



DEPARTMENT OF HEALTH AND HUMAN SERVICES

TELECONFERENCE MEMORANDUM

Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

Date\Time: November 8, 2006 \ 12:00 pm

CBER

Representative: Lori Tull

Sponsor's

Representative: Elizabeth Smith

STN : 125197/0

Subject: Request for information regarding clinical study 9901

Discussion: I communicated the following requests to Ms. Smith.

For study 9901

1. Regarding the Deviation data listing table (DEVI_LOG.xpt) listed the data from 138 subjects. How many of these subjects had major protocol deviation? What happened to 11 subjects who were not randomized (138 total – 127 randomized)?
2. In the TTP Kaplan Meier Curve, each circle represented a censored value at a given time point. How many subjects were censored at each point?
3. Data on death certificates. Which subjects had death certificates? This information could not be found in the Data listing table DEATH.xpt (death summary report).
4. The PCHEMO.xpt file listed the data from 135 subjects. Why was the number of subjects 135, and not 127?

Ms. Smith replied that she would get back to me with this information. She also mentioned that the final submission for the BLA would likely be submitted tomorrow (11/9/06). The call ended.

OCTGT:IOD:Tull:11/8/06

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