Meeting Minutes

CDISC-HL7 Stage I-B
February 26, 2009
11:00 am – 12:00 pm (EST)

Attendees / Affiliation

Chris Tolk/CDISC (Co-Chair)
Jay Levine/FDA (Co-Chair)
Julie Evans/CDISC
Scott Getzin/Eli Lilly
Terry Hardin
Wayne Kubick/Phase Forward
Pierre-Yves Lastic/Sanofi-Aventis
Mary Lenzen/Octagon
Rich Mansky/Abbott
Donald Palmer
Mitra Rocca/Novartis
John Troxell/Merck
Diane Wold/GSK
Gary Walker/Quintiles

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 discuss the draft Subject Data story board relating to ADaM and rolling NDA and provide project updates.

Discussion

- The February 12, 2009 meeting minutes were approved.

- Updates to Story Boards at http://wiki.hl7.org/index.php?title=Stage_IB_Project_Page#Story_Boards: Previous story boards were defined by the FDA and expanded by this team. The ADaM would like to have appropriate story boards to cover their needs. John Troxell and Jay Levine will work together to develop these story boards. Discussion of these will not take place until at least after the March/April F2F and all other story boards and the DAM have been completed.
  - Story Board 1
    - Minor typo corrected

- Study Board 5
  - Additional work needs to be done. Pierre-Yves will be draft a story board to address coding for a rolling NDA and will be discussed at the March 12 TC.

- Story Boards 6-8 were reviewed. Number 6 has a couple of minor changes. No changes were made to 7 or 8.
- We will continue to review the story boards starting with number 9 at the March 12 TC.

- Industry Story Boards: Joyce Hernandez submitted a new use case. The players are sponsors and labs. Text is as follows:
  Sponsor sends the high level study design to the lab. They send the lab tests that and portions of the study design that pertain to the lab's participation in the trial. I expect this scenario to possibly break down into a set of sender - receiver or requester - responder interactions which might also use some of the orders and observations messages in addition to study design. In either case, the study design components being used will be a subset of what you have model. I don't expect to get into the lowest level of details

  This group agreed that Industry Story Boards could be posted on the Wiki, but this story board is not ready for posting. The use case is not relevant to Subject Data for sponsor to lab communication. Some part of the use case may be relevant to Study Participation. It could also be part of Study Design. The question was raised that the V3 Lab Message should be used not the Subject Data Message for actual subject-related Lab information, but this use case was determined not to be for Subject Data. This use case needs to be rewritten to document two use cases appropriate to the other messages. Then this team will determine if it's use case we want to pursue, and if so, we'll prioritize it with the other use cases.

  This group agreed that currently Story Boards should not be expanded to include payments or an audit trail.

- The F2F meeting has been scheduled for March 31, 10-5 and April 1, 9-3 at the Park Lawn Building in Rockville, MD. It was suggested that Leonard Sacks present information on the audit trail for the group at the F2F meeting. Jay will contact him. Chris and Jay will coordinate with Leonard the timing of his attendance.

  The agenda for the F2F meeting will be to finalize the story boards, if not done in the next 2 TCs. The remainder of the meeting will be devoted to understanding the components of the Subject Data message. We will need to review the Clinical Statement RMIM, and possibly other RMIMs to understand how it maps to BRIDG so we can build the DAM for Subject Data. Jason Rock will attend to walk us through the Clinical Statement RMIM and other necessary RMIMs. Jay confirmed that he is available both days.

ACTION ITEMS:

1. Pierre-Yves will draft a story board to address coding for a rolling NDA to be reviewed at the March 12, 2009 TC.
2. Joyce rewrite the use case for exchanging study design data between sponsors and labs.
3. Jay contact L. Sacks to plan to attend part of the F2F meeting to discuss the audit trail.

Drafted: CTolk/2-27-2009
Approved: CTolk/3-12-2009