Meeting Minutes

CDISC-HL7 Stage I-B
October 9, 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)
Sue Dubman/Genzyme
Julie Evans/CDISC
Scott Getzin/Eli Lilly
Terry Hardin/IBM
Wayne Kubick/Phase Forward
Mary Lenzen/Octagon
Saurin Mehta/Novartis
Barrie Nelson/Amgen
Chris Tolk/CDISC
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 mapping of the Domain Analysis Model (DAM) to the Study Participation and Study Design messages and Subject Data requirements.

Discussion

- Required items to complete Study Design and Study Participation
  - A Domain Analysis Model (DAM) for the scope of the message
  - Map to BRIDG – have done most of this on September 16th meeting in Vancouver but have a few more items to map

  - Map between the DAM and the message RMIM –
    - the DAM will help people understand what is in the RMIM
    - the ballots received many negative votes due to the lack of understanding of the messages, therefore an agreement made during the ballots reconciliation meeting in Vancouver for Stage IB to map to DAM to RMIM
    - National Cancer Institute (NCI) will provide the resource to map the BRIDG to RIM
  - Dave will work with Julie Evans and Diane Wold to complete the mapping

- Subject Data Requirements – the following FDA requirements for Subject Data message were provided by Jay for discussion.

  - The CDISC-HL7 Subject Data message will provide an HL7-RIM based data exchange standard that:

    1. contains the observed values for all subject data specified in the Study Design message,
    2. is capable of containing any subject care data not specified in the Study Design message,
    3. contains the relationships between the subject data and the Study Design, Study Participation, and ICSR messages,
    4. contains, in conjunction with the Study Design message, Study Participation message, and ICSR, all of the subject data needed to construct CDISC SDTM and SEND data views.

    FDA understands that these requirements may include data that is not on the case report form, but is needed for a comprehensive review of safety and efficacy.

  - It was discussed that the group needs to develop 4-5 subject data storyboards to capture the following points:

    - Data collected in accordance with the plan. The Study Design message conveys (among other things) the plan for data collection, the Study Participation message includes information on the subjects in the study, and thus those two messages imply an expected set of data to be collected. The subject data message needs to be able to convey that data.
    - Data collected in connection with ICSRs. It should be easy to make connections between data in the ICSR and other data conveyed in the Subject Data message. At minimum, this probably means that the Subject Data message needs to include unique identifiers for ICSRs.

- The review of subject data may raise questions which can only be answered by means of additional data, data which was not collected as part of the clinical trial effort. This data resides at the source, rather than with the trial sponsor. If a retrospective data collection effort is undertaken to retrieve such data, then the Subject Data message should be able to convey the data.
- Subject Data may be conveyed in multiple stages, rather than as a monolithic data transfer. Therefore, the message must be capable of conveying both new and updated data.

- Discussion on which description is more appropriate - Subject Data or Study Data. It was agreed that "Subject Data" is the best description.

ACTION ITEMS:

1. Dave will work with Julie Evans and Diane Wold to complete BRIDG gap analysis.
2. Ensure that all of the subject data needed to construct CDISC SDTM and SEND data views and that the message can achieve this.
3. Validation check - relationships between the subject data and the Study Design, Study Participation, and ICSR messages.

Drafted: PGarvey/10-15-2008
Approved: 10-23-2008