ADNI biostat conference call, 10 April 2007
On call: Laurel, Danielle, Qian, John, Monica, Mike Welch, Paul Maguire.

Laurel reports from Executive Committee that UCSD has forms for several of the summary measures but there is not yet any data in them. ADCS is trying to get the sites that are creating summaries to send some data.

Danielle and Qian reported that they have been able to get data successfully from LONI but that access is essentially to a zip-file of a data dump of everything UCSD sends. Karen Crawford is collecting information on what people want for query options, though it isn't clear if the query tool will only be available for the images or if it will be possible to query the clinical database as well.

Danielle will emphasize on MRI and PET calls the need to get data as soon as possible, even if not complete.

Laurel reported that presentation of the analytic plan went well. The FDA people gave some excellent presentations of their expectations and ideas; the slides will be posted soon, and we will have access.

One concern raised by Eric Siemers and some others is whether our data presentations could affect "blinding" of the clinical evaluations at follow-ups. We discussed this at Executive Committee and concluded that it is ok to present data summaries provided we emphasize the heterogeneity within group, its importance to our analyses, and the need for clinicians to assess individuals in a fashion that is sensitive to individual variation and not trying to fit a perceived template.

We need to address these issues in imaging, also. Serum and CSF biomarkers are blinded, according to John T. Some imaging measures are blinded, e.g. hippocampal volume, but others may not be. We should encourage blinding wherever possible, and documentation of what information is available and how bias is avoided in other cases.

Use of the phantom is not explicit in the analysis protocol. Paul mentions that there are two ways to use the data. One is to monitor performance during the trial, and the other is to correct individual patient data during analysis. If one makes the phantom part of the analysis, then the official surrogate marker would need to be "image plus standard phantom plus standard correction protocol". Paul does not recommend that because he feels that it would be very hard to prove that this adds validity, and that variation in phantom measurements may be a QC problem not something to adjust for. Laurel suggests this may be analogous to the use of standards for viral load and CD4 count in AIDS clinical trials. Paul recommends that the specific use of the phantom data be emphasized more in the analytic plan to say that it will be used for QC but not to correct individual images. It is important to be able to show consistency across sites as well as within site longitudinally.

Next call is Tuesday, 24 April.