ISO/TC 215
Progress Report
HL7 Projects in ISO/TC 215 WG 2

- ISO 17113, Health Informatics - *Exchange of information between healthcare information systems – development of messages* (based on HL7 V3) is in press

- ISO 27931, Health Informatics – *HL7 V2.5 Messaging Standard* is in DIS stage

- ISO 27932, Health Informatics - *Clinical Document Architecture (Release 2)* is in DIS stage

- ISO 21090, Health Informatics - *Harmonised data types for information interchange* is up for NWIP ballot
ISO 27951, Health Informatics – *Common Terminology Services, Release 1* is in DIS stage
HL7 Projects in ISO/TC 215 WG 6

ISO NWIP, Health Informatics – Pharmacovigilance - Individual Case Safety Report is up for NWIP ballot (VA and ISO lead)

ISO NWIP, Health Informatics – Pharmacovigilance - Structures and Controlled Vocabularies for Laboratory Test Units for the Reporting of Laboratory Results is up for NWIP ballot (VA and ISO lead)

ISO NWIP, Health Informatics – Identification of medicinal products – Data elements and structures for the exchange of regulated product information for drug dictionaries is up for NWIP ballot (VA and ISO lead)
ISO NWIP, Health Informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Pharmaceutical Product Identifiers (PhPIDs) is up for NWIP ballot (VA and ISO lead)

ISO NWIP, Health Informatics – Identification of medicinal products – Structures and Controlled Vocabularies for Ingredients is up for NWIP ballot (VA and ISO lead)

ISO NWIP, Health Informatics – Identification of medicinal products – Structures and Controlled Vocabularies for Units of Measurement is up for NWIP ballot (VA and ISO lead)
ISO NWIP, Health Informatics – *Identification of medicinal products – Structures and Controlled Vocabularies for Pharmaceutical Dose Form, Units of Presentation and Routes of Administration* is up for NWIP ballot (VA and ISO lead)
ISO NWIP, Health Informatics – *EHR System functional model* is up for NWIP ballot
Other Items of Interest

- ISO/CEN 13606-1, 2,3,4, Health Informatics-Electronic Health Record Communication are being processed

* Separate update by Mr. Mark Shafarman.
ISOTS 27790 NWIP, Health Informatics – *Document Registry Framework* is up for NWIP ballot

*Note: ebXML based CDA registry and collaborated with IHE*
Other Items of Interest (3)

- TF e-Business will continue
  - ebXML (Frans will update)
  - Smart card in healthcare
  - EDI in healthcare
- TF Multi-disciplinary Clinical
  - Technical Report
  - Promote clinician involvement
ISO/TC215 Plenary Meeting was held during March 26-29, 2007 in Montreal, Canada.

3rd GHITSS (Global Health Information Technology Standards Summit) was held in Montreal, Canada on March 25 (Sun), 2007 – with HIT Clinician, ICH, IHE, CDISC Reps.

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.

1st HIMSS-Asia Pac will be in Singapore during May 15-18, 2007.
Engagement in
ISO/TC 215
ISO TC215 Structure

Technical Committee

Executive Council

H & O Committee

WG 1
WG 2
WG 3
WG 4
WG 5
WG 6
WG 7
WG 8

Sub G 1
Sub G 2

TF Multidiscipline

TF e-Business

Date April 29, 2007
HL7 Spring WG Meeting, Cologne, Germany
ISO TC 215 Membership

‘P’ Member Bodies = 22

Africa : S Africa (1)

N America : Canada, USA (Secretariat) (2)

S America : None

Asia : Japan, Korea, Malaysia, Turkey (4)

Europe : Austria, Czech Republic, Denmark (13)

Finland, France, Germany, Italy

Netherlands, Norway, Russian federation

Serbia, Sweden, United Kingdom

Oceania : Australia, New Zealand (2)
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<th>ISO TC 215 ‘P’ Member Bodies</th>
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<tbody>
<tr>
<td>Australia (SA)</td>
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<td>Canada (SCC)</td>
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<td>France (AFNOR)</td>
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<td>Italy (UNI)</td>
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<td>South Africa (SABS)</td>
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<td>Turkey (TSE)</td>
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<td>USA (ANSI)</td>
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ISO TC 215 Membership

'O' Member Bodies = 20

Africa : Zimbabwe  Kenya  (2)

C America : Ecuador  (1)

S America : Argentina,  Brazil  (2)

