Official Meeting Summary – Date Drafted: January 23, 2008

Meeting type – CDISC - HL7 Stage II

Meeting date & time – January 23, 2008, 2-3pm (Eastern time)

Meeting format – Webinar / Conference call

Meeting Leader(s) – Jason Rock

Meeting Recorder – Erik Henrikson

Attendees – Name / Affiliation -

Jason Rock / GlobalSubmit
William Rosen / Pfizer
Erik Henrikson / FDA
Terry Harden / IBM
Bill Friggle / Sanofi
Jay Levine / FDA
Armando Oliva / FDA
Mead Walker / MWC
Fred Miller / Genentech
Mary Lenzen / Octagon
Monica Mehta / Genzyme
Wayne Kubick / Lincoln Technologies

Background and Objectives

a. History of events leading up to the meeting –

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.

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 January 9, 2008 Meeting Minutes

No unfinished business from last gathering.

Presentation

Mead Walker covered the Individual Case Safety Report (ICSR) – One driver is the need for FDA to address the need to receive reports on a wide range of regulated products (drugs, biologics, cosmetics, devices etc.) Typically each Center has a different method or data base in place to receive, track and analyze reports.

The ICSR Model is broken in to three parts: base model, product use, and product information.

The base model is from the perspective of an event. An example of an event would be a rash from a child whose mother is taking a substance for postpartum depression.

When an event occurs an ICSR message can describe the event, how serious the event is, attach source report (e.g. doctor's notes, lawyer letters), who was the author and receiver of the notification, reactions of the subject (e.g. rash) and what products (e.g. drug, device, cosmetics) are suspected to be the cause of the problem.

From the investigative subject you can capture the subject's medical history as well as any relevant family members' medical history. In addition you can capture if the subject is currently enrolled in a trial. The Subject Data message could be similar (if not the same) as ICSR but at the point of view of a subject, instead of an event.

The reaction can be linked to a subject, the subject's medical history, the suspected product and any related reaction (e.g. fever one week ago).

The second part is the product use model. The product use model describes the suspected product, how the product was used, and what measures were taken based on the event.

The third part is the product model. This model is harmonized with both SPL and the medication domain model. This model describes the product with such characteristics as lot number, model number, active ingredient and alike.

Decisions/agreements reached

a. Action items ownership –

- Examine / presentation on Clinical Statements & how HL7 models this.

Date(s) for follow-up - February 13, 2008, February 20, 2008

Related Documents

- Meeting Minutes from January 9, 2008

Other

Meeting Minutes Drafted/Author – Erik Henrikson