



**ISO/IEC JTC 1 N 9421**  
**ISO/IEC JTC 1**  
**Information Technology**

2008-11-24

**Document Type:** Other Document(Defined)

**Document Title:** TC 215 Liaison Report to JTC 1 at Plenary in Nara, Japan

**Document Source:** JTC 1 Secretariat

**Reference:**

**Document Status:** For Information

**Action ID:** For Information

**Due Date:**

**No. of Pages:** 23

# **ISO/TC215 Health Informatics**

## **Report of JTC 1 Liaison**

### **Nara, Japan**

**2008-11-14**

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# Outline

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- **Formalisation of ISO/TC215 liaison**
- **ISO/TC215 overview**
  - scope, composition, structure, environment
- **ISO/TC215 activity**
  - interaction with JTC 1 SCs
- **The hard road – progressing harmonization**

# Progress with TC215 Liaison

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- Oct 2007: JTC1 resolved to establish Liaison with ISO/TC 215 (Health Informatics)

Richard Dixon-Hughes appointed Liaison Officer from JTC 1 → ISO/TC 215

- Jun 2008: ISO/TC215 accepts JTC 1 Liaison at Plenary Meeting in Gothenburg, Sweden

Dr Adrian Stokes appointed Liaison Officer from ISO/TC 215 → JTC 1

- 12-15 Oct 2008: Liaison Officers at TC215 Joint WG meetings & Mini-Plenary in Istanbul, Turkey

# TC215 Scope

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*“Standardization in the field of information for health, and health ICT to achieve compatibility and interoperability between independent systems. Also, to ensure compatibility of data for comparative statistical purposes (e.g. classifications), and to reduce duplication of effort and redundancies.”*

# TC215 Composition

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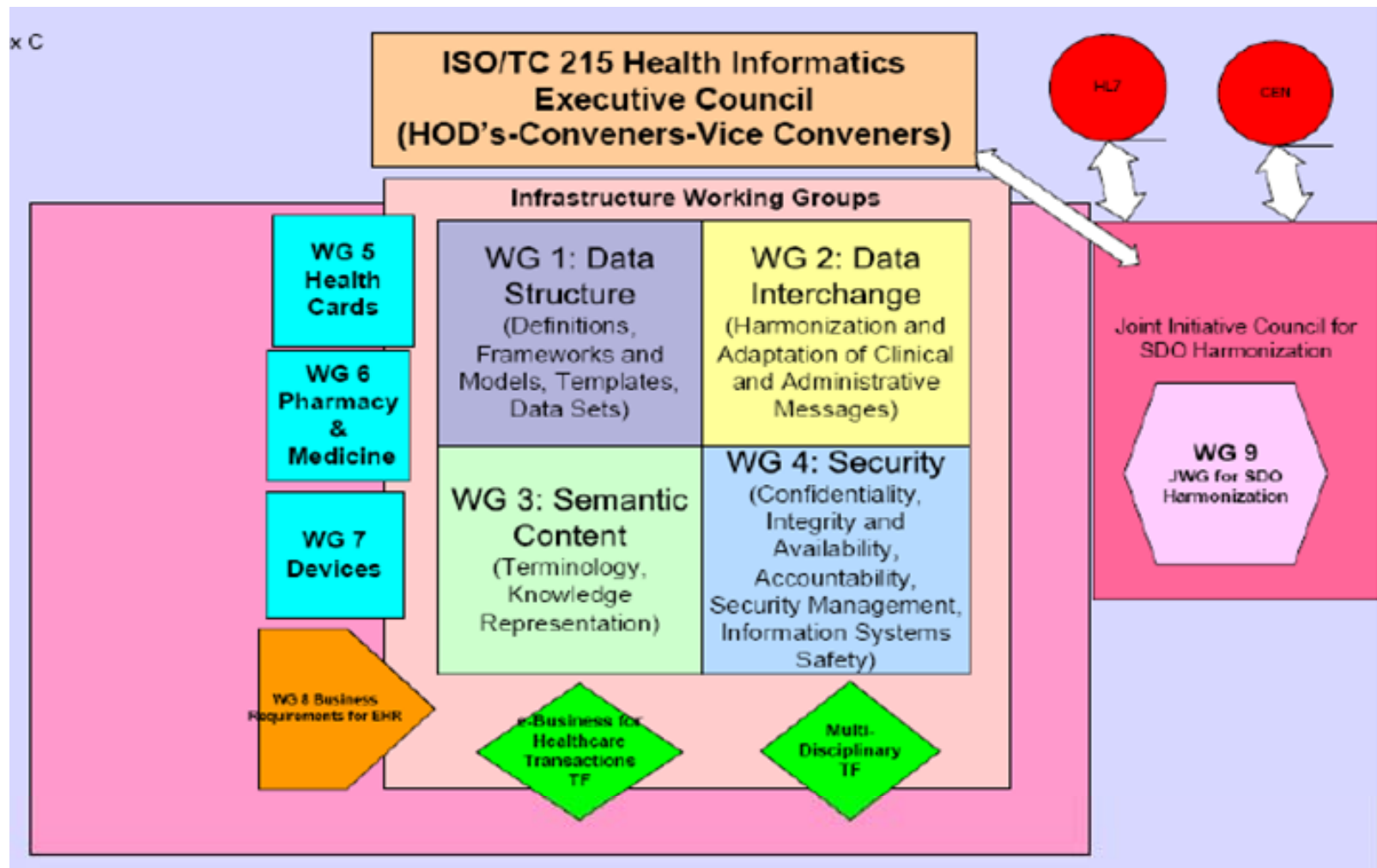
- Chair : Dr Yun Sik Kwak (Korea)
- Secretariat : ANSI (USA) Delegated to HIMSS
- **24 ‘P’ Member Bodies**

