Minutes for JIC Executive Sessions  
Bron Kisler (CDISC), Chair  
Audrey Dickerson, Secretary  
Thursday, 10 February 2011 Conference Call

1. Welcome, sign in and agenda approval  
   a. Approval of agenda and minutes from 23 November 2010  
      i) No changes Christian Hay /Chris Chute motion to approve minutes.

2. Membership decision  
   a. Candidate members?  
      i) No new members.  
      **ACTION:** Decision to leave this section off the agenda for now as there are not new members for the present. If/when new members approach item will be re-instated on the agenda.

3. Current and future work items  
   a. Discussion and Vote for Dose Syntax (Orlando face2face meeting)  
      i) To be discussed and voted on in the face to Face (F2F) meeting in Orlando.  
      ii) As soon as approved will work to place on ballot, so as to have results by the Finland meeting.  
      **ACTION:** Re-send documentation for dose syntax with Orlando packet  
   b. Status Check on Joint Work  
      i) Biomedical Research Information Domain Group (BRIDG) Model  
         (1) Passed CDISC and HL7 ballot and ISO ballot New version for DIS  
         **ACTION:** In ISO/CS processing since December 22, 2010. Usually takes 8-12 weeks.  
      ii) Integrated Case Safety Report (ICSR)  
         **ACTION:** Check on dates for FDIS do not yet have dates for FDIS  
      iii) Identification of Medicinal Products (IDMP)  
         (1) Check on HL7 dates Feb 18 to March 20  
         (2) ISO dates close February 23.  
      iv) Clinical Trials Registry  
         **ACTION:** Bron to check on  
   v) Data Types  
      (1) To be published on the 15 February 2011  

**Other Items to be discussed in the F2F meeting – Orlando**  
(2) EHR-FM R2 - Check Durham minutes (see excerpt)  
(3) Excerpt from the Durham minutes:  
   c. The EHR-RM template document is introduced. There is expanded interest the EHR-FM topic.  
   d. 90% of the comments were on the V1 and V1.1. Comments went into R2.  
   e. Strong interest in JWG9 led by HL7 jointly balloted with TC 215. Much interest and want to be sure that all of the comments are revised into the document.  
   f. At the Edinburgh meeting there were recommendations for EHR-FM.  
   g. When versions happen with fast moving projects may need to solve problem (s) not just this document.  
   h. WGs 1/8 active interest with this document. The document needs a project lead.  
   i. Question: Need project lead.
MOTION: subject to list for project lead----- ISO- yes; HL7 - yes; CEN - abstain; IHTSDO - yes; CDISC - yes

1. Need to have someone from HL7 to participate in discussion
2. Is an JIC project - problem at ISO WGs 1 and 8
3. ISO is happy or not Where is problem originating from?
4. Is the problem a lack of communication on ballot coordination?
5. If only HL7 and ISO are using the HL7/ISO agreement are these items JIC?
   a. No. Need 3 SDO’s to be JIC.
   b. Items published under the agreement, RIM, CDA R2, CTS R1 and HL7 V2.5

ACTION: To discuss further in Orlando

ii) Additional items/issues to resolve regarding Joint Work in preparation?

iii) Glossary and Document Registry (SKMT) - now a tool and not a document up for ballot

iv) Detail Clinical Models / Clinical Data Modeling

v) Data Types Implementation Guide

vi) Others (e.g. WG-3 definitions)
   1. Countries not addressing the definitions during the NWIP vote
   2. How to ballot definitions so NMB’s are not confused and will make appropriate decisions

ACTION: To discuss further in Orlando

4. Policy and procedures
   a. Introduction to JIC processes (aka “dummy guide”) JIC process in general
      i) Who would do this? It is needed
      ii) How does it get done and what is the process
      iii) Logistics of generating guide
   b. Updates to existing JIC documents - Policy and Procedures
   c. SDO process / balloting slide deck
      i) Take the next steps and who might have the time to approach
      ii) Policies and procedures and more transparent
      iii) Sorting through items that work and
      iv) Right set of information other than logistics
      v) Christian within a couple of days for the GS1
      vi) Charter work and had some exchanges reviewed with Melvin and Don
      vii) See the next version - will send out as part of the Orlando package
   d. Ballot alignment across SDOs; how can we improve handoff?
   e. JWG and JIC coordination and process

ACTION: To discuss further in Orlando

5. Access for emerging and developing countries
   a. To standards - Need to coordinate with ISO-- [http://www.iso.org/iso/developing_countries](http://www.iso.org/iso/developing_countries)
   b. To meetings - provide the status of the 2 documents in Orlando package
   c. Issues from JIC - why is this a JIC issue and not TC 215
   d. Issues relative to WHO and the donor community - look for valid pathways forward -
   e. We need to keep the projects up to date

ACTION: Secretary to send documents

6. Reports
   a. Brief update and report from member SDO’s (6)
   b. 215 -
i) TC 215 should focus on a smaller number of higher impact standards. Many of the ISO standards do not have high impact nor have they been implemented.
ii) Makes more business sense and help people focus and go into slightly smaller groups. Help from other people - help on the development side.
iii) What is needed is an understanding about what the NMB's want and what do they need and what is needed to strategically drive forward.

- HL7 no report but asking if other SDO's want to be part of the detailed clinical models from HL7.
- CEN - plenary meeting March 9 - nominations for the new chairperson and will begin to discuss the structure of the TC and wait for the results of the Taskforce.
- IHTSDO - April meeting upcoming - updated and changing processes. WHO agreement signed and 2 batches work and mapping SNOMED to ICD-10 and now a reality.
- CDISC - move standards in more of a clinical direction and first 2 diseases acute coronary syndrome and TB. New projects and new standard for other diseases. Key direction around specific diseases. Emerging and developing countries and because of AIDS, Hepatitis and TB
- GS1 system of standards - current in ballot and review process and for how it works together. Happy to share with JIC and small documents (less than 100 pages) Business point of view - AIDC work for special healthcare products - work started - progressing well - no deadline yet and ambition is wide.
  i) Impact of EU Medical device directive
  ii) Status of EU Mandate M403 e-Health-INTEROP
     (1) ACTION ask for an update from Melvin and Kees
  iii) Other pre-announcements? US FDA?

**ACTION:** Request either Melvin or Kees to send updates on EU items.

7. **Next Meetings**
   a. Logistics / Agenda for JIC F2F in Orlando Sunday, 20 February 2-5:30 p.m. US Eastern room 305
   b. Review 2011 meeting schedule

8. **AOB to address in Orlando (e.g. JIC response to questions from ISO TC215 Task Force)**
   New issue - HL7 and JIC participate in WoHIT have a joint contribution -

**ACTION:** Ask Sean to attend the end of the meeting (done) He said he will come.