

## Meeting of Joint Working Group

### Open Forum

Oct 10, 2010 Rotterdam

The JWG Harmonization Open Forum met on October 10, 2010 from 2 - 4pm

#### 1 Joint work

Reports from project leads:

##### BRIDG model – Bron Kisler

- CDISC-led Analysis model in medical research or provide data for use cases
- Streamlines info from protocol (analysis through reporting), facilitates data sharing between
- Initial step for integration between
- 2005/2006: CDISC, HL7, national cancer institute, want to bring in more stakeholders
- Officially a BRIDG project in 2009; 1<sup>st</sup> CDISC standard late 2009
- Ballots for BRIDG closed
- BRIDG 3.0.2 in Aug. 2010 addressed comments and resolutions for ISO
- Next steps; keep CDISC, ISO and HL7 aligned, ballot in May next year (simultaneously, with co-ordinated dates)
- BRIDG Board Of Directors will have election in next few weeks. Would like to see someone from ISO on the Board
- Q: the May ballot will formalize and align the ballot?  
Yes.  
*(Don) International standard in ISO, next ballot in May 2010 (simultaneously, with co-ordinated dates). Needs unanimous ballot and we need to work strongly towards that.*
- Agenda item q2 in BRIDG slot WG2 – ballot resolution

##### Independent Case Safety Report (ICSR) – Tim Buxton

- ICSR (independent case safety report); adverse reaction when drugs are administered – normally sent by marketing authorization holders to regulators. The existing ICH equivalent needed revision (difficult to identify which drug it was) and is not an ISO document, this version was therefore brought forward; went through 2<sup>nd</sup> disc ballot; passed with comment; resolution in WG 6 for this meeting.
- This time round we had fewer comments; passed through CEN and HL7, and asking for resolution this meeting.
- Q? (Melvin) Were comments raised as editorial, or are some tech?  
*None tech, so we believe we will not go to further DIS, but to FDIS. Slated for Tuesday morning.*

##### Identification of Medicinal Products (IDMP) – () Tim Buxton

- Purpose of standard is to identify medicinal products uniquely where it has been authorized around the world (dose and conjunction). Purpose is to support case safety report. Went into DIS on Sept 23/10, will close of Feb. 23/2011. Vienna agreement invoked through CEN, balloted in HL7, CDISC. Maintenance was topic of discussion.
- Q? In terms of process are you seeing need for assistance? (ICSR was bumpy)  
*> Fair share of bumps and lessons learned. But we are not anticipating any*

difficulties. *It might be worthwhile to identify someone in your WG to assist – and identify that person to JIC-WG9.*

> Thanks, will do

### **EHR functional model (EHR-FM) – Gary Dickinson**

- EHR system functional model brought by HL&, CEN, brought forward last fall, published Nov 2009. Since then working on R2, #of issues that need to be addressed, and need to incorporate DSTU (HL7), also series of recommendations from HL7 personal health record model, also health info interoperability. Additionally functional profile on 1.1 in records mgmt and evidence functional profile will be in r2. Very good input from CHI (blueprint 2015 recommendations brought forward and included). Behavioural, nursing home, public health, vital records have also be incorporated into r2. Hit certification in ambulatory care, e-prescribing. In functional model r2. Significant amount of work, effort; teams meet several times a week. Ready to ballot for HL7 in Spring 2011, then back to ISO in Summer, 2011. Look forward to comments
- Q? (Don) – you mentioned PHR and functional models – any overlap in requirements and how are we ensuring alignment?  
*Some overlap in models, but coordinated to ensure alignment – personal health record will inform EHR functional model.*  
(Don, want to make sure we are building on previous work.  
*Yes, we have same people working on it , so that should happen*
- Functional profile, what is the def?  
Functional model is extensive list of functions. Way we originally designed is through functional profiles (i.e. ambulatory care) – base model is horizontal platform, and the functions are vertical taken to care setting. As functional models are developed then findings are built on and added to base model.
- Q? (Mark S): interesting at HL7 take out of visual text form and functional model decomposition into DCMs.  
*This could be good opportunity to bring into; informative and useful. Might help pave the way*
- Gary, to clarify balloting; committee level ballot targeted for spring, normative ballot in summer (joint ISO, HL7)
- Q? (Don) have you chosen which level?  
*Already in is in 1.1. paperwork can come (CD1) to ISO.*  
Don – let's touch base on Tuesday morning (10:45-12:15) to discuss process.

