The Joint Initiative Council (JIC) for Standards Harmonization

At the opening session of the ISO TC/215 meeting in Vienna, Austria there was an overview of the Joint Initiative Council (JIC) status and plans, based upon the JIC Strategy Session that took place all day on 22 September 2012. Bron Kisler, CDISC VP, Strategic Initiatives and current Chair of the JIC, delivered this overview and facilitated discussions with panel representatives and a large audience representing National Member Bodies from around the world. He first introduced members of the JIC and gave special thanks to the Austrian Standards Organization for hosting this meeting at the Wirtschaftskamara Osterteich (WKO) Austrian Economic Chamber; to Christian Hay of GS1 for arranging for the meeting space for the JIC strategy session; and, to Lisa Spellman and AHIMA for supporting the secretariat needs of the JIC. Bron also gave special recognition to Richard Dixon Hughes (HL7, ISO, Australia), who is JIC Chair Elect, as well as IHE (Integrating the Healthcare Enterprise) for recently being voted the newest member of JIC.

Members of the JIC: With the recent addition of IHE there are now 7 global Standards Developing Organizations (SDOs) that make up the JIC. The founding members include - International Standards Organization Technical Committee 215 (ISO TC/215), Health Level Seven (HL7) and Committee European de Normalisation (CEN). When they became interested in the work of the ICH (International Conference for Harmonization) in the area of clinical research, CDISC was invited to apply and became a member in 2008. IHTSDO (International Health Terminology Standards Development Organization) and GS1 were voted-in as member of JIC in 2009 and 2010.

The JIC Purpose: “The Joint Initiative on SDO Global Health Informatics Standardization enables common, timely health informatics standards by addressing and resolving gaps, overlaps and counterproductive standards efforts.”

Vision: Speaking with one voice, facilitate achievement of coherent, coordinated and usable global health informatics standards providing value to member SDOs and their constituencies.

The Strategy Session: The theory behind JIC is to cooperate as global SDOs such that standards can be coordinated upfront and then ‘balloted’ simultaneously across different SDO processes, becoming a joint standard as an end product. This enables SDOs to work together above and beyond existing 1-to-1 Memorandum of Understandings. It is recognized that standards coordination is difficult work with room for improvement. Therefore, on Saturday, 22 September, the JIC (1-3 representatives per SDO) participated in a full day Strategy Session, facilitated by Bron Kisler (CDISC) and Don Newsham (ISO, Canada). A full SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis was conducted in advance and discussed thoroughly at the meeting. The outcome was agreement on the Strategic Goals and a set of Key Actions to guide JIC the next 3-years and facilitate progress on key JIC cross-SDO activities.

Strategic Goals:

a) Greater collaboration across SDOs
b) Coordinated standards approach, process and work programs
c) Resolution of overlapping and counteracting standards within and across participating SDO work programs
d) Make standards available through multiple SDO communities with preference to ISO
e) Greater communication and engagement with stakeholder communities

Key JIC Actions: After the SWOT analysis, the JIC developed a list of key actions and each SDO agreed to ‘own’ several of these, although they will all be collaborative efforts. See the list below.

a) Managing project status and addressing issues (ISO)
b) Communication; document lessons learned (CDISC and HL7)
c) Bring a project end-to-end, documenting steps (CDISC)
d) Understand what our customers want and need and common ground (HL7)
e) Explore harmonizing value sets (IHTSDO)
f) Use and implementation of SKMT – Shared Glossary (ISO and GS1)
g) Understand shared view of standards impacting Medical Devices (IHTSDO and GS1)
h) Resolution and distribution, publication and dissemination of joint standards, e.g. IP, formatting (All)
i) Affirm adopted charter and bylaws across members SDOs (All)
j) Assessment of impact with other key HIT initiatives outside of JIC, e.g. CIMI (IHTSDO and CEN)
k) Coordinate standards implementation and adoption across members to reduce variability (IHE)
l) Collaborate to address quality criteria for testing and certification (IHE)
m) Concurrent use of architecture and frameworks (CEN)
n) Proactive analysis of SDO members standards to identify gaps (and synergies), overlaps and counterproductive actions, choosing top 5-6 potential JIC activities (All)

There are also important ongoing discussions around standards for Low and Middle Income Countries. Look for an update on this work in a future newsletter.

**JIC Projects (Current Work Program)**

<table>
<thead>
<tr>
<th>Project (Standard)</th>
<th>Lead</th>
<th>Participating SDOs</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHR Functional Model R2</td>
<td>HL7</td>
<td>HL7, ISO, IHTSDO, CDISC</td>
</tr>
<tr>
<td>Automatic ID and Data Capture Marking and Labeling</td>
<td>GS1</td>
<td>GS1, ISO, HL7</td>
</tr>
<tr>
<td>Structured Dose Information for Medical Products (SDMP)</td>
<td>HL7</td>
<td>HL7, CDISC, ISO,</td>
</tr>
<tr>
<td>BRIDG Model</td>
<td>CDISC</td>
<td>CDISC, ISO, CEN, HL7</td>
</tr>
<tr>
<td>Clinical Trial Registration and Results (CTR&amp;R)</td>
<td>CDISC</td>
<td>CDISC, ISO, CEN, HL7</td>
</tr>
<tr>
<td>EHR Clinical Research Functional Model</td>
<td>CEN</td>
<td>CEN, ISO, CDISC, HL7</td>
</tr>
<tr>
<td>Detailed Clinical Models (DCMs)</td>
<td>ISO</td>
<td>ISO, HL7, CDISC</td>
</tr>
</tbody>
</table>

A number of standards have previously been coordinated across SDOs via the JIC, including Data types, Identification of Medicinal Products (IDMP) and Individual Case Safety Report (ICSR).

**ISO TC/215 Meeting (23-27 September)**

One primary interest of CDISC during this ISO meeting was to facilitate a pathway for BRIDG through the ISO process. BRIDG is already a CDISC and an HL7 Standard with version 3.2 recently released. The path through ISO (to become an ISO and CEN standard through the ‘Vienna Agreement’) has not been as smooth as was hoped. Standards take on average 3-5 years to go through the ISO process. BRIDG is forging new ground in ISO and represents a very different kind of standard (with UML representation and frequent update cycles)...one where the current static ISO publishing model, initiated decades ago, does not readily apply.

After spending several years ‘socializing’ BRIDG across the ISO community, we are now scheduled to bring BRIDG through ISO on a ‘fast track’ (leveraging the CDISC Liaison A status with ISO) and within a new ISO TC/215 Structure led by Dr. Christopher Chute, Chair of ISO TC 215. Julie Evans has developed a document describing BRIDG and pointing to the model (which can be updated frequently); the document will be balloted through the ISO process. After working within the ISO system for a few years now, CDISC has garnered wide global support for the BRIDG model. Many thanks to Mike Glickman, chair of ISO TC/215 Workgroup 2! We hope to announce in 2013 that BRIDG is not only a standard for CDISC and HL7 but also for ISO and CEN. And, we hope this will help inform the JIC process in the future.

The ISO meeting concluded with Bron Kisler receiving special recognition for his leadership of JIC.