

Minutes for Joint Initiative Council

Kees Molenaar, Chair

Audrey Dickerson, Secretary

23 June 2010 1600 - 1700 CET

1. Welcome, sign in and agenda approval

a. agenda:

i) Approval of agenda

(1) No additions were added to the agenda.

ii) Approval of minutes of 11 May 2010 meeting

(1) All of the pages were asked about separately.

There were questions about the motions listed, and explanations were given. The minutes were approved without changes.

2. Work item decisions

a. Discussion status of joint work

b. Status check joint work

i) JIC work item registry, draft attached

(1) Exactly what we need registry of work items. Valuable for us and much needed.

(2) —Would like hyperlink to formal document or project scope document

(3) Goal is to make available with evolution over time.

ACTION: Kees to work on registry online with Melvin and Don. Please send specific comments to Kees.

c. Status Check Joint Work

i) Clinical Trials Registry, new item needs history completed.

(1) Reconstructed history

(2) Registry document--Not yet complete -

ACTION: To avoid further misunderstanding, please review and send feedback and comments.

ii) Standards Knowledge Management Tool (SKMT),

(1) There are still some outstanding issues waiting for resolution.

(2) Feedback still waiting for info from Heather or Andrew.

(3) Should have minutes from the harmonization track to begin work of monitoring.

iii) automatic identification and data capture standard patient ID and Care Giver ID,

(1) Documents received from all SDO's and assigned contacts for GS1

(2) Needs nomination of interested experts to participate

(3) Join internal process over the next month

ACTION: Provide GS1 with experts who are interested in this topic.

iv) EHR-FM V2 will be coming to ballot.

ACTION: Requesting TC 215 secretary to send an informative note about coordinated ballots for all NMBs. Get back with date for ballot - work offline with project lead to help with documentation.

d. Issues to resolve regarding Joint Work in preparation

i) Data Types Implementation Guide

(1) No template available

- ii) Detailed Clinical Models
 - (1) No template available
- iii) Audit trails - No template available *Privacy steering committee?*
- iv) Generic model for dose syntax
 - (1) Not yet distributed received---needs to be distributed
 - (2) Ask feedback before the meeting to be able to discuss before meeting.
 - (3) Feedback by the 31 of July 2010.

ACTION: Secretary to distribute Dose Syntax by July 1 for feedback by July 31.

- v) Clinical terminology
 - (1) No Template available
- vi) Other
 - (1) Discussion ---JIC/GS1 and HL7 lead with ID for medical devices -
 - (1)(2) Secretary Note: TC251 request to wait until after Rotterdam meetings for NWIP/JIC coordinated ballot times to begin.

ACTION: HL7 asked for an email from GS1 to begin work on this.

- e. "Shepherding" joint work—
 - i) Discussion:
 - (1) Get access when have questions
 - (2) Need names for all of the projects and not time now
 - (3) Showing who has interest for what work items
 - (4) Someone from the council to be shepherd
 - (5) A liaison whose responsibilities what are the expectations fundamentally that need clarity related to the role. What do we want the person to do.
 - (6) Expectation independent of the project lead so they could identify the issues and get them resolved with some independence. Status and progress check.

ACTION: Work off line and submit names discuss in September meeting.

4.3. Policy and procedures

- a. Guide to the Joint Initiative
 - i) Updated documents;

ACTION: Begin work and discuss at the next meeting. Leave on agenda for next time.

- b. Follow up discussion on Coordinating ballots slide deck
 - i) Progress on the slide deck for balloting - Not available.
 - ii) Tabled until next meeting.
- c. Hosting the Joint Initiative website
 - i) Discussed HL7 and John will look into.
 - ii) Let us know by email.

4. Reports

- a. Brief report from member SDO's
 - i) GS1 no report.
 - ii) IHTSDO close to agreement with the registry.
 - iii) ISO no report.
 - iv) CEN approved matching resolution about the fast tracking and time alignment with ballots on IEEE may be relevant for other (multi-SDO) ballot coordination requirements.
 - v) HL7 no report.

vi) CDISC and discuss BRIDG ballot. One more ballot through TC215.

b. Update on medical device directive

- i) No decision on clarification in EU until at least September¹. Draft Guidance has not yet been formally distributed.
- ii) Canadian time line for Device Class 1 is 12 months and Device class 2 is 18 months. Canadian FAQ have some definitive Information, but FAQ not yet distributed
- iii) The documents from the joint CEN/TC251 and CENELEC/TC62 taskforce on SAMD are available for the JIC members. Kees will send documentation to support the OF session on software as medical devices in Rotterdam.
- iv) **New information:** piece of formal guidance that has some impact. The "MEDDEV 2.4/1 Guidance document - Classification of medical devices" has been re-issued as Revision 9 (June 2010) and can be found at: <http://tinyurl.com/32av8rr>

c. Report from task group on access for emerging and developing countries (see attached)

- i) 2 documents circulated with small task group of 6 people
- ii) What could JIC do
- iii) First document the options are listed
- iv) Second documents are how to do tasks ---did get some feedback
 - (1) Access to standards
 - (2) Access to implementation
- v) 4 possible actions including specific uses---see attached document.
- vi) Preparing document may be more successful together - identifying
- vii) Discussion:
 - (1) Good and appropriate list. Captured strategies and how to make a difference. How to participate. Moving in a good direction for JIC.
 - (2) Excellent start - significant challenges for ISO and CEN
 - (3) HL7 chapters have fallen into lapsed category.
 - (4) Work with other members of 215 - "O" and some "P" members as well.
 - (5) Valuable to each SDO do their write up
 - (6) Countries each SDO has access to. May be an appendix. CEN has some mentoring arrangements.

ACTION: Proposal to move forward:

- (7) Appendix 3 box table to ID relationship to country. Door open but no one has walked through. ID where priorities are. When would like to have done. ? Should be done by end of July to complete two tables. Discuss on September call.
- (8) Don would like to have info available and publish. Jane will pick up any items for IHTSDO when Jennifer leaves.

5. Next Meetings (15 min)

a. JIC meeting schedule 2010 - 2011 to avoid future conflicts

- i) List for all members that are already scheduled

ACTION: Send all schedules to secretary

- b. Review meeting schedule
 - i) Rotterdam meeting
 - (1) 2 quarters for JIC
 - (2) 4 quarters for JI Harmonization Track including 2 quarters dedicated to software as medical devices
 - (3) 1 quarter for JI Open Forum
 - ii) Draft agenda for JI Open Forum
 - (1) See attached
 - (2) Announcing detailed agenda add set of info on Open Forum get feedback this week and send out by next week.
 - iii) Draft agenda for JI Harmonization Track
 - (1) See attached
 - (2) Need harmonization agenda, waiting on minutes.
 - (3) Agenda by end of July or mid August.
 - c. Secretariat
 - i) support for harmonization track
 - ii) JIC
 - iii) teleconferences
6. Any other business
- a. National coordination between JIC Member bodies (requested by Italy)
 - i) will send by email move to next call.
 - ii) Supported by HL7 international affiliates
 - b. Jennifer Z last call -thanked for all contributions to JIC. Jennifer Z stated "... pleasure to work with all of you".
Meeting adjourned 17:15 CET,