### **Clinical Trial Registration and Results – Bron Kisler**

- Clinical trial registration and results
- Joint HL7 and CDISC, Scott Getzin stewarded through JIC process.
- CTRR seeks to create harmonized message through pharmas and global registries (US clinical trials, GV, EMA, who clinical trials registry
- Great collaboration
- Project goals trial registration and results. We are going to focus on clinical trial part, then on results. Aligning with HL7. CTRR team has used the BRIDG model and extended to meet CTR requirements. Bridge then CTRR and completely harmonized through JIC process. Ballot on clinical trial re for WHO in Jan 2010, then May 2010 the demand analysis model , then CTR v3 which passed as
- NWIP is next step. Plenty of time to catch up and align, getting NWIP now, and fact that it is broken in 2 parts will ensure we meet ISO process and align with ISO for ballot periods.

*Melvin – we need to be clear if it is one or 2 pieces to ensure we avoid confusion again. By tomorrow afternoon we can hit some of these issues in the WG*

- (Bron) – How long is the DSTU cycle? Who are the guinea pigs? Two primaries (sponsors) bare Abdul Shakir Malik and Scott Getzin. Target may get moved to Tech Spec then, and then folded back in as a Standard. For CDISC – not sure what this means

#### **Data types – Audrey Dickerson**

- Tech Edits ISO in progress due by wed.
- Beginning process on v2 (new partner Patrick Lloyd Canada)
- FDIS publication stage once edits are done
- Reference to version 2? Audrey does not know any more. Wanted more additions in v1, but this was not possible.
- John Quinn from HL7 perspective may be good
- (hl7y delegate) Changes will be modest, not big. Will double check with Graham Grieve (editor) what he intends. Patrick Lloyd is very competent –
- 1<sup>st</sup> FDIS ballot; this is a VA from CEN and HL7 and 215 – forcing the FDIS
- Being a dual ballot it had significant changes out of HL7, and needs to get to ballot in ISO
- (Don) with good luck we can publish in Feb 2011. Do asap ; long awaited and we need to move forward because r2 is in the works
- Melvin – think about who can facilitate the process
- Let's remember that the biggest bump it hit was big ISO editor changes which changed the content
- 10:45 on Tuesday, lets catch up there/.

#### **Health informatics glossary (SKMT) – Heather Grain**

- 2,000 terms in it, but not all included; putting procedures in place to assist with this issue
- Each of the orgs needs to figure out how they want to be engaged
- Utility to help us maintain terms to documents; also links stakeholders; harmonize definitions
- Highest level to solve problem, is single doc creation (HL7 glossary) then all the terms can be linked to that but we don't know which group within HL7. Have issue in how we harmonize. Decide in how they engage with tool, then how u want to use them.stage) . Only when you update doc – you check with glossary for modifications or change. Each org determines at what level they want to engage and what they want to contribute. 2 is mgmt process (cleanup
- Done small trial; need to show in standardized way.
- Looking at metadata
- Which of those defs suit doc and will suit in all circumstances (gen def)
- Balloting terms
- If we put that in process at end, should we put it at the beginning? Yes, designed to put in sooner than later, then we can know that others are doing it and will ease harmonization.

*Don – will take as item for JIC WG.*

- Wonderfully evolving work, in Canada we have already used it to influence reg , thanks Heather and Andrew
- There is access to training site for background for end users if needed.
- Andrew – Dutch and Brazilian standards using, Australia and Canada, so 4 countries using it.

