Agenda for JIC Executive Sessions
Bron Kisler (CDISC), Chair
Audrey Dickerson, Secretary
Sunday, 20 February 2011 2:00 – 5:30 p.m. US Eastern

CDISC	Becky Kush, Bron Kisler
CEN/TC251	Robert Stegwee, Kees Molenaar (via phone)
GS1	Not represented
HL7	Chuck Jaffe
IHTSDO	Jane Millar
ISO/TC215	Chris Chute, Audrey Dickerson, Don Newsham

1. Welcome, sign in and agenda approval

    a. Approval of agenda
        Agenda was summarized and approved (EHR-FM added under 2b)
    b. Approval of minutes from Feb 10 2011
        Clarify that CDISC comments (ballot) will close on 23 February (Bron requested to add this to the minutes).

MOTION: With this change, a motion was made and seconded to approve the minutes; the minutes were approved.
ACTION: Secretary to make change on February 10 2011 minutes. (done)

2. Current and future work items

    a. Discussion and Vote for Dose Syntax
        Discussion: has been a topic for less than 6 months. This has been prepared as an NWIP in TC215; it will go forward to ballot in TC215 independently of the JIC vote. However, once the JIC has voted about whether it will be a JIC project, then Dose Syntax can move forward with participating SDOs.
         Issue: there seems to be significant overlap between the Dose Syntax document and IDMP.

MOTION/ACTION: Go to the author and have a presentation to JIC on how these two items fit together. (Voted and approved)
MOTION: We support the basic philosophy and work direction with the item, but register concern with supporting materials that show clear overlap with IDMP.
ACTION: Chair to call to explain issues and path forward to project lead and WG-6 leadership. Add to agenda for May F2F meeting in Kuopio Finland meeting.

b. Status of Joint Work Items and Lessons Learned

i) Biomedical Research Information Domain Group (BRIDG) Model
The BRIDG team finished their documentation for the 5-month DIS ballot and sent it into ISO, listed as ISO #14199. A date will appear when they are part way through the processing (usually 4-8 weeks). There is no status yet, but it should be ready around mid-March (since we are nearing the 8-week mark). If there are technical issues, we will need to do an FDIS. If the comments are not major/technical, this will be the last ballot. (BRIDG is already an approved CDISC and an HL7 standard.)
Secretary Note: Document refused for DIS – in general we need to pay closer attention to the ISO rules for standards format. Will work with the BRIDG team to revise the document.

ii) Integrated Case Safety Report (ICSR)
HL7 fixing something on this (per Don Lloyd), so expect FDIS this summer

ACTION: Secretary checked and now has the links to the completed documents. Working to prepare to send to ISO/CS for the FDIS ballot.

iii) Identification of Medicinal Products (IDMP)
ISO/CEN/DIS ballot to close on 23 February 2011.
CDISC ballot/comments to close on 23 Feb.
HL7 ballot 18 February 2011 – 20 March 2011

iv) Clinical Trials Registry

ACTION: Message sent to clarify the document title and ISO time track.

v) Data Types published Feb 2011

vi) EHR-FM
EHR-FM - The relevant questions on EHR-FM were: What does JIC need to do? [Background: HL7 already doing work on Release 2, the value of ISO having a discussion on Release 1 was questioned. Canada wanted Release 1 approved by ISO since they wish to use it as soon as possible. Hence, this went through a ballot within HL7 (as Release 1.1). It was agreed that the work on Release 2 should be joint work, and it was proposed to come to JIC to become a JIC project. The TC 251 Chair-elect, Robert Stegwee read from an e-mail from Shirin Golyardi (TC 251 Secretary)– NWIP closed on 9 Feb for EHR-FM Release 2 (ISO Number has been assigned - #10781). Interest from IHTSDO, CDISC and CEN expressed at this meeting.

ACTION: Each organization needs to identify their lead, but the primary lead is Gary (HL7).

GS-1 Project – Working on an NWIP for ISO.

General:
In the minutes, are shown the discussion of the JIC Project Registry. The registry was updated during the meeting and discussion. Please see attached, comment section from the date of the minutes completion.

3. Discuss additional items or issues to resolve regarding Joint Work in preparation?

a. Glossary and Document Registry (SKMT) – See 4.f. below

b. Detail Clinical Models / Clinical Data Modeling
DCMs – confusing and no form yet on this one either; there is a discussion on Scope and it is still a Pending Project "Small Semantic Models"; other considerations include Archetypes-OpenEHR, OceanEHR; DCMs, CEMs, Templates, Scientific Models, Scientific Concept (CDISC SHARE), also Quality Datatypes/Elements

ACTION: Bron will meet with Stan Huff about his recent trip to Europe and get feedback to better understand how the JIC should address this.

c. Data Types Implementation Guide
Pending Project; JIC has not received a request for this to become a JIC project from the project leads.
d. Others (e.g. WG-3 definitions?)

4. Policy and procedures
JIC currently leverages the Vienna Agreement between ISO and CEN as well as other agreements between members to allow ballot coordination as part of the JIC standard infrastructure and allowing issues coordination. Liaison A has become the mechanism for CDISC, GS-1 and IHTSDO. This helps to avoid some of the copyright issues. The goal is to have harmonized shared comments for the same standards document.

