Official Meeting Summary – Date Drafted: January 10, 2008

Meeting type – CDISC - HL7 IB / Sub-Group

Meeting date & time – January 10, 2008 11am – 12:30pm (Eastern time)

Meeting format – Conference call

Meeting Leader(s) – Jay Levine

Meeting Recorder – Erik Henrikson

Attendees – Name / Affiliation -

Jay Levine / FDA
Erik Henrikson / FDA
Jason Rock / GlobalSubmitt
Julie Evans / CDISC
Armando Oliva / FDA
Cara Willoughby / Lilly (Pharma)
Ed Helton / CDISC
Wayne Kubick / Lincoln Technologies
Mary Lenzen / Octagon
Scott Gibson / Lilly
Becky Kush / CDISC
Marti Velezi / Booz Allen Hamilton
Andy Siegel / Genzyme
Terry Hardin / IBM
Saurin Mehta / Novartis

Background and Objectives

a. History of events leading up to the meeting –

On going series of regular conference calls among Sub-Team members as the path forward on CDISC-HL7 IB activities. (see MM from 12-13-07)

This is the fourth in the series. Being the 4th call, we have envisioned that 1 in 4 of the regularly scheduled calls would be opened up to the larger group in order to allow a means to keep progress updates as open as possible. Thus included on the invitation is the list serve (CDISC HL7) distribution list and extended the time for discussion is planned.

We will be receiving & discussing updates for both IB and Stage II activities during this extended time

b. Meeting was requested by – FDA

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

Discussion

Participant members were noted and discussion ensued.

Update: Jay Levine concerning IB Activities:

From FDA's perspective -

- The next generation data exchange standard will be more than SDTM flat files in an XML wrapper.
- FDA envisions that this next generation exchange standards will be similar to the HL7v3 ICSR
- Part of the rationale for this is FDA desires that the intrinsic structure of data be retained by the exchange standard.
- The exchange standard will enable data to be readily loaded into the Janus data warehouse.
- Janus will be used to produce SDTM datasets and other data views that FDA finds useful in review work.
- We intend that the new exchange standard will be less ambiguous, and easier to check for errors compared to the SDTM standard

There was a side bar discussion of time lines regarding this transition. Many if not all of the dates are DRAFT and subject to change.

- The document "HL7 -CDISC-HL7 Message Project" sent on 12-19-2007 (updated 1-2-2008) by Dave Iberson-Herst was mentioned with regard to the project driver's section provided by FDA to the document

Update: Jason Rock concerning Stage II:

- This endeavor concerns Message development
- The group is currently reviewing other models
    - The BRIDG m Model was reviewed and discussed during the 1-9-2006 webinar / call
    - Next on the schedule is an overview of ICSR
- Most business requirements should be contained within current models (BRIGD, ICSR etc.)

Decisions/agreements reached

a. Action items ownership –

- Invite IB Sub-Group to hear the ICSR presentation during an upcoming Stage II call
- Send IB Sub-Group names to rcrimcdisc@lists.hl7.org distribution list (Word attachment) for member review as to whether additional participants may be included on IB activities (citeria - can productively contribute in a fashion not currently represented)
- Schedule Mark Gray (FDA) to discuss PDUFA IV IT Plan with IB & Stage II groups

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

Currently - none

Date(s) for follow-up - Post HL7 San Antonio meeting, 2008 (January 24, 2008 then, weekly?)

Related Documents

- Dave Iberson-Hurst's updated Stage 1B document (Sent 1-2-2008)
    - FDA Driver's

Other

Meeting Minutes Drafted/Author – Erik Henrikson