



**Joint Initiative on SDO Global Health Informatics Standardization
Joint Working Group (WG9)**

Meeting Minutes

Meeting 3
Orlando, United States
23 February 2008

CEN Co-Chair	HL7 Co-Chair	ISO Co-Chair	Secretariat
Melvin Reynolds	Charles Jaffe	Don Newsham	Elizabeth Hanley
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Attendance

Country	Name
Australia	Richard Dixon Hughes
Australia	Heather Grain
JWG Secretariat	Elizabeth Hanley
JWG co-chair	Don Newsham
France	Alice Rideau
Japan	Ken Toyoda
Japan	Tetsuro Kiyotani
ISO TC 215 Chair	Yun Sik Kwak
HL7	Robert Stegwee
CEN TC 215 Chair	Kees Molenaar
Sweden	Hakan Nordgrun
Sweden	Helen Broberg
United Kingdom	Jeremy Thorp
United States	Luann Whittenburg
United States	Jill Kaufman
United States	Rita Sachlone
ISO TC 215 Secretariat	Audrey Dickerson
United States	Todd Cooper
United States	Robert Owens
United States	Chris Chute
HL7	John Quinn
JWG co-chair	Charles Jaffe
ISO TC 215 Secretariat	Mike Kroll
United States	Mark Shafarman
United States	John Ritter
United States	Bill Rosen
United States	Bill Friggle

1 Welcome and introductions

Don Newsham, convenor of WG 9 and co-chair of the Joint Working Group (JWG), welcomed attendees to the third meeting of the JWG, held in conjunction with the ISO TC 215 business planning meeting at HIMSS 2008.

2 Opening of the meeting

a. Apologies

Anthony Maeder (Australia), Marion Lyver (Canada), Grant Gillis (Canada), Melvin Reynolds (United Kingdom), Adrian Stokes (United Kingdom), Julie James (United Kingdom), William Goossen (The Netherlands)

b. Confirmation of the agenda

The agenda was confirmed, with the following amendments to headings at item 5 (a) i (Parts 1 – 5); and item 5 (c) (Pharmacovigilance).

c. Confirmation of minutes from JWG Meeting 2 – October 2007, Dublin

The minutes of the last meeting were accepted.

d. Actions from JWG Meeting 2 (see item 9)

See item 9.

3 ISO / CEN / HL7 Work Program Harmonization

a. Joint Working Group Integrated Work Program

b. Key questions / criteria for review

It was reported that the JWG Integrated Work Program, version 1.1, circulated for the meeting, has included the January 2008 versions of the CEN and ISO work programs. This document has been reviewed by Shirin Golyardi, secretariat of CEN TC 251.

John Quinn reported that he will send HL7 Project summaries for inclusion, including current and new work items, to Elizabeth Hanley shortly, after internal approval.

Comments were as follows:

- Jeremy Thorp noted that 13606-2 may be in conflict with other Standards, however, the principle of harmonization is that there will not be Standards in conflict as further work is done.
- Kees Molenaar reported that CEN currently have no preliminary work items other than prEN 13940-2, and will wait for the European mandate and this JWG work to propose any new work items.
- Mark Shafarman suggested that it would be helpful to add separate sheets for each SDO work program.
- Kees Molenaar suggested that the title of the document should be changed from JWG integrated work program to “Joint SDO work program inventory”.

Action 3.1 Update the Joint SDO work program inventory with current HL7 work items.

c. Next steps for analysis

It was reported that it was agreed at the last JWG meeting that an analysis of the integrated work program should be completed by 30 May 2008 for review at the May JWG meeting in Sweden.

4 Standardization processes

a. Current processes

- ISO
- CEN
- HL7

Sources for information on participating SDO's current standardization processes were CEN/CENELEC *Internal Regulations, Part 2: Common Rules for Standardization Work*, 2006; HL7 *Co-Chair Handbook*, 2006; ISO/IEC *Directives, Part 1*, 2007; ISO *Supplement*, 2001.

Participating SDOs may provide further information. The HL7 Development Framework was noted. It was further noted that HL7 are currently developing new processes.

b. Harmonised Joint Initiative processes

- High level process map

Don Newsham reported that the document circulated for this meeting was based on information provided from HL7, ISO and CEN and is an overview document.

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This is a living document and will be updated with further input or amendments from ISO, CEN and HL7. As other SDOs join the Joint Initiative, then their processes will be added.