Asia : China  India  Iran  (7)
       Israel  Mongolia  Singapore  Thailand

Europe : Belgium  Croatia  Hungary  (8)
         Ireland  Poland  Portugal  Spain  Switzerland
## ISO TC 215 ‘O’ Member Bodies

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<td>Zimbabwe (SAZ)</td>
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ISO TC 215 Leadership

ISO/TC 215, Health Informatics

Chair: Yun Sik Kwak (KR)  
yskwak@knu.ac.kr
Appointed for 2nd term (2003 – 2009)

Secretary: Audrey Dickerson (US)  
adickerson@himss.org

WG 1, Data structure

Convenor: Grant Gillis (CA)
Appointed for 1st term (2007-2010)

Vice-Conv.: Tetsu Kiyotani (JP)

Secretary: Andrea Ciemny (CA)
ISO TC 215 Leadership (2)

WG 2, Data Interchange
Convenor: Mike Glickman (US)
    Appointed for 1st term (2005-2008)
Vice-Conv.: Michio Kimura (JP)
Secretary: Adrian Stokes (UK)

WG 3, Semantic content
Convenor: Heather Grain (AU)
    Appointed for 1st term (2007-2010)
Vice-Conv.: Kathryn Hannah (CA)
Secretary: Pat Village (UK)
ISO TC 215 Leadership (3)

WG 4, Security
Convenor: Ross Fraser (CA)
    Appointed for 2\textsuperscript{nd} term (2007-2010)
Vice-Conv.: Lori Fourquet (US)
Secretary: Alison Gardner (CA)

WG 5, Healthcards
Convenor: Frans van Bommel (NL)
    Appointed for 1\textsuperscript{st} term (2005-2008)
Vice-Conv.: Juergen Sembritski (DE)
Secretary: Heike Moser (DE)
ISO TC 215 Leadership (4)

WG 6, Pharmacy and medication
  Convenor: Ian Shepherd (UK)
      Appointed for 1st term (2006-2009)
  Vice-Conv.: LuAnn Whittenburg (US)
  Secretary: Shirin Golyardi (NL)

WG 7, Device
  Convenor: Todd Cooper (US)
      Appointed for 1st term (2005-2008)
  Vice-Conv.: Thomas Norgall (DE)
  Secretary: Melvin Reynolds (UK)
ISO TC 215 Leadership (5)

WG 8, EHR business requirements
  Convenor: David Rowlands (AU)
            Appointed for 1st term (2005-2008)
  Vice-Conv.: Marion Lyver (CA)
  Secretary: Elizabeth Hanley (AU)

TF Chairs
  Multi-disciplinary Clinical – Kathryn Hannah (CA)

  e-Business – Frans van Bommel (NL) & Yun Sik Kwak (KR)
“Retired” Convenors

Ed Hammond (WG2) – now is ISO/TC 215 Ambassador to developing countries since 2004
Gunnar Klein (WG4) – Liaison to CEN/TC 251, Health Informatics
Ray Rogers (WG6)
Don Newsham (WG1) – Head of delegation, CA
Christopher Chute (WG3) – Head of delegation, US
### ISO TC 215 Liaison Organizations

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<td>WHO</td>
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ISO TC 215 Partnership Organizations

CEN/TC 251 (VA Agreement)
Health Level 7
IEEE
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### ISO TC 215 Liaison Committees

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## ISO TC 215 Liaison Committees

| ISO/TC 150 | ISO/TC 154 |
| ISO/TC 168 | ISO/TC 170 |
| ISO/TC 171 | ISO/TC 172 |
| ISO/TC 194 | ISO/TC 198 |
| ISO/TC 210 | ISO/TC 212 |
| ISO/TC 229 |
CEN, ISO, HL7 Agreement on Collaboration, Cooperation and Coordination
Outcome of GHITSS

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

1\textsuperscript{st} 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”
MoU from 2000

“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”
Enforce existing three party MoUs

Goal is to make “Common Standards”

Proposed charter organization is not going to make standards, but coordinate the efforts

Open standard development principles will be applied

Additional SDOs are welcome!

(ISO TMB approval is necessary)
CEN/TC 251, ISO/TC 215, HL7 Agreement on Collaboration and Cooperation

Signed by Chairs on October 11, 2006 in Geneva
Joint Initiative on SDO Global Health Informatics Standardization

CHARTER

Final Draft(v7) - March 30, 2007
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
Standards and work in progress

The ISO/TC215 is requesting HL7 experts’ participation to meet the expectations of its stakeholders and members worldwide!

