

Minutes for JIC Executive Sessions

Kees Molenaar, Chair

Audrey Dickerson, Secretary

Rio de Janeiro Brazil

11 May 2010 0900 - 1200

1. Welcome, sign in and agenda approval
 - a. agenda:
 - i) Approval of agenda
 - ii) Approval of minutes of 14 April 2010 meeting
 - (1) Minutes approved -Spell out acronyms
2. Membership decisions -----none listed
3. Work item decisions
 - a. Vote on Patient ID- not discussed at this meeting
 - b. Status Check Joint Work
 - i) Biomedical Research Information Domain Group (BRIDG) Model --not discussed at this meeting
 - ii) Individual Case Safety Report (ICSR) not discussed at this meeting
 - (1) Add update on balloting for this item.
 - iii) Identification of Medicinal Products (IDMP) not discussed at this meeting
 - iv) Clinical Trials Registry -HL7 led project Scot Getsin (sgetsin@lilly .com) CDISC, HL7
 - (1) Look at the history and came to be a JIC item
 - (2) Missing piece is ISO - Does TC 215 want to be part of the Clinical Trials Registry work. If so, where would the WG 'home' be for the work?
 - (3) Need to construct the history and see what needs to be changed, if anything
 - (a) Done and attached to the minutes.
 - (b) History aligned with WHO
 - (c) On agenda for June conference call meeting.
 - v) Data Types not discussed at this meeting
 - c. Issues to resolve regarding Joint Work in preparation
 - i) Glossary and Document Registry (SKMT)
 - (1) New way of harmonizing words in context
 - (2) Look at the proposal
 - (3) Update on SKMT -
 - (4) Not breaking any copyright laws, using the scope statement from the NWIP/scope of the document to identify the context of the standards where the terms are from.
 - (5) Is it a tool or document? Content of tool is published, standard glossary, Copyright info:
 - (a) Maintenance what about copyright
 - (b) Canada - signed to maintain SKMT Sherbrooke University to maintain
 - (c) 3 year agreement - until 2012-

- (d) Rules of the product/tool on paper, who owns what/ what is the length of time
- (e) ISO copyright - issues - Need to make clear - during the harmonization track
- (f) The basic copyright information is below.

Secretary Note: ISO/CS does not deviate much from the statement below. When I have asked in the past, what I received is a reiteration of the statement below.

Copyright excerpt from ISO/IEC Directives, Part 1:

2.13 Copyright

The copyright for all drafts and International Standards and other publications belongs to ISO, IEC or ISO and IEC, respectively as represented by the office of the CEO.

The content of, for example, an International Standard may originate from a number of sources, including existing national standards, articles published in scientific or trade journals, original research and development work, descriptions of commercialized products, etc. These sources may be subject to one or more rights.

In ISO and IEC, there is an understanding that original material contributed to become a part of an ISO, IEC or ISO/IEC publication can be copied and distributed within the ISO and/or IEC systems (as relevant) as part of the consensus building process, this being without prejudice to the rights of the original copyright owner to exploit the original text elsewhere. Where material is already subject to copyright, the right should be granted to ISO and/or IEC to reproduce and circulate the material. This is frequently done without recourse to a written agreement, or at most to a simple written statement of acceptance. Where contributors wish a formal signed agreement concerning copyright of any submissions they make to ISO and/or IEC, such requests must be addressed to ISO Central Secretariat or the IEC Central Office, respectively.

Attention is drawn to the fact that the respective members of ISO and IEC have the right to adopt and re-publish any respective ISO and/or IEC standard as their national standard. Similar forms of endorsement do or may exist (for example, with regional standardization organizations).

Additional notifications in Supplement Annex, SM and page 10 Directives, Part 2.

<http://www.iso.org/iso/copyright.htm>

- (g) Voting to agree is a JIC item, need to work to find needed answers but do the work together. Agreement process bring back to group. May need several meetings before all agree and issues are settled.
- (h) Approve a standard work item, not approve a standard, just the work.
- (i) The TC 215 glossary item is a different type of item, not a standard but a tool to be used with standards development.
- (j) Opinions? Like the idea of having a tool—something new to have as an item.
- (k) Where most standards are for outward consumption—is an enabling tool for the participating SDO's to use. Envision a number of tools.
- (l) Consider the ISO timing issues - general problem is the standards take much time to develop.
- (m) Are there reports from the tool and what is the content of the report. The tool may generate an online report.
- (n) Thoughts of JIC work item as a tool - and the general idea is a good one
- (o) HL7 wants to read the tool -what is the context of the tool? How much of HL7 work products end up in the TC 215 glossary repository?

