Individual Case Safety Report (ICSR) Update

HL7 Phoenix SDO Harmonization Activities Meeting

January 17, 2009
ICSR Update

- Published as ISO multi-part standard April – September 2009:
  - ISO 27953-1: ICSR Framework Reference Model
  - ISO 27953-2: Human pharmaceutical reporting requirements for ICSR

- Publishing format was a hybrid between ISO and HL7 formats
  - Ballot produced using HL7 publishing environment

- All SDO ballots closed September 30, 2009
  - All ballots failed due to substantial negative comments
ICSR Update

• ISO/CEN comments were positively reconciled during the ISO Durham meeting last October:

  – HL7 provided assurances that publishing challenges will be addressed and that work will continue on how to resolve copyright issues (for non-HL7 members) and streamlining HL7 content unique to the ICSR JIC ballot
  – Need an independent, non-HL7 Normative Edition version of ICSR Part 2 to be made available for ISO/CEN implementers
ICSR Update

• HL7 ballot reconciliation has been slow due to scheduling conflicts and HL7 co-chair illness:
  – All major negative comments have been reconciled
  – Expect completion of remaining minor negative and editorial comments during Phoenix meeting
ICSR Update

• Generated test schemas for ICH and GlobalSubmit alpha-testing:
  – Results received from ICH Japan
  – XFORM tool development identified some minor issues

• Upon successful completion of alpha testing ISO JIC ballot package can be generated
ICSR Update

• Next SDO DIS ballot will continue to use a hybrid format and be generated using the HL7 publishing environment:

  – Ballot as two separate topics in the HL7 PORR Domain
    • Safety Reporting Management Topic: Part 1
    • Regulated Human Pharmaceuticals Reporting: Part 2
ICSR Update

• Goal is to produce material for ISO CS review by mid-February and assume a 4-6 week review cycle:

  – Upon successful review SDO DIS ballot can be released

  – Anticipate that two month ballot will not close until after the Spring HL7 and ISO Brazil meetings
ICSR ‘Food for Thought’

• Lessons learned/JIC points to consider:

  – SDO harmonization is difficult. We need to consider how the growing list of SDOs affects project timelines, cost and workgroup logistics
    • Current paradigm is not efficient and is **costly**

  – Need a quick (but formal) public process for evaluating whether or not a project is really a good candidate for SDO harmonization (pre vs. post harmonization checklist?)
    • Need alignment between HL7’s Project Scope Statement Process and ISO NWIP Process
ICSR “Food for Thought”

- Standard development and ballot processes need to be reevaluated as current process adds substantial workload, time and cost to complete a standard
  
  - JIC process is still not finalized, and there is no guidance for how new projects are expected to navigate “undocumented territory”. Need to create a short term guidance document for new projects.
  
  - What is considered a reasonable timeframe for SDO harmonization to occur and how do we manage short/long term needs and goals against the overall timeframe? Who decides?
  
  - Seems to be a disconnect between JIC processes and the “real world” need to get standards through the process quickly to meet specific business needs/drivers. How can this perception be improved?
ICSR “Food for Thought”

- Need an alignment of balloting options between SDOs to help project teams better understand the level of commitment needed to move the standard through the process:
  - EX: Informative ballot vs. technical report, DSTU vs. IS?
  - May need to establish an alternative, reciprocal system for managing “equivalent” ballot stages between SDOs. Is an HL7 Informative ballot equivalent to an ISO CD Ballot?
  - Need to reconsider the use of ISO balloting timelines or establish criteria for when to abandon them
  - Eliminate the need for duplicate comments across SDOs
  - Help reduce the SDO ballot reconciliation burden and burn-out

- Processes need to be consistent, documented and transferable to all participating SDOs and their workgroups
ICSR “Food for Thought”

• Consider major overhaul of ballot publication rules/requirements across all SDOs, especially ISO CS. Requires:

  – Create an HL7/ISO publishing environment to help convert or auto-convert HL7 publishing format to ISO publishing format.
  – Document the ISO publishing format and procedures.
  – Align the way topics/domains are setup in the HL7 publishing DB with the creation “ISO/CEN” subsets.
  – Work out and clarify the process for purchasing/acquiring standards documents published by multiple groups.
  – Create “easy” tools/templates for project sponsors and project teams, and consistent, dependable guidance and response from ISO CS.
  – Establish equivalent HL7 facilitator roles in ISO (and other participating SDOs): modeling, publishing, vocabulary, etc.
ICSR “Food for Thought”

- Need to establish a formal process for managing the migration of JIC standards to Release 2 Data Types. Who is responsible for this after the initial project team is disbanded if there are no business drivers to convert? Does it matter?

- Consider the strengths/weaknesses of all SDOs including its project sponsors and workgroup bandwidth: Need to know when to lead and when to follow – joint project management may not be a sustainable model