

Meeting Minutes

CDISC-HL7 Stage I-B

August 28, 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)
Julie Evans/CDISC
Terri Hardin/IBM
Joyce Hernandez/Merck
Lou Ann Kramer/Eli Lilly
Mary Lenzen/Octagon
Barrie Nelson/Amgen
Armando Oliva/FDA
Gary Walker/Quintiles
Diane Wold/GSK

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 HL7 Working Group Meeting (WGM) agenda and Subject Data message storyboards.

Discussion

- HL7 Working Group Meeting (WGM)
 - Stage IB will have an all day meeting on Tuesday, September 16th
 - Q1 and Q2 will focus on the BRIDG GAP analysis for Study Participation and Study Design.
 - Q3 and Q4 will focus on the Subject Data storyboards. Diane will provide additional documents from the SDTM domain working sub-group for the meeting.

- Subject Data Message Storyboards
 - Jay will provide additional storyboards.
 - Armando will provide a general, board storyboard that focus on submission of study data (data collected to submission to the FDA).
 - It was discussed whether the Janus requirements should be captured in the storyboards. It was agreed that Janus should be reviewed and doing this will help drive the concepts for the storyboards.
- Domain Analysis Models (BRIDG)
 - It was agreed that Stage IB should develop a domain analysis model.
- Dave expressed his concern regarding the scope of the project. There are two issues:
 - Visibility to working documents to those outside of the group without appropriate context. This results in a lot of rumor and speculation.
 - Mention of items, such as SEND, within the project scope that will not be incorporated into messages until a long way in the future.

Care needs to be taken to ensure the wrong messages are not conveyed to those not intimately involved in the project. There is also a need for more detail around the future content that will be included within these messages.

- The next meeting is scheduled for Thursday, September 11th. This meeting will finalize plans for the Stage IB WGM on September 16th.

ACTION ITEMS

1. Jay will provide additional Subject Data storyboards.
2. Armando will provide a general, board storyboard that focus on submission of study data (data collected to submission to the FDA).
3. Diane will provide additional documents from the SDTM domain working sub-group.

Drafted: PGarvey/9-1-2008

Approved: DIbersonHurst/9-2-2008