CA		AT	BE	CZ	CS	DE	JP
KR							
US	ZA	FI	FR	IT	NL	NO	ML
BR		RU	SE	TR	UK		AU
NZ							

- **20 ‘O’ Member Bodies**

AR	KE	BU	CH	CY	ES	HR	CN
IN	IR						

# TC215 structure - Overview



# TC215 Working Groups

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WG	Domain description	Leaders	Secretariat from
1	Data structure (models & applications)	Canada/JP	Canada
2	Data interchange (methodology + architecture)	USA/JP	UK
3	Semantic content (inc: vocabulary, knowledge)	Australia/CA	UK
4	Security (inc: access, privacy, archiving)	Canada/US	France
5	Health data cards	Germany	Germany
6	Pharmacy & medications	UK/US	Netherlands
7	Devices	USA/DE	vacant
8	Electronic Health Record (EHR) requirements	Canada	Australia
9	Joint WG on Health IT harmonization	Joint	Australia



# TC215 Environment -1

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- **Global Health IT Summits (GHITS)**
  - I Hamamatsu 2005: National Health ICT programs**
  - II Geneva 2006: Health ICT vendors/suppliers**
  - III Montréal 2007: Clinical services & providers**
  - IV Gothenburg 2008: Consumer perspectives**
  - ... 2009 national/regional programs revisited**
- **Ageing of population and rising cost of care**
- **Care responsibilities - devolving, distributed & shared → information access & sharing**
- **Implementation challenges – clinician desktop**

# TC215 Environment - 2

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- **Rise of personal health record (PHR):**
  - **ICT vendor-driven (MS, Google)**
  - **Health service provider approaches**
  - **National health service approaches (UK, DSP)**
  - **Employer/insurer/commercial PHR provider**
- **Move to greater portability of health service delivery and information**
- **New clinical technologies (e.g. genomics)**
- **Codification of health information and knowledge**
  - **terminologies & ontologies**
- **TCM and TOM initiatives**

# TC215 Environment - 3

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- Hammond has identified >50 SDOs, including :

– ISO	132	IEEE	8+
– CEN	93	CDISC	8
– ASTM	66	ICH	5+
– HL 7	63	IHE	5+
– CHF	20	DICOM	5+
– NCPDP	18	caBIG	5
– ADA	15	HIPAA	4+
– X12N	15	Medbiquitous	2+

