Official Meeting Summary – Date Drafted: December 20, 2007

Meeting type – CDISC - HL7 IB / Sub-Group

Meeting date & time - December 20, 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)
Mead Walker / GlobalSubmitt
Julie Evans / CDISC
Becky Kush (CDISC)

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)

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.

The document "HL7 -CDISC-HL7 Message Project" sent on 12-19-2007 by Dave Iberson-Herst was discussed. It is envisioned to serve as:

1. A written mechanism to assist Sub-team members in order to understand IB activities within a common document
2. Later it can serve as an information tool for others to understand IB activities

It was agreed the HL7 -CDISC-HL7 Message Project document will serve as the primary deliverable for the Sub Team regarding IB activities.

Decisions/agreements reached

a. Action items ownership –

- When will FDA release / publish their IT Plan for 2008? (Erik Henrikson)
- In order to understand the HL7 process a link which can provide direction will be sent to team members (Jason Rock)
- FDA Drivers section of: HL7 -CDISC-HL7 Message Project, will be penned by Dave Iberson-Herst
- More specifics regarding message (a.b.c.) content will be added (Jason Rock, Julie Evans, Diane Wold)
- Availability of FDA Guidance on Annual Report content (Erik Henrikson)
- Overall Project Charter (Jason Rock, Dave Iberson-Herst)

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

- With regard to items a, b & c in the HL7 -CDISC-HL7 Message Project document, it is hoped that much of the material needed for messages will exist in BRIDG – basically which details go with which of the 4 messages and around which industry can work in the future

Date(s) for follow-up - January 3rd, 10th, 2008

Related Documents

- 12-13-07 Meeting Minutes
- HL7 - CDISC-HL7 Message Project (sent 12-19-2007 by Dave Iberson-Herst)
- link to the HL7 Development Framework: http://hl7projects.hl7.nscee.edu/frs/download.php/278/HDF_Version_1_2.zip
- CDER has withdrawn draft guidance (2nd attachment along with these Minutes) The best description of material in an annual report is **21 CFR 314.81**.
- Dave Iberson-Hurst's updated Stage 1B document (Sent 1-2-2008) containing suggested text for the FDA business case.
- Diane Wold's thoughts re: the data content (Sent 1-2-2008)

Other Meeting Minutes Drafted/Author – Erik Henrikson