Comments were as follows:

- Audrey Dickerson noted that “NP” and “NWIP” are terms used interchangeably in ISO, and further noted that the NWIP ballot also sought the nomination of experts.
- Kees Molenaar noted the need for precision in the use of terms and that he will check the section on CEN TC 251 processes. He advised that references should be included.
- Mark Shafarman noted that HL7 also develop “informative” documents. As this document has been developed for “normative” Standards, could a parallel document for informative standards materials be developed? John Quinn noted that informative documents are now being done as implementation guides in HL7.
- Dr Kwak noted that only ANSI approved Standards are brought into ISO. It is at the ANSI approval stage that other SDOs may be involved because they have a similar Standard.
- John Quinn noted that automatically all HL7 standards go to ANSI for approval, and that the approval stage for HL7 will probably be ANSI approval.

c. Joint Working Group Processes

- i. Assessment / joint work program processes
- ii. New development process (decision making process)
- iii. Joint development / common work process (Task Groups)
 - 1 Policy and Procedure version 2
 - 2 Template for harmonized task groups
 - 3 Lead SDO development processes
 - 4 Coordinated ballot and comment resolution processes
 - 5 Document formatting
- iv. Engagement processes (for existing projects)
- v. Standards map / identification of required standards process
- vi. Briefing notes (need, development, use, communications) processes
- vii. Resourcing / expert engagement processes
- viii. Meeting Scheduling processes
- ix. Communication processes

Don Newsham reported that a document was circulated prior to the meeting on Joint Working Group Common / Harmonization processes to start building a set of common harmonization processes. This document has arisen because of many comments regarding the need for a common process for harmonized standards development. The document is the first version to start rationalization of input.

General comments from those present included the following:

- The JWG does not develop standards, and this is a process to assess joint conflicts, to resolve confusion, and to provide advice to assess parallel work in SDOs. The JWG facilitates and supports joint work.

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- There are two ways of doing harmonized development –
 - bring in existing work into the joint initiative
 - start new standards development with joint participation
- The process will set out the means of raising issues /conflicts to JIC, identifying overlaps, and providing information for decision making at the JIC.
- Problems and issues can be brought to JWG table in a flexible way from any country or any SDO.
- The need for spontaneity, flexibility and timeliness.
- The need to ensure that individual SDO processes are followed during balloting.
- The standards road map has not yet been formally discussed.
- Will the JWG will do scans, or identify requirements for standards, or identify where work could be done?

Jeremy Thorp spoke to the standards decision tree diagram appended to the JWG Common / harmonization processes document. Jeremy stated that the intent of the diagram is to identify the questions / criteria that need to be asked at each stage. The decision tree is applicable for SDOs or national programs. He further noted that for joint work, some extra decisions and entry points may need to be added to such a decision tree.

Comments regarding the decision tree diagram were as follows:

- The concept of harmonization is missing from this diagram – the “resolve” box needs expansion to make reference to harmonization.
- Does the diagram relate only to standards?
- The life cycle management of standards should be mentioned (including withdrawal).
- Clarification of the term “monitor usage” was requested as levels of usage can vary within countries.
- The decision tree can be elaborated to guide decision making around joint work.
- The decision tree diagram needs an overarching document of explanation.
- Relate text in process document to this decision tree diagram.

The following comments were made regarding common processes for adoption of standards:

- At this point, the direction is from HL7 to ISO for adoption of published standards.
- The adoption process should take the most recent published version.
- Amendments to the document being adopted by a second SDO should also occur in the originating SDO in their next version.
- Where a standard has been adopted by a second SDO, is the originating SDO responsible for revisions?

Further comment in regard to the document on joint processes for common / harmonized standards development were as follows:

- The intention of the process is not to slow down the process, but to identify at whatever entry point, how the joint work can be done.

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- The mechanism for receiving work by the JWG may be informal but there is a need for communication points to share information amongst individual experts involved in the joint work.
- It is not clear yet if it is possible for all SDOs to use the same comment form for ballots.
- The need to synchronize ballot dates and to have co-ordinated collection of comment was noted.

John Quinn reported that HL7 could set up a five month ballot cycle and set up a process to collect comments for a joint project (comments go into a database).

Action 3.2 Update the high level and detailed process documents based on feedback at the JWG meeting and circulate to the JIC for review by 1 April 2008.

Action 3.3 Following the JIC review, circulate updated version of process documents for May JWG meeting.

