

Meeting of Joint Working Group (JWG) Harmonization Track

May 11, 2010 & May 12, 2010

ISO/TC215 Rio de Janeiro

Attendees at both May 11 / May 12 2010 Meetings

Don Newsham	Sharon Stanford	Heather Leslie
Jane Millar	Jean Narcisi	Greg Zeller
Gary Dickinson	Kees Moenaar	Stephen Kay
Shirin Gloyardi	Ian Shepard	Emma Melhuish
Arletty Pinel	Wendy VerHoef	Julie Evans
Bron Kisler	Mark Shafarman	William Gossen
John Quinn	Reymond Wilaisono	Linda Bird
Victor Chai	Chris Chute	Richard Dixon Hughes
Bernd Blobel	Ross Fraser	Heather Grain
Andrew Grant		

May 11, 2010

The JWG Harmonization Track met on May 11, 2010 from 1:15 – 3:00p at the Windsor Barra Hotel in Rio de Janeiro. The meeting was called to order by Mr. Don Newsham. The agenda for was reviewed and approved by the group. Mr. Newsham noted that the purpose of the JWG Harmonization Track was to look at the process being used from a joint perspective amongst the member organizations for Joint Initiative Work Items. The JWG Harmonization Track does not look at content issues.

The three discussion topics for the meeting were: 1) HL7 clinical trial registry 2) GSI patient identifiers and 3) SKMT project.

HL7 clinical trial registry. The HL7 clinical trial registry is in conjunction with CDISC, National Cancer Institute, FDA, European Medicine Association, IHTSDO and WHO (ad hoc). Currently, this has not yet been identified as a new work item in ISO or CEN. The intent is to be at the table to provide input and for this to potentially become a standard in ISO or CEN. One possibility is under ISO WG2 (harmonized with BRIDG). The group will be looking to bring other SDOs into the project.

Patient Identifiers. Christian Hayes, GS1 Healthcare, gave a presentation on the GS1 System of Standards. He noted that all standards are based on GS1 identification keys. GS1 is working together with HL7 to increase the dependability of the supply chain. The objective of the working group is to:

1. Describe business scenarios
2. Establish boundaries
3. Gather business requirements
4. Create business requirements
5. Perform a GAP Analysis
6. Write Implementation Guide (no GAP)

The GS1 GSMP WG is now pending in ISO and is frozen at the business requirements stage. The WG is looking for additional players and is open to new subject matter experts. It will be a multi-standards work group with GS1 rules being applied. The WG deliverable to be formulated will be as an ISO DIS.

The group discussed that there will be multiple numbers by patients and the key is how to manage that number in healthcare. It was mentioned that this would be applicable in a hospital wristband situation but not in a population application. One use may be for a patient identifier in process controls. It could also be a common foundation for identifiers that gives a hierarchical nature. There could be an import of the existing identifier to map to different set of standards for bar code; be identifiers in the supply chain world; patient identifiers that get applied to bar codes in process control; electronic business messaging in the supply chain administering to patients; and may apply the mechanism for a patient from a test to operating and then to match with drugs, etc.

It was agreed that this work item is most directly noted as “patient automatic identification data capture”. There needs to be a public review from the different SDOs for review and development of an application for the proposal. The Joint Working Group requested that the scope be redefined so there can be agreement to develop the common understanding of the proposal.

It was requested that experts from ISO, CEN, HL7 (interested SDO's) be identified to Christian to work with GS1 on this work item.

SKMT Project. Heather Grain presented the SKMT project noting that it was approved as a Joint Initiative Work Item. She noted that this was not only standards; that it is in support of collaboration and cooperation between SDOs and addresses requirements and work processes from a process point of view.

The following items were discussed:

1) Scope: What terms are going to be included in glossary?

The project is looking at core principles identifying where there are terms that should be shared with the entire healthcare community. The project looks for terms that are currently in documents so it would include terms defined in glossaries of standards and terms that the healthcare community has decided would be useful or have relevance.

2) Consensus approach: What do we use for approval of glossary reconciliation?

The vote is in ISO context and would be taken to other communities so that they could put through them their own processes. It was noted that this is only intended for future revisions, reaffirmations, and work in progress. There is no intention to go backwards to existing work. The use of the ISO process has organizations provide support of definitions, i.e. provide context or use case for use of definition

3) Publication: The group did express some concern that the content in the glossary gets published at some point in time so have you can have version control. They are now looking for a process on how that this would be done.

4) How is this going to be maintained, who owns intellectual property, who owns software?

ISO Central Secretariat will be consulted regarding distribution of the “document” and confirm the IP rules of glossaries/terms submitted to it. They are looking for an understanding of who owns the software tool, the database, and there needs to be a clear statement. Ms. Grain answered concerns regarding access control issues, continuity, etc. and discussed that there are looking at the portability of data, etc. Also, they are also looking to develop a process to check documents before they go to FDIS ballot.

