Official Meeting Summary – Date Drafted: December 19, 2007

Meeting type – CDISC - HL7 Stage II

Meeting date & time - December 19, 2007, 11am – 12 Noon (Eastern time)

Meeting format – Webinar / Conference call

Meeting Leader(s) – Jason Rock

Meeting Recorder – Erik Henrikson

Attendees – Name / Affiliation -

Jason Rock / GlobalSubmitt
Wayne Kubick / Lincoln Technologies
William Rosen / Pfizer
Monica Mehta / Genzyme
Kristi Eckerson / CDC - Northrop Grumman
Lindsay Prendergast / Genzyme
Erik Henrikson / FDA
Andy Siegel (Genzyme)
Brooke Hinkson (Genzyme)
Bob Birmingham (J&J)
Diane Wold (GSK)
Barbara Westrum (Medtronic)
Saurin Mehta (Novartis)
Lise Stevens (FDA)
Dana Soloff (Genzyme)
Greg Anglin (Lilly)
Julie Evans (CDISC)
Kristofer Spahr (Wyeth)
Julie Evans (CDISC)

Background and Objectives

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.

Project Scope / framework document was discussed. Also the differences between IB & Stage II activities were clarified.

Basically the overall project intent is to create standard messages that regulated industry can use to transfer data to FDA. Existing standards such as CDISC and HL7 will leveraged. No new requirements are foreseen.

Sponsors of this endeavor include:

- CDISC
- RCRIM
- FDA
- NCI

The Team includes:

- Jason Rock – Project Manager
- Mead Walker – Modeling facilitator
- Peggy Leizear - Publishing facilitator
- Bron Kisler – Vocabulary
- Jay Levine – Business requirements
- Dave Iberson-Herst – Business requirements

Currently 4 messages are envisioned:

1. Study Design
2. Study Participation
3. Subject Data
4. Adverse Events

The operating plan => BRIDG domain analysis model => Messages

An overview of the HL7 Development Framework (HDF) was providided

The HDF calls for a few phases: project initiation, requirements analysis, specification design and specification profiling

Basically 2 documents are needed for this project to move forward (project initiation)

1. Project Scope Statement (2 pages) – currently with the HL7 steering division
2. Project Charter (20 – 40 pages & developed from Project scope, updated as needed.) – currently being developed in stage 1B

Business requirements (Stage 1B activities) require storyboards (narrative explanation of requirements, use case (UML model of storyboards), process flows, and data models.

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

Specification profiling describes and implementation of the message/standard.

Decisions/agreements reached

a. Action items ownership –

- Review Project Charter (all participants), when available
- Examine which artifacts are appropriate in BRIDG / ICSR(all participants)
- Examine other clinical models Detailed Clinical Model, Clinical Statement, others
- Distribute Project Scope & .ppt slide deck to all participants (Erik Henrikson)

Date(s) for follow-up - January 9, 2008 January 23, 2008, February 6, 2008

Related Documents

- Project Scope document (2 pages)
- Slide Deck (HL7 Development Framework)

Other

Meeting Minutes Drafted/Author – Erik Henrikson