# Meeting Minutes

# CDISC-HL7 Stage I-B
# March 12, 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
Joyce Hernandez/Merck
Terry Hardin
Wayne Kubick/Phase Forward
Mary Lenzen/Octagon
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 boards and agenda items for the March 31/April 1 meeting.

## Discussion

- The February 26, 2009 meeting minutes were approved.

- The F2F meeting has been scheduled for March 31, 10-5 and April 1, 9-3 at the Park Lawn Building in Rockville, MD. Attendees should send an email to Jay if they plan on attending. Chris and Jay will send out an agenda shortly.

- Recent Emails - How would information currently represented in define.xml be handled? This is not part of the care record. How do we expect to show traceability and link to the CRF? Where is this in the message? HL7 does not have a CRF. We will need to go through the define element by element. It is still a FDA requirement to submit the define document. The other concern that was raised was how we reconstruct SDTM domains for viewing. The team decided that this is not an issue because it is the FDA's responsibility to do this. The information needed for the reconstruction will be in the message. In addition, we will have to address the concept of experimental unit when Jason is available at the meeting at the FDA.

- Story Board 5- Pierre-Yves sent the following Story Board related to coding:

*Acme Pharmaceutical has been submitted results of a phase IIA, Proof of Concept study with adverse events coded using MedDRA version y.z. One year later Acme submits the results of its phase IIB, Dose-ranging study; however, this second study uses MedDRA v. y.z+1 since a new MedDRA release occured in the mean time. Acme then submit a first phase III, pivotal study using MedDRA version z.1 and the second one six months later using MedDRA z.3, along with an Integrated Summary of Safety (ISS) using this same last version of MedDRA. When analysing pooled data from the different studies in JANUS, Roger Reviewer find different counting of adverse events than the one in the ISS, due to the fact that some events that were under the same code in MedDRA y.z are now split under three different code in version z.1.*

We had a discussion around the story board above. We decided that the problem is a known coding problem not a message content problem. This issue will not go away when we have a HL7 message. But Jay indicated that the message will allow multiple coding per variable in HL7. But we know that sponsors do not want to recode individual studies.

- Story Board 9

The team decided to drop this story board because coding is a FDA policy issue, not a message issue. As above this is a current issue and will not go away when sending HL7 messages.

A Study Participation Message would be sent each time new subjects were enrolled, but no message would be sent to indicate that the site or study was no longer enrolling. There would not be a status if the site was open, enrolling or closed. This should be covered in the Clinical Trial Registration and Results Message. We need to ensure that harmonization with all messages occurs at with BRIDG.

- Story Board 11, 12 and 13

The team decided that story boards 11, 12, and 13 are regulatory use cases and should be removed.

- The next TC is March 26. Chris will be on vacation and Julie will lead the TC. The goal is to complete the review of the story boards and discuss the agenda for the meeting at the FDA.

**ACTION ITEMS:**

1. *Team to send contact information to Jay if they are planning on attending the March 31/April 1 meeting at the FDA.*
2. *Chris will discuss with Patty where we are keeping story boards that we decide to delete.*
3. *Chris and Jay will send out the agenda for the meeting before the next TC.*

***Drafted: CTolk/3-14-2009***
***Approved: 3-26-2009***