It was agreed that Heather Grain and Andrew Grant would return to the Joint Working Group (and JIC) with a response to all the above issues that documents, confirms and summarizes all necessary processes, structures and agreements for the SKMT’s effective use and operation. Both short term and long term issues should be addressed.

Meeting of JWG Harmonization Track

May 12, 2010

The second meeting of the JWG Harmonization Track was held on May 12 from 3:15 – 5:00pm. Mr. Don Newsham welcomed the delegates and proceeded with self-introduction of those in attendance. The purpose of the JWG Harmonization Task Group was reviewed noting that the intent is the discussion of different processes issues, joint SDO issues, nature of work, and interest from SDOs, etc. He noted that content issues will only be discussed for questions on clarity.

The following items were proposed for discussion:

1. Clinical information models
2. Drug Dose Syntax
3. EHR Functional model
4. Medical Devices
5. Privacy and audit trails
6. Criteria for clinical terminologies

Clinical information models. This project was first approved in 2008 and then resubmitted in 2010 with approval. It gives a particular representation of a clinical artifact. The document specifies use within medical devices and ensures that clinical data can be transferred from the device to the clinical record (within HL7) Data Clinical Models (DCM). It was noted that the ISO/CEN 13972 Quality criteria and technologies was of interest to HL7 and that it is complimentary with the BRIDG model. One particular reason for working on this project is due to the association of DCMs with quality criteria. Also, HL7 has other projects for DCMs; a template for DCM registry for particular topics and a registration function. HL7 is still trying to work out exactly what a Detail Clinical Model is, as far as criteria.

The next stage is a Committee Draft (CD) for ISO 13972 after the October meeting with ISO lead. HL7/ISO/CEN/IHTSDO are potential organizations for the joint work item with the completion of the template with the Secretariat as the next step.

Drug Dose Syntax. It was noted that the current climate has changed and that electronic e-prescribing now has more potential. The group is looking to a cross SDO Task Force with ISO, CEN, CDISC, IHTSDO, GS1, and HL7. It is intended to introduce a NWI proposal in the plenary with ISO lead and a Committee Draft by the end of 2010. Issues concerning use, copyright, etc. will still need to be resolved. The scope will be formed later this year. John Quinn volunteered to work with NCPDP and prepare a template for review by the JIC.

EHR Functional Model. Gary Dickerson introduced this item and noted that the ISO/HL7/CEN Ballot was published as ISO 10781. There are different groups working on the Functional Model for oncology, clinical research, dentistry, emergency care, long term care public records, etc. Release 2 activity is now underway. The NWIP for Release 2, with ISO lead, will be introduced at this meeting in WG8 with the intention for it to be completed for discussion of comments in Rotterdam.

Mr. Newsham confirmed that this was a joint initiative project (template already completed) and that the joint ballot between HL7 and ISO will take place in late 2010. There was discussion on whether this was under the ISO/HL7 agreement or if it was a Joint Initiative Project. It was suggested that there be one set of comments distributed rather than multiple. The firm plan between ISO/HL7 for balloting will be finalized between Mr. Dickerson and Mr. Quinn.

Medical Devices. The group began with a discussion around software licensed as a medical device. It was noted that this topic has been bantered for several years and that the updated European Medical Devices Directives names “stand-alone software” and that there is now development of use-cases scenarios to develop criteria to try to establish this.

Voluntary reporting by FDA has detailed a number of fatalities and that this is now an issue within TC215. Canada has issued medical device regulations for “Patient Management Software”. A desire for a single policy regarding this was noted and the group discussed looking to coordinating with other ISO TCs that deal with medical devices.

The question was asked if we have an understanding/definition for health information software. The response was that there is not a single definition of “software” and that there are numerous issues with this type of software and what is applied. The group considered whether ISO/TC215 would have a contribution to make or if the TC should let others resolve this issue. One suggestion was to give guidance to IEC 62A (that provides the framework) and perhaps give some clarity to the software question in medical devices. It was agreed that a report from IEC 62 would be beneficial for the next meeting. Mr. Lewelling also made the comment that regulatory agencies will ultimately decide the definition and regulations for a software regulated medical device.

It was agreed that the Joint Initiative should monitor medical device software licensing and that a further, educative and more extensive discussion be held at Rotterdam.

Privacy and audit trails. Mr. Ross Frasier presented a verbal report and stated that the ISO privacy commission has a group called PSC01. He noted that this is a historic opportunity to bring in HL7, ITSDO, CEN, and ISO together in a way that is coordinated from the beginning. He reported that this group should be aware of the privacy projects. One initiative is the Ad Hoc Task Group which will communicate the privacy activities in various groups and any coordinated activity (if any) within the JIC and report this back to the commission. There is also a need to communicate the unique aspect of privacy in the healthcare standards world. A one day conference is being held just before the TC215 meeting in Rotterdam and a report will be given at the next harmonization track meeting in Rotterdam.

The Joint Working Group Harmonization Track meeting adjourned and will be reconvened at the Rotterdam ISO/TC215 and CEN TC251 meetings.

