Meeting Minutes

CDISC-HL7 Stage I-B
November 20, 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)
Terry Hardin/IBM
Pierre-Yves Lastic/Sanofi-Aventis
Mary Lenzen/Octagon
Armando Oliva/FDA
Chris Tolk/CDISC

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 storyboards.

Discussion

- The November 6, 2008 meeting minutes were approved.

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

    - Storyboard 1: Submission SDTM and ADaM Data

        Study A1234 is complete and Acme Pharmaceuticals now wants to send to the FDA all the observations recorded for each subject during the study as part of their study report submission. Acme uses the CDISC-HL7 subject data message to provide all the recorded observations, as well as all the key derived parameters resulting from those observations, as defined by the CDISC SDTM and ADaM standards. The message contains all important relationships, such as the relationship between an observed and planned assessment (or lack thereof), and the relationship between unplanned assessments and other observations (i.e. finding of jaundice led to a bilirubin measurement). Those observations that were previously reported in a spontaneous adverse event report are not re-submitted, but rather updated and referenced.

Additional discussion will be needed on:
(1) Do we want ADaM data included here for the first version of the message?
(2) How should “Key derived parameters” be defined?

The group decided that it would be best to have an ADaM team member review the storyboard and provide feedback on the group’s questions/concerns.

- Storyboard 2: FDA Completeness Check

  The FDA has received the data for Study A1234 and wishes to assess the level of completeness of the data submitted by Acme Pharmaceuticals. The reviewer accesses the Janus data warehouse and runs a check to assess if all planned activities were performed. The reviewer should be presented with a report that provides a detailed view of the missing observations.

  This requires access to the plan held within the Study Design message and needs to allow for all paths to be evaluated at a high level of detail definition (sufficient to allow for a machine to perform the check). Note that this is a check of what is missing against the plan and does not consider additional data that may have been collected.

- Storyboard 3: Periodic Submission

  Acme Pharmaceuticals study XYZ123 being conducted and has some potential toxicity issues. The FDA requested that subject data be submitted quarterly while the trial was ongoing. Subject data was submitted on 5 occasions while the trial was ongoing including updates to previously submitted data points. After the trial concluded, all of the subject data was sent to the FDA as a final transmission.

  The following questions need further discussion:
  (1) We are seeing a need for an update facility (transactional mechanism). We do we send all of the data again at the end?'
  (2) Do we need status information for such things as "finishing early" and "last message"?
  (3) How does SubjectData in this use case relate to the use of StudyParticipation? and the status info carried there?

- Storyboard 4: Non-duplicative Adverse Event

  ABC Pharmaceuticals is running study 123A. One of their sites PharmaCRO reports an SAE. ABC Pharmaceuticals collects all the relevant information and promptly submits a report via the ICSR to the FDA (referenced by HL7 identifier 2.16.840.2.113883.4.125)

A year later, ABC pharmaceutical is preparing their submission for study 123A to the FDA utilizing the Subject Data message. As part of their submission process, the information previously provided in the ICSR is filtered out and a link is inserted in it's place which points back to the ICSR report.

This storyboard needs further thought given the possible impact on the sponsor system given the current separation of CDMS-type systems and Safety systems.

- Dave solicited thoughts on whether the all day Stage IB meeting during the Orlando HL7 Working Group Meeting (WGM) should be changed from Wednesday, January 14th to Tuesday, January 13th. Keeping the meeting on January 14th would conflict with the RCRIM Business meeting during the 3rd quarter. Since today meeting participants were limited, Dave will send an email to more individuals to get their feedback.

ACTION ITEM:

Dave will send an email to solicit individuals' thoughts on whether the all day Stage IB meeting during the Orlando HL7 Working Group Meeting (WGM) should be changed from Wednesday, January 14th to Tuesday, January 13th the Stage IB working meeting during the Orlando HL7 WGM.

ADDENDUM:

Based on feed back from several individuals the all day Stage IB meeting will be changed to Tuesday, January 13th.

Drafted: PGarvey/11-21-2008
Approved: