Meeting Minutes

CDISC-HL7 Stage II
July 23, 2008
11:00 am – 1:00 pm (EST)

Attendees / Affiliation

Jason Rock/Global Submit (Chair)
Christi Eckerson/CDC
Julie Evans/CDISC
Patty Garvey/FDA
Scott Getzin/Eli Lilly
Joyce Hernandez/Merck
Marcelina Hungria/Image Solutions
Wayne Kubick/Lincoln Technologies
Pierre-Yves Lastic/Sanofi-Aventis
Mary Lenzen/Octagon
Jay Levine/FDA
Saurin Mehta/Novartis
Armando Oliva/FDA
Mitra Rocca/Novartis
Diane Wold/GSK

Background

FDA wishes to receive, in regulatory submissions, standard clinical study information content developed by the Clinical Data Interchange Standards Consortium (CDISC) in an Health Level 7 (HL7) message exchange format. This is key to the FDA strategic initiatives to improve public health and patient safety.

This project is currently broken into two stages: requirements analysis and message development. Stage IB team was developed and tasked with the requirements analysis responsibilities. Stage II team was developed and tasked with the message development responsibilities.

The purpose of the meeting is this meeting is to review the Study Design and Study Participation DSTU ballot package submitted to HL7.

Discussion

- The May 14, 2008 meeting minutes were reviewed and approved.

- Jason shared the location of the Study Design and Study Participation DSTU ballot package on the HL7 website: Ballot/Universal Domain/Regulated Study.

- Jason identified the following changes that were made to the ballot package:
    - Description of Applicant – as defined by Regulated Product Submission (RPS) and Structure Product Labeling (SPL).
    - RMIM changes in study site – data collection and registration event (subject accrual)
    - Name change in study design – experimental unit from investigator object
    - Time point definition is other level of organization (study cell vs segment). The study cell and segment joined into 1 concept because they have the same elements and in study conduct there could be further organizations.

- The following issues were raised regarding the BRIDG GAP analysis and harmonization:
    - Who is responsible for documenting GAP analysis and presenting these GAPs to the BRIDG Technical Committee. It was recommended that Stage II chair would be responsible for these activities. However, it was pointed out that the Project Charter indicated that this GAP analysis would be the responsibility of Stage IB. Patty will have a meeting between the Chairs of IB and II to discuss the responsible group for the analysis. The discussion will be shared at the next Stage II meeting on August 6th.

    - It was suggested that BRIDG harmonization be completed prior to modeling.

    - Armando indicated that harmonization after DSTU will prevent harmonization two times and DSTU may also identify other GAPs. He also indicated that the BRIDG Board of Directors have different opinions on when the best time would be to bring GAPs to the technical committee, but currently it is acceptable that requirements be DSTU ballot without harmonization.

- At the next meeting on August 6th, Jason will take a domain from SDTM and map it to the HL7 clinical statement.

ACTION ITEMS

1. STAGE IB and II Chairs/Co-chairs will discuss and determine who will be responsible for BRIDG harmonization activities.
2. Mitra - Alignment matrix
3. Mapping documents – is mapping going to be done and which mapping?
4. How to represent or document at different level?
5. Jason and Wayne will determine which SDTM domain to map to the HL7 clinical statement for the next meeting.

Drafted: PGarvey/8-5-2008
Approved: 8-6-2008