- (p) Terms are those used and published by an SDO. For example: Rose Tree tool - much of the HL 7 content of the Rim vocabulary could conceivably be in the TC 215 glossary tool.
- (q) The intent of the glossary tool, is to define terms in the context of the standard where the term is defined. To have SDO's participating in JIC to have their terms in the glossary tool, so all of the terms for published standards be in one place.
- (r) There have been numerous overview presentations on glossary issues but details should also be discussed.
- (s) HL7 glossary and the ISO terms from standards from TC 215 - went to each SDO and asked what is the glossary. From HL7 only their glossary has been discussed.
- (t) Coordinating standards - "back office collaboration" is very important.
- (u) CDISC glossary is just terms and definitions to align with others. Then there are coded terms and definitions embedded in the standards is much larger and more involved than just the glossary.
- (v) Coordination of collaborative tool as an example, the definitions within the RIM - HL7 concern is related to a needed scope discussion for the TC 215 glossary.
- (w) Glossary does need to be scoped and then careful of the message to be sent to all experts and delegates.
- (x) Three decisions needed to think about:

MOTION:

- (i) Accepts work items that are part of collaboration having items
- (i) Phrasing accepts items that support collaboration and coordination.

Do we consider this tool/project important to the joint work

Stephen Kay/Chris Chute Motion: Unanimous

MOTION:

- (ii) Work item is a scoping exercise make a distinction between the final product and the work item - the work is to get us to the final product.

SKMT work item to address issues and requirements for completion and finalization of the tool. Jennifer Zelmer/Stephen Kay Motion: Unanimous

- ii) Detail Clinical Models /-in terms of process- has not submitted the proposal -
 - iii) Data Types Implementation Guide - do not have the proposal yet
 - iv) Audit Trail—do not have the proposal yet
- d. JWG- Harmonization Track
- i) Content and Process new possible items:
 - (1) Drug dose item
 - (2) Clinical terminologies
 - ii) Some harmonization items under way - with some new items to work on
 - iii) See conflicts and then open active debate
 - iv) Agenda for harmonization track sent out to delegates and experts
 - v) Proposal for harmonization track - invited co-Convenors and project leads to discuss items
4. Which SDOs are interested in patient identification work begun with GS1 -
- a. CEN have done previous work with ID - CEN would be interested (2 workgroups have done work in the area of patient identification.

- b. HL7 same idea for the US but otherwise is interested
- c. TC 215 -US is in a awkward position---privacy discussion during Clinton administration - privacy advocates -
- d. IHTSDO -NO
- e. CDISC yes
- f. GS1 Yes and lead SDO

Discussion: Big concern is how to coordinate the work already done in CEN and TC 215. It would not use the need for IHE to cross-match. Make things safer and items should be more harmonized. Nothing to do with privacy protection - and reasonable to work on.

5 out of 6 SDO members said yes, would like to work with this topic.

Project is agreed to for a JIC Project.

Next Step: SDO's send in form with positive response and with a person to help with the work. All of the work that needs to be considered with this work. Agree to this process?

Meet this afternoon in the harmonization track -

5. Policy and procedures

- a. Review of Open Forum
 - i) First of a new series. Briefly would like to have feedback.
 - ii) Sound quality in hotel meeting room was very poor. Hotel worked to accommodate. "Dead" spots in the room.
 - iii) Suggestions for improvement - communicate in advance—Agenda late - expectations were not clearly understood by the audience. Posting agenda earlier - audience should be more prepared.
 - iv) See more presentations, similar to Heather's. Short to stimulate discussion.
 - v) People were unclear about participation, did not know if they could participate. The room set-up should have been different.
 - vi) The un-conference needs structure. Rather than have open call for participation - Number of slots available for people to discuss. Should not be open-ended. May want to have this section earlier in the proceedings. So people could have their say and then have some discussion.
 - vii) Delegates and experts liked the content information - some times do not have to have be in a separate group to hear about all of the items.
 - viii) Give details on what kind of items should be in this time slot. Open mic - 3-5 minutes - enough structure so people do not "pack up and leave". It is a way to voice criticism as it is more open then not necessarily about the new item.
 - ix) Big lesson - better preparation and better communication of what to expect - invite to discuss items. Invite to discuss with those in the JIC.
 - x) Draft agenda in the next teleconference.
 - xi) Report during open plenary to discuss what about open plenary

Secretary Note: Open plenary happens only once each year and is specifically designed to allow sponsors and country NMBs to welcome delegates. Usually is not an early completion to open plenary.