ACTION: Please see the updates for the agreement matrix. Such a matrix would be useful so that it could be determined whether the 'lead' on a JIC project would influence the pathway through the balloting process within JIC.

a. Logistics to develop introduction to JIC and processes
   i) Previous JIC Chair Kees Molenaar, began the "Dummy Guide"
   ii) It was not finalized although some discussion and work was done.

ACTION: JIC Chair to continue the work from the previous chair.

b. Discuss recent updates to existing JIC documents - Policy and Procedures
   i) Christian made suggestions in the charter.
   ii) We may want to vote on the P&P separately.
c. Vote on Update JIC Charter – Put this off until GS1 is available
d. SDO process / balloting slide deck
   i) Tabled as not enough time to review.
e. Ballot alignment across SDOs; how can we improve handoff and ballot synchronization
f. JWG and JIC coordination and process
Example: Decisions were made in JWG-9 that were not getting back to the JIC. The result was that there was information going back to WG-3 about a project being a JIC project when it was not. In Rotterdam, the glossary was presented and there are terms that have multiple definitions. It appears there is not a Governance process around the Glossary.
Suggestions:
1-JIC had decided not to play a role in harmonizing definitions.
2-The individual SDOs should use the Glossary, but would not have a vote on the definitions through the SDOs.
3-There are no action items for SKMT as a follow up.

4-JWG-9 may need to address the ACTION items from their minutes within a report to JIC as was done in the past so the JIC minutes have listed/discussed the JWG-9 items. There are extensive minutes from Rio and Rotterdam from WG-9. The JWG (WG-9) leadership needs to bring these to the JIC for review and consideration.

ACTION: Bron to discuss with Don (done)

5-In addition, there is an HL7 Cross-SDO meeting that is informative and trying to bring awareness about the JIC projects, but this is not a JWG meeting. The JWG is to provide a 'home' within ISO for the type of work that the JIC is doing. There are two such groups that are in the directives of ISO – a) devices and b) harmonization. In prior JIC meetings, Don brought a report from the JIC; this would fit with our current agenda when we go through the initiatives to see how they are all going.
Kees suggested that we make sure to prepare the JWG agenda ahead of time; this may need extra attention.

5. Access for emerging and developing countries
   Discussion:
   A survey and other documentation on this topic were brought to the JIC previously by Don Newsham-ISO and Jennifer Zelmer, former CEO-IHTSDO. Work continues through a number of different avenues to try to get standards to emerging and developing countries and to facilitate encouraging participation in meetings (by providing funding). Another initiative is how to build awareness and education. There was discussion around the potential roles of the JIC, donors and others to work together in a "very meaningful way" to assist emerging and developing countries. The WHO has workshops going on where we might be able to participate, but 'we are not there yet'. Work continues through EDC (Education Development Center?) and DEVCO (ISO resources for developing countries)
   Continue to identify 2 sections of information: 1- Engagement and education; 2-Improve access to standards and how standards are implemented. EMA (European Medicines Agency) would like to participate in the education section. Workshops are needed to build engagement. Roles from individuals, SDO's and others should be identified. African Union wants the FDA and EMA to work together.
   JIC Chair- Bron reported on the TB meeting in Ethiopia where the country leaders were present and expressed they don't have the resources needed to get engaged the way they would like to participate.
   IDRC/eHealth wants a 'roles' map and more tangible activities articulated.

ACTION: Dr. Kush to find the Bellagio proposed resolution and share.

ACTION: JIC-Chair and Don Newsham-ISO to discuss further to see what JIC might be able to do (done – recommendations to be brought to the JIC)
   a. To standards
   b. To meetings
   c. Possible JIC projects to address public health needs in developing countries (e.g. TB, HIV/AIDS)

6. Reports (15-mins)
   a. Update and report from member SDO's (6) – JIC should basically continue to monitor
      i) Impact of EU Medical device directive

Devices: Waiting for some information TC 62 (equivalent to IEC 62). There will be an important meeting on 10 March to determine whether they will be an active task force or otherwise. Additional documentation is needed on the issues raised last year. One effort will be to classify medical device software.

ii) Status of EU Mandate M403 eHealth-INTEROP
Project proposal was approved but director generals in the EC are arguing about the budget.

iii) Other pre-announcements? US FDA guidance documents and directives need list
JIC members may want to be aware of the FDA Guidance on eSource that was released recently, with comments due by 7 April.

ACTION: Becky to send out links to the FDA eSource Guidance and the related EMA Guidance.

7. Next Meetings
   a. Review 2011 meeting schedule

8. AOB to address in Orlando (e.g. JIC response to questions from ISO TC215 Re-Org Task Force)

Representatives from HIMSS-Europe met with JIC (Christine and Sean) – HIMSS Europe (10-12 May in Budapest for eHealth week). Proposal is to participate in the eHealth week as JIC (one large logo with small logos for 6 underneath) see current logo on the website.

ACTION: Bron to send the agreement for all to review (which we can revise as appropriate) and then sign on behalf of the JIC.