Thank you for your participation!

http://www.iso.org
CEN/TC 251, ISO/TC 215, HL7 Agreement on Collaboration and Cooperation

Signed by Chairs on October 11, 2006 in Geneva
HL7 Chair, Chuck Meyer, stated that “we already have cooperative relationships with ISO and CEN and are undertaking a strategic initiative which will further develop our capacity and structure for coordinating our work program”. HL7 has clearly demonstrated great standards delivery capabilities and has a huge global volunteer contingent that participates in standards development.

Kees Molenaar, Chair of CEN TC251, provided an overview of the TC’s Business Plan, which includes an assessment of the current environment and the TC’s work program. “CEN is not in the business of competing in standards development and will be collaborating and cooperating with other SDOs, along with the vendor, government and provider communities as we fulfill our role in the EU.”
Dr. Yun Sik Kwak, Chair of ISO TC215, agreed with the importance of engaging the three communities, particularly noting the recent Global Summit’s for National Health Information initiatives in 2005 and the just completed summit with health IT vendors here in Geneva. “ISO TC215 is undertaking a leadership role in the harmonization of globally based health informatics standards. This important effort is in response to a call for such action by government and industry leaders, and reflects the evolving business model of ISO TC215 which includes a greater global focus on orchestration of standards.”
The meeting identified a number of principles that will be incorporated into a draft terms of reference for SDO collaboration, coordination and cooperation. Building on the shared goodwill of the organizations, the principles included agreement to:

- Continue to accommodate member bodies needs and processes, individual SDO mandates and external influences,
- Be business requirements driven,
- Be customer focused through strengthened connection with governments, vendors and providers,
- Undertake joint strategic and operational planning,
- Coordinate standards starting at the beginning of the standards development processes,
- Jointly determine which standards to harmonize and include in respective work programs,
- Be topic and project-focused in undertaking collaboration, coordination and cooperation,
- Support, facilitate and effectively use collective resource capacity and expertise in the development of health information standards, and
- Provide common communications to our various external stakeholders and communities of interest.
These principles will be applied to the processes for choosing, launching, communicating, resourcing, marketing and supporting standards that need to be developed or are being developed.

Recognizing the commitment of ISO/TC 215 to serve as a coordinating mechanism and focal point for the collective work of the SDOs, the three SDOs clearly acknowledged that they will be inclusive and open to other international SDOs joining in this growing and evolving harmonization effort.
A small work team has been assigned the task of detailing and continuing the planning process in time to table a full plan for the next ISO/TC 215 meeting in Montreal, in March 2007. At that meeting, further specific plans will also be tabled for collective harmonization work targeted for delivery in 2008.

Keer Molenaar
Chair, CEN TC251

Dr. Yun Sik Kwak
Chair, ISO TC215

Charles C. Meyer
Chair, HL7
Joint Initiative on SDO Global Health Informatics Standardization

CHARTER

Final Draft(v7) - March 30, 2007
CEN, ISO, HL7 Charter

Whereas:

- Standards Development Organizations (SDOs), their respective technical committees and their stakeholders for health informatics standardization have collectively identified a need and opportunity to collaborate, coordinate and cooperate in delivering global, implementable standards,

- Standards are a necessary enabler of interoperability in the health care domain to meet demands of all health care participants, to meet national and regional mandates for health care and thereby to create and sustain a global informatics market,

- The overarching vision for collaboration, coordination and cooperation is one of harmonization, where “one standard-one test” is a fundamental paradigm,
Whereas:

- Harmonization of standards involves an engagement continuum, from common scope and purpose, to aligned development and agreement on content, to a single best standard for each problem, and finally to full mutual recognition and endorsement of standards, and

- Working together, SDOs can leverage standards development resources, solve shared issues in a timely and responsive manner and avoid overlapping and counteracting standards.
It is affirmed that:

- Standardization in health informatics is vital to quality, safe, timely and coordinated health care,

- Standardization is the only real solution to semantic interoperability in health informatics and by working together SDO’s will increasingly achieve interoperability on a global scale,

- There is a strong and positive will amongst the SDOs to collaborate, coordinate and cooperate to provide the set of standards necessary to resolve health care problems and fulfill health care requirements,

- Standardization is supported by volunteer subject matter experts that work with and among the SDOs, as well as by clients and stakeholders of SDOs standards,
It is affirmed that:

- Standardization and standards coordination, collaboration and cooperation starts at the beginning of the standards life-cycle and extends through the full life-cycle from requirements identification, to development, testing, implementation and to support and maintenance, education, training and reissue or withdrawal,