- b. Dummy guide
 - i) Updates needed in existing documents;
 - ii) Updated the documents
- c. Follow up discussion on slide deck on balloting
- d. Hosting the Joint Initiative website

- i) Much documentation is on the HIMSS site and on Australian Standards site
 - ii) Need a place to post info from the JIC, HIMSS is only available for this next year until 2011.
 - iii) Looking for alternatives with documentation, ISO and CEN are not easily used
 - iv) Need to rely on others and how can we work with this - HL7 may wish to host - could have a response next week-
 - v) Configure so email address gives a permission - should be open - so all others can have access. Show the six logos- HL7 site is more open -get appropriate info this next week.
 - vi) Once that is done, work out process of how items move to the site - deal with the content. Content is how the JIC council deals with the items.
 - vii) Policy and procedures - deal with how content is actually sent to the website - Need to vote?? Joint environment and have on the agenda for next meeting.
6. Access for emerging and developing countries
- a. To standards:
 - i) What needs to be done example CEN/ISO what are the options and possibilities. IHTSDO: SNOMED open for all low income countries and opportunities for education and sharing experiences. Practice meetings do not have registration fees. Had some discussions with some foundations to support travel
 - ii) Back office collaboration: Could all JIC SDO's develop a proposal together and then go to foundations for funding to help developing countries.
 - iii) Work with DEVCO RE: ISO (see attached document)
 - iv) HL7 works ad hoc - when a group comes and asks to form WG, request is granted.
 - v) ISO is tightening alignment with NMBs and other partners and JIC is the natural partner/forum to have this take place. As TC 215 re-structures and begins to work
 - vi) Proactively, can JIC fill in the gap and how would this be done?
 - vii) HL7 does remote education and fund travel for specific individuals ---some of our standards meetings are hard to appreciate if you are not in the room.
 - viii) HL7 is using webex for the first time due to the cost of projectors.
 - ix) Still issues with using webex in developing countries.
 - x) Donor foundations had some communication with, accountable use of their \$\$.
 - xi) JIC collectively speak to the foundations to make connections.
 - xii) Meeting attendance - best! Holding in developing countries. Some level is good.
 - xiii) Consider Africa to hold a meeting -HL7 comment - concerned about countries that spend tiny amounts of money/person may not be ready for an informatics meeting.
 - xiv) People building enterprise architectures - and may have 2 dozen people - standards of interest
 - xv) CDISC worked HL7 and with NIH on tuberculosis best practices for use in developing countries. Not sure how to implement.
 - xvi) Brazil showed how to implement//role should JIC play //how to measure what role to play//Best Practices forum// When/Where??
 - xvii) GS1 way to communicate - if product is expired and in a remote place -what to do.
 - xviii) Give enough information to work better -
 - xix) Small meeting - What should this council do? JIC would like to address and pay attention to. Put on the agenda for next meeting
 - xx) X-SDO alignment and go to developing countries to have a meeting.

- xxi) May be some issues and have Don and Jennifer (Volunteer) write a proposal
- xxii) Need others involved in this discussion. Task Group with additional experts.

ACTION Don and Jennifer with an expert from Brazil to develop a proposal.

- b. Reports
 - c. Brief report from member SDO's (all six)
 - i) GS1-have discussion with HL7 and others
 - ii) CDISC- 3 SDO's development 150 comments and BRIDG released - 14 affirmatives/ with only 1 ISO comment/ Many comments from HL7. Passed both TC 215 and HL7 ballots
 - iii) IHTSDO: Working with other SDO's. Main streams on website.
 - iv) HL7 happy to say harmonization is working. And meetings are less contentious.
 - v) CEN:
 - (1) Impact of EU Medical device directive—extend Medical Device stand alone HIS system
 - (2) Mappings and algorithms. Currently meetings - with the CENELEC group (TC62) responsible for the medical device safety standards, having some difficulties in gaining consensus with all of the participants.
 - (3) How to do testing? Major device players - so can impose will on smaller concerns - real potential to be ill-informed.
 - (4) Extreme and will be disruptive to industry. 251/TC 62 now have JWG and to work with medical device directive. May be some similarity there. Need to sort out what should be done.
 - (5) Issue is huge in Canada - caught by surprise. Issue of software safety - another group - key consideration for Canada. SDO's should be providing guidance and the definition of software - what are Health Information Systems. What is patient Management software. Documentation in progress. Share what is in progress. Need to provide some guidance.
 - (6) Prepare an harmonization track - bring to the JIC making efforts as to cost! Everyone is quite worried. Standards Org should provide guidance.
 - (7) Statement of concern from all of us, where will it end? If we have been remiss in looking at safety and then generic issue when to Health Informatics things become devices
 - (8) When do standards become devices. What are the things need to do to standards? Moving into risk management -legal area—seek advice -
 - d. Status of EU Mandate M403 eHealth-INTEROP
 - i) No contract signed
 - ii) Meeting yesterday - suggestion to have Best Practice Forum -
 - iii) Get money to support forum expect to have a contract with EC. Disseminate standards material.
 - e. Other Reports
7. Next Meetings
- a. Review meeting schedule
 - i) Conflict HL7 and ISO/CEN meeting

- ii) No update - yet --
- b. Secretariat
 - i) support for harmonization track
 - (1) need secretariat support.
 - (2) ID what do we do for support for the harmonization track?
 - (3) May need to find support for teleconferences and secretary support.
 - ii) JIC
 - iii) teleconferences