

**Minutes of JIC Harmonization Open Forum
2010 - 05 - 09**

Kees Molenaar, JIC Chair

Don Newsham, JW69 convener

Audrey Dickerson, TC 215 Secretary

Reports on joint work, reports from JIC and JW69 and unconference

Open Forum on Joint Work

Session Chair: Don and Kees

Kees: Welcome to the first Open Forum. Please see the meeting notice.

Don: The JIC is refining the harmonization processes. What you are seeing is the change to work better together. First part of the agenda is to update information related to specific documents:

1. Reports from project leads
 - a. Biomedical Research Information Domain Group (Bridg) Model (Bron Kisler)
 - (1) ISO comments to be addressed this week and HL7 comments next week.
 - (2) Also have a talk Q4 on Monday about CDISC standards work.
 - b. Integrated Case Safety Report (ICSR) (Ian Shepherd)
 - (1) Both documents, Individual Case Safety Report (ICSR) 1 and 2 about to go out for 2nd Draft International Standard (DIS) ballot no additional discussion on these items.
 - c. Identification of Medicinal Products (IDMP) (Ian Shepherd)
 - (1) Learned how to overcome issues and help process of the future. WG 6 and JIC now have a better understanding of who is taking part in this work. JIC now have more representation than previously. With all of the people involved a better communication process has been developed; as communication with each other is extremely important. Over 100 people are involved for teleconferences and F2F meetings, issues discussed and the consensus process was enormous. Who has the right to hold a meeting, which venue can hold a meeting. First ballots, not synchronized, a large amount of work was involved, content and work processes. Then the ballot results are in different formats, experts have many "hats" each. Resolve properly - Testing - some of the standards need to be tested to do what they said they would do. Publishing and who owns the copyright - to recognize all of the work contributed.
 - (2) Don: with the processes for working with a large group established, some best practices are established.
 - d. EHR Functional Model (Gary Dickinson)
 - (1) 1.1 is published. And a number of items from 1.1 ballot comments will be integrated into W2. Work being done in the HL7 EHR WG. Spreadsheet comments now being integrated into V2.
 - (2) Capturing some comments from the US work with HITSP (Health Information Technology Standards Panel) into the HL7 EHR-FMV2 model for the V 2 NWIP. The NWIP ballot in TC 215 should run parallel with HL7 and CEN.

- (3) All of the implementation/uses for the EHR-FM is quite gratifying. Primary focus has been on informatics standards. Functional standards are not the norm from TC 215. Functional standards are new.

e. Clinical Trials Registry (Bron Kisler)

Under HL7 process - and will have update ready for next meeting

f. Data Types (Status) (Audrey Dickerson)

Update -Document is at ISO/Central Secretariat for FDIS (Final Draft International Standard/Publication stage. Should begin the 2-month FDIS ballot prior to the August summer recess in ISO/CS. Then be published shortly there after in 2010.

2. Q+A

Is there a clean /up-to-date list of active Joint Initiative projects?

Above list of items. And will begin to publish after the meeting. Working on getting JIC open and available as soon as possible. Any questions on the joint work please ask. Does not currently include preliminary discussion items.

JIC reports

Session Chair: Don

Report from the chair - sharing information on the harmonization work is important.

Background for JIC:

- Charter voted on at a plenary 2007 Brisbane Australia
- Ed Hammond, was elected chair in 2007. The JIC Chair role evolved and now the role is for one year and then renewable for one year. Kees Molenaar was elected to the JIC chair position in 2009.
- JIC now has 6 SDO's committed to working together, ISO/TC 215, CEN/TC 251, HL7, GS1, IHTSDO and CDISC.
- Work item discussions:
 - What is a JIC work item and what does it mean? Harmonized ballots and comments among the SDO's who are participating on the work item. Should be at least 3 of the 6 SDO's to be a JIC item.
 - New work item Patient Identification discussion in the council meeting on 11 May. Work Item proposal amongst all interested and participating SDO's .
- Meeting model has changed:
 - Important to get input from experts in the audience. Thus, the Joint Open Forum was developed to have reports on JIC projects progress or lack of.
 - Joint Initiative harmonization track a place to discuss possible new JIC items, timelines for development of the new item, discover who the experts are to work on the new item. Now introduced a JIC-harmonization track. Work with experts on issues to solve.
 - JIC is an executive session where Chairs work - make decisions on new items and additional membership. Minutes are now to be public and will be put on a website.
 - Dave Iverson-Hurst (CDISC) prepared a comparison of the balloting—not complete yet. What the timelines are and how a JIC item may be managed. Want to avoid unnecessary delays.

- Guide to JIC or/ 101---Demo of Guide - will bring "live" as soon as possible.
 - Want to be as open and transparent as possible.
 - Since the Durham meeting, JIC has been working on the new meeting structure to provide openness and transparency.
 - No additional questions were offered from the audience.