- Run the risk on language and harmonizing (e.g. actor) – how do we handle this?
- Tool is built to handle this , but we should look at this

### **Patient and carer ID – Christian Hay**

- Challenge to define labeling format which secures automatic identification data capture to an IT system.
- How should the id be put on the label
- Working on starting block ; we meet twice a month
- JIC experts are invited to join; to receive info about gs1 gsmp processes
- Q? Any plans to integrate GS1 into pharmacy work or HL7?  
*Christian – no, we have not done it but would like your help Mark to ensure alignment*
- Tuesday q1 is work session on standard

## **2 Report on the Joint Initiative Harmonization track**

Reports and introductions on work being prepared:

### **Detailed clinical data models (DCM) – William Goossens**

- Wg 9; 2 different projects (320 and CEN WG 1 and ISO WG 1)
- Specification for content to include in EHRs and messaging
- Raises questions on scope and purpose; in Boston we tackled a few items, but we will have separate call handling it.
- Repository y and governance large area of agreement
- Patient safety – work underway, first straw man discussed
- Still some concerns patient safety concern on max data set and how much needs to be included
- Participants would like to know what is progress
- Plan this week is to focus on whether we can go for committee draft (WG 1)
- Tomorrow morn; WG task force , then Monday afternoon WG1 discussion on recommendations and Tuesday morn
- Q? archetypes and template space; where is core weight , what is main group driving?  
*Discussions in Brisbane on templates not matching – so UML to be used as overarching structure. Specified content at independent data level.*  
*When will it be expressed in these technologies?*  
*Semantic content done in HL7 then into hmi then into more tech ...but this is point of discussion.*
- Not happy – UML does not prevent old based representation – don't believe we are on right track skipping this; this was missing in your presentation.  
*Melvin – this is tech/policy and as member of task force it can be discussed then.*  
*(good issues but too detailed for this session)*
- Heather – lots of groups doing modeling and methodologies – how is this being aligned (similar levels of maturity) by ISO? ISO CEN have been inclusive (openEHR, Korean modeling, US, HL7 etc) so we did try to explain there is not one methodology.  
*Melvin – sources of info that are not adequately feeding in – so they should be included in expert task group - should be inclusive of these groups.*
- Don - This is a pending work item, on agenda in JIC WG 9. 10:45 on Tuesday.

### **Data types implementation guide – Heather Grain**

- Trying to get things stable; no current work to report.

### **ISO Privacy Security Committee (PSCO) input– Elaine Sawatsky**

- PSCO; just came from Berlin; reps from other orgs ; invited speakers European data protection, ISO Tc 215, Allesandra Pastorini, Elaine Sawatsky, Lori Reed.
- One issue: expectations around standards that were needed; issue of lack of communication and how we can do a better job, then to TMB as list of recommendations for Jan 14 . Liaisons responsibility to liaise (TC s and SCS to ensure they get info!
- Spring meeting planned for end of march, PCC 01 will then make recommendations
- Telecom in Dec 2010 to discuss scope of work asked by TMB (tools and glossary); recognized that there are business sectors with standards, still requirement to make them relevant
- WG 4 meeting; will scope out work
- Privacy mgmt standards; “pms”
- How does it relate to JTC1 SC 27 ?  
*Elaine – discussion in room at meeting was that SC 27 is liaison*
- Concern that this group is not integrated ;  
*Elaine agrees, ensure that communication is handled by Elaine and Allesandra back. Tuesday at 3:15 is good time to catch up with this WG.*  
*Shirin reminded there is a European WG item also covering it. (data flow and protection 1:15 on Monday)*
- Richard (JTC1 liaison); JTC1 plenary coming up in Belfast – we need a liaison here and I can find one of we need.

### **Dose Syntax Model – Steve Kay for UK proposer**

- Business requirement looking at structure and content of dosing info; in UK will be used in e-prescribing in primary care. new work item proposal
- CEN WG 1 is traditionally where we liaise, so potentially an interest and resolution to be taken. Currently very English and NHS centric. In Rio, we all approved taking it forward and looking at interested members for task group.
- HL7 and CEN contributing
- WG 1 and WG 8; work item Monday q 3 (WG 1)
- Stephen; representative of many WG items – so where it should be discussed and with who? Should this go together. Yes Ian, (WG6) agree.

## **3 Report from the JIC Chair**

The final report from the Chair in a face-to-face meeting included announcement of a JIC project register to be held at the new website: [www.jointinitiativecouncil.org](http://www.jointinitiativecouncil.org) where all council work items can be traced and JIC materials are located.

The Co-Convenors thanked the JIC Chair for his leadership and productive work during his period of office.