ADNI Biostatistics Conference Call
Minutes for 9 December 2008

Present on call: Laurel Beckett, Danielle Harvey, Hao Zhang, David Shera, Fred Immerman, John Kornak, Mike Donohue.

Danielle updated us on data status. The PET labs have processed almost all of the 12-month images available, about 90%. The MRI labs have processed data although there is not a lot of data change on the LONI system. Danielle requested that they begin uploading so that we can see what has been processed and what still needs to be done. Nick Fox will be doing a large upload. Paul Thompson will do a first wave in a week or so and another in early January. Colin Studholme is doing some TBM and will be able to submit a batch in a few weeks. No one else on call was able to give an update. Danielle emphasized on the call that we need to do analyses for ISAB in January and we would like not to report the exact same stuff as last July.

The upcoming target dates are: an update of the July analyses during January using the markers with the most data completed; a full analysis in April for the ISAB meetings; and a final report for the grant renewal in November.

Our goal today is to try to get feedback on the analytic plan outline. One comment that we have already received, very important, is to emphasize the role that biomarkers can play in improving clinical trials and trial design. These roles could include serving as an actual marker or surrogate marker (an endpoint in a Phase II or III trial), being used as a covariate in regression models, and serving to improve designs by targeting treatments or pushing treatment back earlier in the disease process.

Danielle noted that much of the bulleted list is analyses we have already been doing. She also reviewed some of the changes and additions to the document.

One key thing we want to do is look at PIB data. Bill J and Mike W have presented some very interesting correlations between the PIB summaries and CSF and imaging. Mike W claims it has been “up” for a month but we have not been able to find it. Mike D doesn’t know yet either. We want to get access, and Danielle has emailed Bill and will try to find it. There has also been a lot of email discussion about getting meds data. This is a huge task, translating text fields to med codes. The codes are in fact in the database and can be downloaded. The ADCS has done some coding before and has a system, but they use a proprietary drug code system. They are looking into it and Mike D will keep us advised.

We have received several summaries from industry biostatisticians of work their groups are doing. We want to read those carefully to help us understand what is important to industry and what parallel and new analyses are going on.

We can’t expect much on item 17, the item analysis and improved neuropsych, for April because Paul is just starting.

The ISAB feedback on the ADNI II plan included a section on the biostatistics core. The major comment is that they want a broader, more expansive view of biostat contributions, not just ADNI I stuff. We can expand this along the lines we are outlining. One contribution we need to emphasize is the idea of novel clinical trial designs. David

and Fred thought this was important and a good idea. Rusty Katz of FDA had stated that we need to show solid evidence that the biomarker data constitute true surrogate endpoint data (or whatever we are using it for.)

One other topic mentioned briefly was the need to coordinate analytic plans, as in at least one case (Ron Petersen's "baseline" clinical paper) both UCD folks and UCSD folks were asked to do same analyses and a lot of duplicate effort happened, and some differences in coding. We have this one sorted out but will just touch base on papers in the future so we can work more efficiently.

Next call is January 13. Happy holidays to everyone!