Q+A

- a. Are there schedules of "JIC" and "ISO/HL7 project" meetings?
Meetings of projects can be done at any of the 6 SDO's during their meetings. Currently the harmonization track meetings are held during the TC 215 meetings.
- b. Are there meeting minutes posted? Will be on the website, currently there are two websites and JIC is waiting for one website to be either updated or removed.

JIC reports continued:

Chair: Kees

1. Work already underway
 - a. TC Glossary and Document Registry (SKMT) (Andrew Grant / Heather Grain)
 - (1) Get slides from Heather—Requested.
 - (2) Many discussions on definitions, in the context of terminologies and related to HL7 work and
 - (a) 215 work. The terms are defined first as an established standard - Definitions are all in existing in published standards.
 - (b) Who makes the agreed definition status to "standard". Is this an issue? Should the consensus process be an established one such as HL7 or TC 215? We need this work item to be an agreed process.
 - (c) Need to make decision this meeting on this document—Glossary was withdrawn as an active document as it is not a document but a database.
 - b. GS1 Identifier (Christian Hay)
 - (1) Quick overview - 5 years ago, problem in healthcare regarding identification of items; related to the need for naming items in the marketplace. Work done related to identification of supply chain materials.
 - (2) GS1 work on ID for patients/providers is in discussion for a new JIC item. On Tuesday, 11May 2010 present more detail.
 - c. Detail Clinical Models / Clinical Data Modeling (William Goossens)
 - (1) WG meeting during lunch in WG 1 10 May 2010. What are the JIC processes and will be discussed on Wed afternoon, 12 May 2010.
 - d. Data Types Implementation Guide (Heather Grain / Grahame Grieve)
 - (1) Work done by Australians and forward to JIC. Logical way to get work started. Support from the National Infrastructure for the work. Will proceed formally.
 - e. Audit Trails (Ross Fraser / Lori Fourquet)
 - (1) Where is this at or will be proceeding? Work is still proceeding from a security point of view. Larger issue outside of security - HL7 approach broader issues of a clinical audit.
 - (2) Not the appropriate group to work on a clinical audit? WG 4 only did narrow item related to security.

- (3) What is a clinical audit? HL7 work - Clinical decisions that were made - traceability for the clinical event - ISO specification restricted to security aspects.
- (4) IT experts healthcare or not should careful about words used - a clinical audit - may be defined as a review of full case records and whether the therapies and decisions were appropriate for the case. Is not an appropriate topic for TC 215 and not popular with many clinicians. General feeling is there may be other things to audit; perhaps other Health IT areas where items may be set in place. Encourage participation.

Comment [MIR1]: Agree conclusions of discussion re scope. But did the idea of adding "Security" to the title get mooted?

2. New work items:

3 new work items for emerging and developing countries. This work could be addressed by JIC as would like to have other SDO's also address. Would like the message to go through to all. WHO is working on HI framework adopted in some developing countries.

Q+A

- a. What is the difference between the "JIC" and the "ISO/HL7 project"?
- (1) JIC project is harmonized ballots with similar timelines and shared comments of the participating SDO's.
 - (2) ISO/HL7 project is harmonized only with ISO/TC 215.
- b. When a project successfully goes through a JIC ballot. There are no JIC ballots. Only harmonized ballots in each participating SDO.
- c. ,Will the project be an ISO standard?. If ISO/TC 215 was among the participating SDOs
- d. For JIC projects, who does the technical work and discussions? WGs in any of the participating SDOs.
- e. Is there a WG that schedules teleconferences? Not that I know of.
- f. Are they JIC meetings or ISO meetings? JIC meetings happen at any of the participating SDOs, currently TC 215 meetings, TC 251 meetings or HL7.

Comment [MIR2]: ... work initiated within HL7 and brought to ISO for publication. Harmonization is not guaranteed and is dependent on the ISO opinion at ballot.

Comment [MIR3]: But the 'lead' for project organization should be clearly agreed at the project initiation.

Comment [MIR4]: This is true, but project working meetings can be convened and organized wherever and when ever the lead organization determines in consensus with the experts for across the participating SDOs.

Un-Conference

Chair: Kees and Don

1. Suggestions for joint work to resolve issues of gaps and overlap, Topics may include a way to streamline the current process, or looking at the agenda and would like to bring a topic forward for discussion.
 - a. Suggestions may be sent to TC secretary, Kees Molenaar or Don Newsham.
 - b. Suggestions for discussion:
 - (1) May be a short presentation (5-6 slides)
 - (2) May be a discussion point or different perspective on a new or current work item.

At this time, there were no suggestions for discussion.