ADNI Biostatistics Conference Call
1 December 2009

Present on call: Danielle Harvey, Laurel Beckett, Hao Zhang, Mike Donohue, David Shera, Genevieve LaForette, Niclas Sjogren, Fred Immerman, Kisook Yoo.

Laurel gave a report on the WW-ADNI meetings in Japan. The meeting had representatives from ongoing ADNI projects in the US, Japan, Australia and Europe, and potential sister projects in Korea and China. Laurel presented our ADNI-2 application findings to the J-ISAB and a shorter version emphasizing biostatistical challenges to the whole WW-ADNI. Each of the imaging, biomarker and clinical ADNI groups presented findings, and the Japan, Australia and Europe groups also presented their current results. One very interesting discussion was a report by Paul Aisen on a meeting in Las Vegas with industry and FDA people on strategies for working with biomarkers in AD. The FDA is very open to the use of biomarkers to help study designs by sharpening entry criteria, stratification and use as covariates. We just don't have enough data yet in clinical trial settings to support use of imaging or csf as endpoints (either primary or secondary, regardless of trial phase). But the discussion was positive about the idea of demonstration of surrogate marker performance in a disease phase that is farther along (say, later MCI) where we can expect to see clinical change or progression, and then using that evidence plus ADNI-type data to justify using the same marker in a somewhat earlier stage where there is less cognitive change. Laurel hopes this meeting will be followed with a written document to expand on these ideas; this is 3rd hand and we should look for a more official summary.

The MRI and PET imaging groups are moving forward with ADNI GO, and to make the most use of the two years of funding. With PET, we have both FDG PET and AV45. We will also get CSF on everyone in GO, and everyone will have 1.5T MRI. There will be more data coming! As a reminder, virtually all of the 12-month assessments were processed by all the labs. People are now following up on the later assessments, and we should expect to see updates including 2nd and some 3rd year imaging.

Danielle and Laurel reported on ongoing analyses. They are following up mostly on longitudinal models corresponding to the diagram from ADNI-2 application. One area of focus is the normal controls, where there is some evidence of patterns that may reflect early change. Another focus is on modeling multivariate longitudinal patterns.

Mike Donohue has a draft of a paper on impact of biomarkers on clinical trial design, with ideas and simulations for effects of different strategies. They are polishing this and finishing more simulations. He hopes to have it ready to submit soon.

Niclas Sjogren from Astra-Zeneca is looking at power calculations, and looking for patterns for AD conversion. They now want to look at time axis in a different way; time since AD diagnosis or time to AD diagnosis. They want to try to identify stages at which different drug approaches might help, and when do particular biomarkers change.

The next big push is likely to be for the April meetings in Toronto. Watch this space for more news.

Next call: January 5, 2010. Happy holidays, and see you next year!