<u>**Official Meeting Summary**</u> – Date Drafted: January 9, 2008

Meeting type – CDISC - HL7 Stage II

Meeting date & time – January 9, 2008, 11am – 12 Noon (Eastern time)

Meeting format – Webinar / Conference call

Meeting Leader(s) – Jason Rock

Meeting Recorder – Erik Henrikson

Attendees – Name / Affiliation -

Jason Rock / GlobalSubmit
Wayne Kubick / Lincoln Technologies
William Rosen / Pfizer
Monica Mehta / Genzyme
Erik Henrikson / FDA
Diane Wold / GSK
Saurin Mehta / Novartis
Greg Anglin / Lilly
Julie Evans / CDISC
Joyce Niland / City of Hope Medical Center
Marti Velezis / Booz Allen Hamilton
Terry Harden / IBM
Mary Lenzen / Octagon
Bill Friggle / Sanofi
Scott Getzin / Lilly
Jay Levine / FDA

<u>**Background and Objectives**</u>

a. History of events leading up to the meeting –

The US Food and Drug Administration (FDA) receives massive amounts of clinical research data in extremely disparate formats using a variety of proprietary standards. This makes it extremely difficult, if not impossible, to do cross-study and application reviews. FDA wishes to receive, in regulatory submissions, standard clinical study information content developed by the Clinical Data Interchange Standards Consortium in an HL7 message exchange format. This is key to the FDA strategic initiatives to improve public health and patient safety.

The project has been approved as an RCRIM project is awaiting approval from the HL7 Steering division.

This project is currently broken in to two stages requirements analysis and message development.

b. Meeting was requested by – FDA

c. Purpose of the meeting – RCRIM (HL 7 Listserve) members to discuss develop consensus necessary for a path forward on CDISC-HL7 Stage II activities

Discussion

Participant members were noted and discussion ensued.

Briefly reviewed then agreed to Finalize December 19, 2007 Meeting Minutes

Project Charter still in need of 9-0 vote. Presently 7-0, but as per HL7 operating procedure it is OK to move forward.

No unfinished business from last gathering

Presentation 1

As part of our process to examine artifacts relevant to this project, Julie Evans presented an overview of the BRIDG Model, which is a method used to document requirements using the Unified Modeling Language (UML).

BRIDG Release 1.1 Domain Analysis Model – The BRIDG model contains several views, which allow you to see subsets of the model that are of interest to you. The subject data that is going to be part of the CDISC HL7 message is in the "Performed View". Most of the subject data is in the PerformedObservation and PerformedObservationResult classes. The model uses HL7 V3 datatypes and does not yet identify optional or required attributes. For more details on datatypes and other BRIDG information, please see the website at www.bridgmodel.org and the Release Notes for R1.1, which can be accessed through the website.

Specification design (Stage 2 activities) require design information model (based on the domain analysis model), state diagram, sequence diagrams and messages.

Eventually messages will be harmonized into BRIDG by February 2008 * *(True statement?) [I think the question was whether everything in the HL7 messages would be in BRIDG first. Jason's response emphasized that all content doesn't have to be BRIDG before message development can start. He also mentioned that some material needed may currently be in other HL7 domain models, in which case harmonization between BRIDG and those other domain models will be needed.]*

BRIDG release 2.0 is slated for April 2008.

Presentation 2

Diane Wold discussed Trial design and how it is modeled in BRIDG. "Trial Design" is a part of the plan for a trial, and thus is part of the Protocol. The CDISC SDTM standard includes simple datasets for trial inclusion/exclusion criteria and trial summary information, a pair of datasets that describe the high-level design (the study schema), and a dataset for planned visits. Further development on eligibility criteria is being done by the ASPIRE, a subteam of Protocol Representation, and the Protocol Representation subteam on Clinical Trial Registry is developing more structured trial summary information. The TDM suteam is focused on study schema information and on schedule of activity information.

Diane also presented slides of (non-UML) diagrams to illustrate how the study schema is represented using the concepts of arm, epoch, study cell, and study segment. She then presented UML class diagrams, using the classes in BRIDG 1.1, to show how the study schema and schedule of activities concepts appear in BRIDG.   She also showed a diagram that illustrated how the concepts appear in the BRIDG planned, scheduled, and performed "pillars" Julie explained. Finally, she showed a diagram that illustrates how the Performed ObservationResult class (the class that represents most actual clinical trial subject data) has an corresponding PlannedObservationResult class, and that these planned results are what are involved in the planning data collection, as in the eDCI project.

Decisions/agreements reached

a. Action items ownership –

- Examine / presentation on ICSR message * *(Mead Walker?)*
- Specific presentation notes will be provided on respective presentations. (Julie Evans & Diane Wold)
- Both .ppt slide decks will be distributed along with Draft Meeting Minutes (Erik Henrikson)
- Web links will be distributed for down-loading Webinar patch and meeting link (Erik Henrikson)

Date(s) for follow-up - January 23, 2008, February 6, 2008

Related Documents

- Meeting Minutes from December 19, 2007
- Julie Evans / CDISC .ppt slide deck
    - http://WWW.bridgmodel.org for additional background and history
- Diane Wold / GSK .ppt slide deck(s)

- FIRST-TIME USERS - check your system to make sure it is ready to use Microsoft Office Live Meeting. http://go.microsoft.com/fwlink/?LinkId=90703 (scroll down in page as needed)
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Other

Meeting Minutes Drafted/Author – Erik Henrikson