Meeting Minutes

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

Attendees / Affiliation

Chris Tolk/CDISC (Co-Chair)
Jay Levine/FDA (Co-Chair)
Patty Garvey/FDA (Facilitator)
Julie Evans/CDISC
Joyce Hernandez/Merck
Pierre-Yves Lastic/Sanofi-Aventis
Amy Malla/FDA
John Troxell/Merck

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 December 18, 2008 and January 14-15, 2009 meeting minutes were approved.

- John Troxell, ADaM team lead, was invited to this meeting to provide guidance on Subject Data story board 1 "Submission of SDTM and ADaM"

  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), the relationship between unplanned assessments and other observations (i.e. finding of jaundice led to a bilirubin measurement), and the relationship between the derived parameters and the collected data.

  Those observations that were previously reported in a spontaneous adverse event report (ICSR) need to use common identifier, see story board 4.

- John indicated that ADaM should definitely be included in the final version of the Subject Data message.
- He indicated that none of the story boards address statistical analysis plan review.
- He stated that additional use cases for ADaM need to be included. He will work with the ADaM team to develop these use cases for Subject Data. He will try to get these use cases to the group by the next Stage IB teleconference on February 26, 2009.
- He indicated that "parameter" is defined in the ADaM Implementation Guide release June 2008.
- John revised story board 1 to add the following phrase "… relationship between the derived parameters and the collected data" at the end of the story board. He stated that this traceability from SDTM to ADaM is critical to FDA to validate the results of the tests of hypotheses that are the purpose of clinical trials.

- The following updates were provided:
  - Study Participation
    - BRIDG domain analysis model (DAM) will be publish for comment during May 2009 ballot cycle (Julie Evans)
    - Message will be ballot as DSTU in May 2009 (Jason Rock)

  - Study Design
    - BRIDG DAM will be ballot as Informative in May 2009 (Julie Evans)
    - Message will ballot as DSTU for May 2009 (Jason Rock)

  - Subject Data
    - Message will not be ready for ballot in May 2009 since Stage IB has not completed the story boards. We will try to ballot in September 2009.
    - Joyce requested a valid schema to review. Patty indicated that Jason Rock would be responsible for providing this document. This can be discuss further during the Stage II meeting on February 18, 2009.

- The agenda for Stage IB face-to-face (F2F) meeting on March 31 and April 1, 2009 in Rockville, MD was discussed. At this time, the only topic for discussion is Subject Data story board. If there are no other agenda items then the meeting may not be necessary. Chris will make a decision on whether this meeting will occur after she discusses the agenda further with Dave Iberson-Hurst.

- Joyce new proposed story board was discussed. It was decided that this would not be appropriate as a story board for Subject Data. The current story boards have been developed for submission of data to the FDA. This story board is for submission of data between labs and sponsors.

Players: Sponsor to Lab
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.

- The following story board 5 "Rolling NDA" drafted by Pierre-Yves was discussed.

  Acme Pharmaceutical just conducted its first in man study: Full study data are submitted to FDA within x months of last subject visit. Study data include every data point collected, including all PK parameters. Adverse events are coded using MedDRA version y.z. Later in the year Acme submits the results of a repeated dose study; however, this second study uses MedDRA v. y.z+1 since a new MedDRA release occurred in the mean time. As the results of this second study show very strong accumulation of the drug in the liver, accompanied by hefty liver toxicity, Acme decides to stop the development of the drug.

  - Issues: (1) Policy issue, may impact the amount of data to be submitted to the agency. Phase 1 only normally incorporates the safety data. (2) Coding issue in that the data may be coded in different versions.
  - There may be a difference in data submission if FDA requests the development be stopped versus the pharma stops development.
  - ACTION: Create a coding story board (Pierre-Yves) and will be discuss at the next Stage IB teleconference on February 26, 2009.

ACTION ITEMS:

1. John will discuss story board 1 with the ADaM team and have the team draft additional use cases relating to ADaM.
2. Chris will discuss with Dave Iberson-Hurst about agenda items for F2F meeting on March 31 and April 1, 2009. She will make a decision on whether the F2F meeting will still be needed.
3. Pierre-Yves will be draft a story board to address coding for a rolling NDA.
4. Chris will check discuss Dave Iberson-Hurst to see if we want to include industry story boards with the other story boards, possibly in a separate section.

Drafted: PGarvey/2-12-2009
Approved: CTolk/2-26-2009