ADNI Biostat Core Conference Call, 10 October 2006
Present on call: Danielle Harvey, Laurel Beckett, Rob Croop.

Laurel reported on the Chicago meetings and discussions.
1. Limitations of study design: can't use as a study to develop diagnostic markers because not population-based. Need to write up so people are aware of this. We'd like to post a simple summary of what we propose to do and limitations.

2. Rob says his stat folks are aware of limitations about study design. This really is the foundation study to understand the behavior of potential surrogate markers in the target cohorts for clinical intervention.

3. We need also to post a clear summary of the cross-validation: why, what it is, how to use it, maybe a simple analysis example (both for the cross validation version and for the leave-k-out approach.)

4. Mike laid out basic questions:
a. Does this study cohort look like other previous studies clinically?
b. How do markers change, how do they compare with each other? (Also choice of markers)
c. Validation: how do rates of change correlate with the clinical markers?
d. How does that compare across markers? (Both stability and validity of correlation). A marker might t find something useful in Phase II for signal but not Phase III.

5. Mike expressed caution about working on models for prediction. Rob says this is probably more sophisticated than FDA lets you get away with; mostly people use predictors only to get a pretty homogeneous population. Mike: You could also use these as covariates to reduce unexplained variation. Rob and Laurel felt this is not done often in actual trials; rather, they try to get a homogeneous population.

Goals: get updated analytic plan, reflecting some of these ideas. Develop a separate simple language version of aims and cautions. Develop documentation for the cross-validation (both types) including simple example and references.

Next call is 24 October.