Official Meeting Summary – Date Drafted: December 13, 2007

Meeting type – CDISC - HL7 IB / Sub-Group

Meeting date & time - December 13, 2007, 11am – 12 Noon (Eastern time)

Meeting format – Conference call

Meeting Leader(s) – Dave Iberson-Hurst & Jay Levine

Meeting Recorder – Erik Henrikson

Attendees – Name / Affiliation -

Jay Levine / FDA
Erik Henrikson / FDA
Dave Iberson-Hurst / CDISC
Jason Rock / GlobalSubmitt
Diane Wold / GSK (Pharma)
Lise Stevens / FDA
John Speakman / NCI
Mead Walker / GlobalSubmitt
Cara Willoughby / Lilly (Pharma)
Julie Evans / CDISC

Background and Objectives

a. History of events leading up to the meeting –

Initial call held between FDA & CDISC (see 11-29-07 Meeting Minutes) in which the Stage IB - CDISC Development of Requirements for CDISC-HL7 Project was discussed. It was agreed by FDA & CIDISC to conduct a series of regular conference calls for Sub-Team members as the initial path forward on CDISC-HL7 IB activities.

This call series is also in preparation for the January HL7 meeting in San Antonio, TX. The January 10, 2008 call was slated to invite the larger group HL7 ListServe in order to allow a means to keep progress updates as open as possible. However, since we are holding an update call on both IB & Stage II in February 2008, we could forego this plan.

b. Meeting was requested by – FDA

c. Purpose of the meeting – Sub-Team members to discuss options, approach and develop consensus necessary for a path forward on CDISC-HL7 IB activities

Discussion

Participant members were noted and discussion ensued.

The RCRIM Technical Committee has already approved the project. However, there remains a need for a 9-0 vote in the HL7 Domain Experts Steering Division to approve the project. Currently a 7-0 vote is in place because there wasn't a quorum when the vote was taken.

The "4 message" template was discussed (Study Design, Study Participation, Subject Data, Expedited adverse events) in relation to FDA's desire to build or facilitate a coherent means / format for pharma to report / transfer data to FDA.

Modern regulatory business needs are evolving. The ability to have data available for a variety of uses other than "simple" reports is of interest.

Additionally there are other types of submissions that FDA receives including paper, PDF, zipped files etc. The ability to cross reference data as well as associated data would greatly improve the FDA business process and improve public health.

HL7 messages are based on the RIM. The FDA is hoping for better integration of information submitted if everything is submitted using standards based on the HL7 RIM. Better integration of data and associated data is needed potentially eliminating duplicative submissions to FDA. For example, data analysis could be improved with information closer to source data (i.e. adverse reactions => associated data => specifically documented circumstances)

Business drivers for a new framework include:

- Electronic means
- Information closer to source data
- Overall process improvement

A business need for traceability can also be made – not only how results were achieved but ability to understand over-all clinical picture.

Q's / Gaps –

- How FDA sees SDTM views coming out of JANUS?
- Is JANUS up & running? Yes - prototype
- What is JANUS currently being loaded with? SDTM going in – STDM coming out
- Future? Switch to HL7 data going into JANUS (structure of data will be different, not flat-files "wrapped in XML"

Given the above the suggestions is that the group produce a single document (20 or so pages). The document should try to fill gaps, try to in understand how things might work or be needed - a GAP analysis:

- in BRIDG
- in messages themselves
- how messages would be used by pharma
- to facilitate awareness of adoption

It was suggested that the document should refer to the FDA's PDUFA IT plan / standards document

Roles of such a document:

1. Educate RCRIM & community
2. Know where gaps are & requirements
3. Ensure the what is developed in messages accurately aligns with BRIDG

Other content issues:

- How detailed should requirements be?
- Is BRIDG the requirements repository?
- Does BRIDG have all the requirements?
- Are story boards' requirements?

Decisions/agreements reached

a. Action items ownership –

- Create a "To do" list that will act as a nucleus and encompass questions raised during this call. Sub-team members can comment / add / clarify items relating to this list and work towards a roadmap forward (Dave Iberson-Hurst / CDISC).
- It was suggested that members of this team might want to attend the December 19th TC of the Stage 2 group as most of the meeting will be devoted to an overview of the HL7 Development Framework, This could be useful to members of this group who are less familiar with HL7 processes.

b. Agreements

- The substance of each call will be documented via meeting minutes which will be subsequently distributed to appropriate involved parties.
- Be prepared to discuss progress / material(s) / comments for during each subsequent meeting.

Issues requiring further discussion

- Look into holding a face-to-face at some point for white board brain storming. It was hoped to hold one in San Antonio but this does not look to be feasible.

Date(s) for follow-up - December 20th, 2007 & January 3rd, 10th, 2008

Related Documents

- 11-29-07 Meeting Minutes
- 12-13-07 Agenda from Outlook calendar
- CDISC-HL7 Project Document
- HL7 Project Scope Statement
- FDA Rationale for the 4 messages

Other

Meeting Minutes Drafted/Author – Erik Henrikson