Action 3.4 Jeremy Thorp to update the decision tree diagram for discussion at May JWG meeting.

5 JWG Work Program

a. 13606 Electronic Health Record Communication, parts 1 - 5

Status as reported by Dipak Kalra in mid January to the HL7/ISO/CEN collaboration meeting (HL7 meeting, San Antonio) was noted as follows:

13606 Part Standard	Status in CEN	Status in ISO
1: EHR Reference Model	Published in February 2007	Currently out for FDIS ballot
2: Archetype Interchange Specification	Published in July 2007	Currently out for DIS ballot
3: Reference Archetypes and Term Lists	Currently out for Formal Vote	About to be released for DIS ballot
4: Security	Published in March 2007	About to be released for DTS ballot
5: Interface Specification	Informal comment phase concluded. Next step: to be balloted as ENQ/DIS early next year under Vienna Agreement (CEN lead)	

b. Data Types

Audrey Dickerson reported that the ISO Central Secretariat is waiting on documents from Graham Grieve in order to prepare this for ISO DIS ballot.

c. Pharmacovigilance and identification of medicinal products

A project report was circulated with the meeting papers, which was provided to Audrey Dickerson by Randy Levin, HL7 project lead. There was discussion of the appropriate person to provide reports for JWG meetings on projects on the JWG work program. The report was noted.

d. Detailed Clinical Models

A report by William Goossen on the August 2007 Detailed Clinical Models workshop was circulated with the meeting papers. This report was accepted. It was stated that this should be on the ISO TC 215 Working Group 1 agenda.

Action 3.5 Don Newsham as WG9 Convenor to contact the WG 1 chair to ensure that the detailed clinical model work is being coordinated through ISO TC 215 WG 1.

e. Other (Potential)

- i. Personal Health Record
- ii. Document Registry (ISO / IHE)
- iii. Health Summary Record (Clinical Summary) (ISO Technical Report)
- iv. Medical devices
- v. Additional arising from HL7 January 2008 Meeting
- vi. Other

These items were not discussed.

f. Standards for potential "retirement"

- i. Methodology Framework
- This item was not discussed.

6 Harmonization Needs and Issues

a. Raised Issues Tracking / Review

Action 3.6 Add issue to log regarding adoptions and which SDO is responsible for further maintenance and revisions.

7 Communications

a. Joint Working Group website

For information see www.global-e-health-standards.org

b. Meeting updates / releases / means for regular communications to SDO's

This item was held over.

c. Update from HL7 January 2008, San Antonio

It was noted that the Minutes of the HL7 / CEN / ISO meeting held at the January 2008 HL7 meeting were circulated with the JWG meeting papers. These will be posted to the JWG website.

8 Other Business

There were no items of other business.

9 Actions

Action 1.3: Table decision tree for discussion at the next JWG meeting. **2007/10/02** Outstanding. **2008/02/23 See discussion at 4c. Completed.**

Action 2.1: JWG Secretariat to distribute Terms of Reference to Joint Working Group members. **2008/02/23 Completed.**

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Action 2.2: The JWG co-chairs to recommend to the Joint Initiative Council (JIC) that secretariats of CEN, ISO and HL7 add their entire work programs into the JWG's integrated work program. **2008/02/23 See discussion at 3a. Outstanding.**

Action 2.3: The JWG to request the Joint Initiative Council to review and revise the ISO/ HL7 partnership agreement to accommodate joint standards projects and, if required, a pathway to establish joint work and identify technical lead. **2008/02/23 Referred to JIC. Completed.**

Action 2.4: The JWG to request the Joint Initiative Council to consider issue 3 – relevance of outcome of joint standards work – and potentially identify task force. **2008/02/23 Referred to JIC. Outstanding.**

Action 2.5: Mark Shafarman, Dipak Kalra, Bernd Blobel and Charlie McCay to draft briefing note on future harmonization approaches to accompany the ISO FDIS ballot for 13606, part 1. Don Newsham and Melvin Reynolds to add a covering email note for distribution by Audrey Dickerson, with the FDIS ballot for 13606, part 1, with both briefing note and email to be completed by 31 October 2007. **2008/02/23 Completed**

Action 2.6: Table report from the Care Information Model group for discussion at a future JWG meeting **2008/02/23 Completed.**

Action 2.7: Marion Lyver, Acting Convenor of ISO TC 215 WG 8, to table a report on the health summary record technical report at next meeting of the JWG. Sam Heard and Mark Shafarman to also contact Marion for follow-up, particularly with respect to work on profiles. **2008/02/23 Outstanding.**

Action 2.8: Co-chairs and SDO secretariats to provide information on current standardization processes by 28 February 2008 to the JWG Secretariat **2008/02/23 See discussion at 4a. Outstanding.**

Action 2.9: Co-chairs and Secretariats to hold teleconference to discuss recommendations and implications [of joint processes] by 30 March, 2008. **2008/02/23 Outstanding.**

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Action 3.5 Don Newsham, WG9 Convenor, to contact the WG 1 chair to ensure that the detailed clinical model work is being co-ordinated through ISO TC 215 WG 1.

