Official Meeting Summary – Date Drafted: January 3, 2008

Meeting type – CDISC - HL7 IB / Sub-Group

Meeting date & time – January 3, 2008 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
Armando Oliva / FDA
Cara Willoughby / Lilly (Pharma)

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 (updated 1-2-2008) by Dave Iberson-Herst was discussed.

Concerning the FDA Driver's section of this document – Discussed the FDA driver of making available pre-market and post-market observation into a single repository (Janus) and suppor the development of standard algorithms for purposes of analysis throughout

the entire product life cycle. Currently such analyses require many labor intensive manipulations.

CDISC-HL7 will facilitate the ability to link exposure data to detailed product information in SPL.

Decisions/agreements reached

a. Action items ownership –

- Provide substantive comment regarding the Driver's section of the CDISC-HL7 Message Project document prior to San Antonio Meeting (FDA / Armando Oliva, Jay Levine, Erik Henrikson)
- Provide comment on what information should be passed within "4 messages" (reference Diane Wold 1-2-2008 document). *For example, is the information correct, in-line with other standards, contained in BRIGD etc.* (entire IB Sub-Team)

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

- Any specific interpretations of FDAAA of 2007 such as trial registry and/or a results data base that utilizes standardized summary fields should be deferred until FDA counsel has determined what the final interpretations / application of the new law will be.

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

Related Documents

- Dave Iberson-Hurst's updated Stage 1B document (Sent 1-2-2008) containing suggested text for the FDA business case.
- Diane Wold's document re: data content (Sent 1-2-2008)
- Jay and Armando will lead the January 10th call since Dave Iberson-Hurst will not be available

Other

Meeting Minutes Drafted/Author – Erik Henrikson