- Various terminology SDOs 150+

# TC215 Environment – 4

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## Shifting toward

- Web-Services/SOA
- Personal health devices – interfaces/content
- Integrated architectural framework (HL7)
  - business process + information + services + clinical documents + messaging
- Issues: object constraint languages; XML tooling

## Harmonization policy & practice

- Integration profiles, functional profiles & certification
- EC DGIE Mandate M/403 – CEN, CENELEC, ETSI  
+ recognition TC215,

# eHealth Standardization- Other

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- Patient & provider identification
  - identification processes & cards
- Privacy, security and access control
- Health cards (particularly in EU)
- Health concepts and terminology
  - SNOMED CT, LOINC etc
- Information models and representation
- SOA/ web services definitions
- eHealth software safety

# TC215 – some specifics - 1

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**Health Informatics domains provide a practical case study on application of ICT standards**

- **WG1 Data Structure**

- NP on Detailed clinical modelling – quality reqts & methodology – process/information capture
- IS 12967 Health Information Services Architecture (HISA) [application of RM ODP]
- Adopting EN13606 EHR Communication as ISO stds

- **WG1 & WG3 – identification of patients, providers & facilities – mainly processes/metadata**

# TC215 – some specifics - 2

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- **WG2 Architecture – harmonized data types for information interchange (in health informatics)**
  - based on ISO 11404
  - underpin actual document, message structures
  - tooling & implementation issues – XML, UML, ITS
  - major problems with Unicode addressed

**Lesson: will datatype diversity become an issue for JTC 1?**

- **WG2 – ISO 22700 document registry framework**
- **HL7 standards on clinical document architectures (CDA), HL7v2.5**

# TC215 – some specifics - 3

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- **WG3 – Vocabulary project across TC215**  
Use of Ontology tools for greater consistency  
Access/use/value of standard ISO/IEC vocabulary an issue
- **WG3 – Several NWIPs on OID registries for healthcare**
- **Progressing work on standards for maintaining health terminologies**  
(some controversy with formation of IHTSDO)



# TC215 – some specifics - 4

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- **WG4 – IS 22600 Privilege management & access control (PMAAC) largely finalised**

**Use cases may inform some SC27 work**

- **WG4 Scope formally extended to “Security, Safety & Privacy”**
- **Proposed standards for safety of health software have become highly controversial**
- **Revised IS 22857 → DIS ballot**

"Health informatics -- Guidelines on data protection to facilitate trans-border flows of personal health information"

# TC215 – some specifics - 5

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- **WG4 – long-standing attempt to develop standards for EHR Archiving – why is it different?**

- **WG5 – Health cards – currently stable**

**How should how new card/storage technologies be applied in health? commercial pressures ?**

- **WG6 – Pharmacy & medication**

**Pharmacovigilance/ICSR & identification standards**

**A case study in commercial and regulatory pressures  
– demonstrating how effective PM, communication and  
facilitation are essential to global harmonisation work**

# TC215 – some specifics - 6

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- **WG7 – Devices - Fast-track adoption of IEEE 11073 series of standards for “personal health device communication” Examples:**
  - Cardiovascular Fitness and Activity Monitors
  - Weighing Scales
  - Thermometers
  - Glucometers
  - Blood pressure monitors

**Issue about how more detailed data structures should be communicated reliably**

**Subject to liaisons with IEEE, IEC, Continua Alliance etc**

# Standards Harmonization

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- **October 2006 – Joint Initiative Charter**
  - **Joint Initiative Council (JIC)**
  - **Joint Working Group (JWG) (ISO/TC215 WG9)**
- **Participants:**
  - **ISO/TC215, CEN/TC251 & HL7**
  - **On probation: CDISC, IHTSDO**
- **Project inventory prepared**
- **Initial projects – datatypes, adverse event reporting, medication vocabulary**
- **Meet at HL7, CEN and ISO (4-5 times pa)**

# Standards Harmonization

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- **Lessons on harmonization:**
  - Much goodwill and common objectives are key
  - Driven by market need
  - Communication, communication, communication ...
  - Process may need to change guided by the fundamental principles of standardization
  - Progressive process

# Next Meeting - October 2009

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- JTC 1 Tel Aviv, Israel



- ISO/TC215 Durham NC  
19-21 October

# Questions ??