Meeting Minutes

CDISC-HL7 Stage I-B
December 18, 2008
11:00 am – 12:00 pm (EST)

Attendees / Affiliation

Dave Iberson-Hurst/CDISC (Co-Chair)
Jay Levine/FDA (Co-Chair)
Patty Garvey/FDA (Facilitator)
Julie Evans/CDISC
Terry Hardin/IBM
Mary Lenzen/Octagon
Chris Tolk/CDISC
Gary Walker/Quintiles
Diane Wold/GSK

Background

The Clinical Data Interchange Standards Consortium (CDISC) formed a Stage IB group to develop the requirements for the CDISC - Health Level 7 (HL7) Content to Message Project. It was agreed by FDA and CDISC to conduct a series of regular conference calls for sub-team members as the initial path forward on the CDISC-HL7 IB activities.

The purpose of this meeting is to review and discuss the draft Subject Data story boards.

Discussion

- The November 20, 2008 meeting minutes were approved.

- The Stage IB working session during the HL7 January 2009 meeting will be on

    - Wednesday, January 14th – Q1 and Q2
    - Thursday, January 15th – Q1 and Q2

    The agenda will be to continue review and discussion of the draft SubjectData story boards.

- The story boards are located on at the following wiki page address: http://wiki.hl7.org/index.php?title=Subject_Data_Story_Boards

    - Story board 5 – Add the title "FDA Initiated of EDR"

    - Story board 9 – Remind Pierre-Yves Lastic to complete

- Story boards 15 – 19 – Need to determine what to do with these story boards.
  - These storyboards are regarding statistical analysis. These story boards will be developed separately then consider grouping into 1 story board if possible. It was proposed that the story boards be identified as "required association between data and study design".

  - #15-16 story boards are regarding data point with study cell – Diane will draft examples.

  - #17 story board is regarding a mean to be able to know which values are baseline or pretreatment. For example, in a crossover study – during the 2nd period a patient has liver adverse event. The question one would ask is whether the patient has been vaccinated or have had tuberculosis. The question is how to describe the liver adverse event.

  - Diane will share her story board example, so that others may have an idea of how to draft story boards for # 17-19.

- Story board 6
  - Dave will add language to the following:

    Acme is aware of *"issues, need some more detailed explanation here ..."* that suggests that it would be desirable to collect some additional observations.

- Storyboard 1
  - There were a lot of discussion on whether ADaM datasets should be included during this first version. For the near term, ADaM dataset and meta data would be submit but for long term, the message should contain everything needed to be able to construct these datasets.

  - Need further discussion during the working session at the HL7 January 2009 meeting.

ACTION ITEMS:

1. Patty will remind Pierre Yves-Lastic to complete the story board for rolling NDA (story board #5).

2. Dave will add language to story board #6.

3. Diane will draft story boards #15 and 16. These story boards will be shared with the group as an example to help develop story board #17-19.

Drafted: PGarvey/12-22-2008
Approved: 2-12-2009