Action 3.6 Add issue to log regarding adoptions and which SDO is responsible for further maintenance and revisions.

10 Next JWG Meetings

1. ISO / CEN (Sweden – 30 May 2008, 17.30 to 21.30)
2. HL7 (Vancouver – September 2008) – Sunday Sep 14, after international affiliates meeting

It was noted that there will be a Sunday afternoon meeting of the ISO/CEN/HL7 group at the May 2008 HL7 Working Group Meeting. It was further noted that there will be a JWG meeting held at least one HL7 meeting per year and it was agreed that the September plenary is the most appropriate. The future meeting schedule will be discussed at the JWG meeting in Sweden

11 Meeting Adjournment The meeting was adjourned at 12.15pm.

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C Appendix 1

**Joint Initiative on Global Health Informatics Standardization
Joint Working Group - Work Program**

**Overlaps, Duplications and Counter-Productive Standardization Items
As at March 1, 2008**

Name	Description	Action Needed	Assigned	Status ⇒ Potential / Preliminary ⇒ Active ⇒ Complete
13606 EHR Communication	<ul style="list-style-type: none"> - Address differences, consistency and issues between 13606 and CDA (R2, R3) - Additionally address interface requirements for any implementation constraints for 13606 (potential Imp Guide / profile for using 13606 in HL7 V3) - Includes NHS sponsored projects developing implementable transformation between 13606-1&2 and particular templated CDA documents (Discharge Summary) and transformation of openEHR archetypes to HL7 templates 	<ul style="list-style-type: none"> - Resolve technical coherence - Identify transformations between 13606 parts and related HL7 artefacts - Develop implementation guides as useful 	CEN Lead Dipak Kalra and HL7 Representatives (with NHS project participation and input)	Active
Data Types	<ul style="list-style-type: none"> Finalizing common data types both broadly required and specifically useful - including work with abstract data types and ISO data types 	Develop singular standard	Joint Lead (all 3 SDO's) Graham Grieve / Tom Marley (Leads) Task Force	Active - at ballot in HL7; in preparation for 5 month ISO DIS Ballot Coordinated Ballot (with CEN) with common comments and disposition at Joint ISO WG2 / HL7 Meeting pre Vancouver Sept HL7 Plenary Mtg
Pharmacovigilance and Identification of Medicinal Products	<ul style="list-style-type: none"> - Build and support collaboration capabilities across three SDO's and ICH for the specific standards under development - Complete coordinated development with a Task Group hosted in ISO/TC215 WG6. 	<ul style="list-style-type: none"> - Clear communication & identification of standards under development - Task Group Standards Development 	ISO Lead ISO WG6 Ian Shepherd and Task Group Co-Chairs	Active
Clinical Information Models	<ul style="list-style-type: none"> - Assess and identify coordinated standards needs, amongst the various reports and related standards in development – Converge all work towards a singular (set) of necessary standards 	<ul style="list-style-type: none"> - Table discussion paper and target (a set) necessary standards - identify use of existing / under development related standards 	Not assigned yet William Goossen (lead)	Active

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Name	Description	Action Needed	Assigned	Status ⇒ Potential / Preliminary ⇒ Active ⇒ Complete
Personal Health Records	New work being considered in multiple SDO venues (currently a joint ISO / CEN Personal Health Task Force; PHR task group under HL7 EHR TC)		Not assigned	Potential / Preliminary
Terminology used in medication standards	Multiple standards are being developed that may have conflicting terminologies (preliminary work items in ISO WG 3 for harmonisation, mapping)		Not assigned	Potential / Preliminary
Document Registry			Not assigned	Potential / Preliminary
Clinical Summary	The ISO Health Summary Record Technical Report has broad implications both to information model work and to EHR developments - are there related standards that impact or will be impacted by this work (need to link to wider contexts)		Not assigned	HSR TR at ISO DTR ballot, closing end April 08
Methodology Framework	Is this standard out of date?	- Determine if standard to be 'retired'	Not assigned	Potential / Preliminary

