Meeting Minutes

CDISC-HL7 Stage I-B
March 26, 2009
11:00 am – 12:00 pm (EST)

Attendees / Affiliation

Jay Levine/FDA (Co-Chair)
Patty Garvey/FDA
Julie Evans/CDISC
Scott Getzin/Eli Lilly
Terry Hardin
Wayne Kubick/Phase Forward
Pierre-Yves Lastic/Sanofi-Aventis
Mary Lenzen/Octagon
Armando Oliva/FDA
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 draft Subject Data story boards and agenda items for the March 31/April 1 meeting.

Discussion

- The March 12, 2009 meeting minutes were approved.

- Story Board 10. Determine if patients met inclusion criteria

  The NCI-sponsored Study RTOG 93-09 is a randomized, unblinded, multicenter, two arm parallel design study comparing Chemotherapy + Radiation Therapy (CT+RT) vs. Chemotherapy + Radiation Therapy + Surgery (CT+RT+S) for the treatment of Stage IIIa non-small cell lung cancer. A key inclusion criterion requires the presence at screening of a single, newly diagnosed, primary lung parenchymal lesion of stage IIIA (T1, 2 or 3) with ipsilateral positive mediastinal nodes. The reviewer wants to ensure that only subjects meeting this criterion were enrolled. The Study Design message contains the plan to collect these screening data, and the reviewer is able to locate and analyze the collected screening data for each subject from the Subject Data message to verify that this criterion was met.

Use Case: A study is conducted in order to determine if a product is safe and effective in a sub-population of patients. The inclusion criteria are constructed so that only patients in the sub-population of interest are enrolled in the study.

The reviewer wants to ensure that only patients who met the inclusion criteria were enrolled in the study.

- Everything in the storyboard looks okay except the statement "Requirement on Study design message to indicate those observations used to support inclusion/exclusion processing": this is not currently done in pharmaceutical companies. So this is a Study Design requirement, not a Subject Data requirement.
- The following statement should be moved over to the Study Design requirements: Requirement on Study Design message to indicate those observations used to support inclusion/exclusion processing.
- The current study design message doesn't include the data described in the above statement. Some items that are collected at screening don't indicate that they are being collected for IE processing.
- Clinical statement contains why you are collecting certain data and may include data that isn't currently being done in pharmaceutical companies.
- It's an FDA policy issue about what's going to be required in the message.
- There is concern that it might not be possible to build a structurally valid message if you didn't collect the data that is required for the message. It also may not be practical to provide some required data.
- One way to look at a complicated IE inclusion and how it is linked back to the planned assessment is as an analysis plan, which should be deferred to a future release.
- For this first release, we are concerned only about collecting the data.
- The Story board makes sense without the Study Design requirement.

- Story Boards 11 and 12 regarding audit trail will be discuss during the March 31st meeting. Leonard Sacks from FDA Office of Critical Path Programs will be more detail on this FDA audit trail requirements.

- Story Board 13

Estimate mean and variance of subject response in a study cell, and functions of these means and variances.

A reviewer wishes to estimate the mean and variance of a continuous response variable (e.g. blood pressure) at one or more times (e.g. visit) in one or more study cells, and calculate functions of these means and variances.

Rosie Reviewer is interested in understanding how blood pressure is affected, over time, by the treatment strategies being evaluated in the Acme 9999 study. In order to do this, she must know, for each measurement, the subject's treatment strategy and the length of time on that strategy at the time of the measurement. She must also be able to identify the baseline measurement for that treatment strategy. In order to evaluate the treatment effect at various timepoints relative

to the start of treatment, she must select measurements to be included in evaluation of that timepoint. This will involve decisions about which observations are close enough to the timepoint to be included in the analysis, selecting from among multiple "close enough" observations, and deciding whether and how to impute values for subjects with no "close enough" measurements. Once observations have been identified, she will calculate estimate of relevant statistics (means, variances, changes from baseline, etc.) for each treatment strategy and timepoint and also estimate differences between treatment strategies.

- Need to know which data was collected during which treatment strategies.
- Question about how cells are associated within a clinical statement: care plans should have corresponding care records once the plan is executed.
- We need to continue this discussion at the F2F meeting.

ACTION ITEM:

1. *Patty will send a reminder of the meeting on March 31/April 1 meeting at the FDA*
2. *Wayne suggested adding a discussion project timeline to the agenda..*
3. *Patty will create a folder in the wiki for "deleted" Subject Data story boards.*
4. *Patty will renumber the Subject Data story boards.*

Drafted: PGarvey/3-26-2009
Approved: CTolk/6-9-2009