- Individual SDO mandates (e.g. EC Mandate, HL7 Mandate, ISO Mandate, etc.), member requirements, contexts and processes are acknowledged and recognized within this multilateral joint initiative, and

- Openness, transparency, global awareness and flexibility are fundamental to all harmonization efforts.
It is further affirmed that, in their work together, the participating SDO’s will:

- Use accepted best practices for standards development,
- Be business requirements driven with a project-based approach,
- Agree on expectations regarding commonality of strategy and process, using appropriate quality and risk management techniques,
- Coordinate work programs using collective as well as individual resources and eliminate standards work that is overlapping or counteracting,
- Acknowledge and utilize standards work that can be adapted or adopted to health care from other standards bodies and domains,
It is further affirmed that, in their work together, the participating SDO’s will:

- Engage stakeholders, being customer-focused through strengthened connection,
- Provide common communications to shared external stakeholders and communities of interest, and
- Be issue, work and results focused (not having an “umbrella organization” focus).
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:

1. An agreed upon and used decision process for international
   standardization needs,

2. Coordinated standards strategies and plans,

3. An integrated work program and

4. Focused, specific resolution of overlapping or counteracting standards
   within existing work programs.
Governance:

The Governance of the Joint Initiative on SDO Global Health Informatics Standardization is undertaken through:

1. Joint Initiative Council

This Council, operating as a council of equals and as liaison group under ISO/TC 215, consists of the respective leaders and appointed liaison members of the participating SDO’s to a maximum of 3 members per SDO. The Council operates at the strategic level and is responsible to:

- Identify emerging requirements for standardization,
- Proactively drive the identification of needs and the achievement of results to resolve gaps, overlaps and counterproductive health informatics standardization efforts,
Achieve consensus on a work program-driven health informatics harmonization plan,

Achieve consensus on common processes necessary to enable optimal collaboration, coordination and communication, including new member processes and decision making,

Identify criteria and members for the Joint Working Group,

Identify the individuals and lead SDO who have an interest, expertise and contribution to determine a course of action for resolving issues of gaps, overlaps or counterproductive health informatics standardization efforts,

In the spirit of openness, transparency and flexibility, determine appropriate policies that are required and useful across participating SDO’s and,
Determine an overall engagement and communications strategy, including full sharing of deliberations, with stakeholders from the health informatics standards community for the purposes of standards harmonization.

Participating SDOs are ISO/TC215, HL7 and CEN TC251. Other SDOs may be invited to participate as appropriate to the work and domain of the Joint Initiative and that meet specific criteria as identified by Joint Initiative Council.

Representatives to the Council from the SDOs are chosen to support focus, continuity, relationship building and shared responsibility.

The Council is supported by the ISO/TC215 Secretariat.
2. Joint Working Group

This Joint Working Group is hosted by ISO/TC215 and operates at the direction of the Joint Initiative Council to provide the discussion, liaison, advisory and communication forum for achieving the goals of the Joint Initiative on SDO Global Health Informatics Standardization.

This Joint Working Group is a planning, process determination and coordinating group making recommendations to the Joint Initiative Council on resolving gaps, overlaps or issues of counterproductive standardization.

This Joint Working Group consists of a balanced group of committed representatives of the participating SDO’s, selected by the Joint Initiative Council based on specific criteria, and may also include other SDO-identified and agreed-upon international participants.
2. Joint Working Group (con’t)

The Joint Working Group undertakes the assigned work from the Joint Initiative Council and is responsible for:

- Developing an integrated work program amongst the participating SDOs for approval by the Joint Initiative Council, including
  - Collection and summarization of participating SDO work plans
  - Building awareness of relevant standards activity in other related SDO’s
  - Review of participating SDO work plans for purposes of coordination and determining overlaps, gaps and counterproductive standardization.
2. Joint Working Group (con’t)

- Identifying, defining and documenting specific gaps, overlaps, issues and tasks to be addressed,

- Developing, testing and using effective decision processes for international standardization needs and

- Developing common processes, aligned with participating SDO accredited processes, for harmonization activity.

The Joint Working Group is co-Chaired by three members as identified by the Joint Initiative Council.

The Joint Working Group meets up to 4 times per year, at the ISO TC215 meetings and at other SDO meetings.
2. Joint Working Group (con’t)

Secretary support for the Joint Working Group is provided by ISO/TC215.

Signed and agreed upon, as of ___________ (Month / Year) by:

Kees Molenaar                  Yun Sik Kwak                     Chuck Meyer
Chair, CEN TC251           Chair, ISO TC215                          Chair, HL7