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Appendix 2

**Joint Initiative on Global Health Informatics Standardization
Joint Working Group – Opportunities and Issues Log**

**Version 3
1 March 2008**

No.	Opportunity / Issue	Requirements	Outcome <ul style="list-style-type: none"> • Assigned to JIC • Assigned to Secretariat • Resolved • JWG work program • SDO work program 	Date Considered
1	Balloting <u>same draft standard</u> simultaneously through multiple SDOs	<ul style="list-style-type: none"> • Simultaneous ballot - NWIP and draft • Identification of ballot pool • Maintaining one document • Ensuring a consistent format (template) • Version control for drafts • Co-ordination of the collation of comment • Review of comments by expert work group with proposed solution • Distribution of comment summary to SDOs • Resolution of comments • Access to documents (website) • Resolve work progress and representation issues eg HL7 participants in ISO – do they represent NMBs or HL7? • Timely standards development work • Identify lead SDO for projects done jointly • Resolve IP issues 	Assigned to Secretariat to develop draft guidelines for JIC review and follow-up	20071002
2	Pathway for project work coming from ISO to HL7	<ul style="list-style-type: none"> • Resolution of issue 1 • Identify process for project adoption and intent 	Assigned to JIC to further review (agreements) and resolve	20071002

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No.	Opportunity / Issue	Requirements	Outcome <ul style="list-style-type: none"> • Assigned to JIC • Assigned to Secretariat • Resolved • JWG work program • SDO work program 	Date Considered
3	Outcome is relevant for joint standards work of ISO, CEN and HL7	<ul style="list-style-type: none"> • Market and vendor and other relevant stakeholders relevance of standard 	Assigned to JIC to consider and potentially identify task force	20071002
4	Governance for archetypes / clinical information models	<ul style="list-style-type: none"> • Avoid duplication • Repository for archetypes • Common archetype / constraint language 	Revisit at future meeting (watching brief)	20071002
5	Implementation guide for HISA	<ul style="list-style-type: none"> • Availability of use cases (see 10) • Identify global versus member / country decision points eg terminology 	Revisit at future meeting (dependant upon further ISO and CEN work / ballot results on HISA)	
6	Relationship of ICH work in ISO WG 6 with HL7	<ul style="list-style-type: none"> • Clarify timeframe for the ISO WG6 work items 	Assigned to JIC to resolve	20071002
7	13606, part 1, and CDA R2 – is there technical coherence between these standards?	<ul style="list-style-type: none"> • Process issues – see 1 and 2 • Market and vendor relevance issues – see 3 • Coherence issues - Identify areas of alignment / overlap/ difference 	Assigned to expert group to draft accompanying brief document and email for ISO FDIS ballot	20071002
8	How to advance common work effectively across all participating SDOs		Added to 1	20071002
9	Resourcing to support JWG roadmap / 3 year work program	<ul style="list-style-type: none"> • Identify if national /? programs will fund projects 	See minutes of meeting 2 other business 8 (b)	20071002
10	Library of use cases	<ul style="list-style-type: none"> • Identify national versus international uses cases • Identify starting set of use cases eg HL7 EHR Functional Model, HISA 	Revisit at future meeting	
11	Communication about the Joint Initiative's role and work program	<ul style="list-style-type: none"> • Pathway for stakeholder liaison / engagement • Website 	Assigned to Secretariat	20071002

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No.	Opportunity / Issue	Requirements	Outcome <ul style="list-style-type: none"> • Assigned to JIC • Assigned to Secretariat • Resolved • JWG work program • SDO work program 	Date Considered
			Standards Australia to investigate	
12	Transparency of JWG decision making	<ul style="list-style-type: none"> • Document decision process and outcomes 	Follow-up communications about 1,2 and 8	20071002
13	Three-way joint SDO projects eg archetypes, HISA	<ul style="list-style-type: none"> • Identify lead • Maintaining one document • Co-ordination of the collation of comment • Co-ordination of balloting 	Assigned to Secretariat to identify process and options for JWG and JIC consideration subsequent to work on 1, 2 and 8.	20071002
14	Processed for adoptions of Standards	<ul style="list-style-type: none"> • Identify SDO responsible for maintenance and revisions 		20080223