

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
- 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 in to 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
- c. HL7 no report but asking if other SDO's want to be part of the detailed clinical models from HL7.
- d. 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.
- e. 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.
- f. 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
- g. 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 eHealth-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.