version 2.5 messaging standard (in press)

- ISO/HL7 27932 Health informatics - Clinical Document Architecture - Release 2 (in press)

- ISO/HL7 FDIS 10781 Health informatics - HL7 Electronic Health Record System Functional Model - Release 1

- ISO/HL7 DIS 27953-1 Health informatics -- Pharmacovigilance - Individual case safety report - Part 1: The framework for adverse event reporting(CEN prEN)

CURRENT STATUS OF JIC WORKS(3)

- <u>ISO/HL7 DIS 27953-2</u> Health informatics - Pharmacovigilance - Individual case safety report - Part 2: Human pharmaceutical reporting requirements for ICSR (CEN prEN)

- <u>ISO/DIS 21090</u> Health informatics - Harmonized Data Types for Information Interchange

- <u>ISO/HL7 FDIS 27951</u> Health informatics – Common terminology server, Release 1

- <u>ISO/CD 11615</u> Health informatics — Identification of medicinal products — Data elements and structures for the exchange of regulated product information for drug dictionaries

- <u>ISO/CD 11616</u> Health informatics — Identification of medicinal products — Structures and controlled vocabularies for pharmaceutical product identifiers

CURRENT STATUS OF JIC WORKS(4)

- <u>ISO/CD 11238</u> Health informatics — Identification of medicinal products — Structures and controlled vocabularies for Ingredients and Substances

- <u>ISO/CD 11239</u> Health informatics — Identification of medicinal products — Structures and controlled vocabularies for reporting of dosage forms, units of presentation and routes of administration

- <u>ISO/CD 11240</u> Health informatics — Identification of medicinal products — Structures and controlled vocabularies for units of measurement

- <u>ISO/CD 11595</u> Health informatics — Identification of medicinal products — Structures and controlled vocabularies for reporting of laboratory results and clinical observations (Deferred)

SDOs WORKING TOGETHER

- HL7 WG meetings:

  HCD WG, ISO/TC215 WG7, CEN/TC251 WGIV

  work together

- HL7 Winter WG Meeting: ISO/TC215 WG2 meeting

- CDISC experts jointly work with ISO/TC215 WGs

- When ISO/TC215 WGs meet in Europe,

  CEN/TC251 WGs jointly working together

ISSUES AND FUTURE

- Synchronizing SDO work processes

- Participation of industry

- Participation of domain experts and consumer

- Identification of use cases and standards gaps

- Collaboration of TAGs within NMBs

- Participation of terminology/vocabulary SDOs

CONCLUSIONS

- HL7, ISO/TC215, CEN/TC251, CDISC and IHTSDO begin to work together in harmony to provide a single set of standard for a single set of clinical event to the global marketplace to achieve interoperability

- Most SDOs share experts

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ありがとう ございます.

Thank you.

감사합니다.

Q & A

CONTACT INFORMATION

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