ADNI biostatistics call minutes
9 September 2008

Present on call: Laurel Beckett, Danielle Harvey, Hao Zhang, John Kornak, Fred Immerman, David Shera. Bill Billings, Joanna Fueyo.

The training session is scheduled for next week, September 15 from 8 am to 12 PM Pacific time. So far 54 people have expressed interest in attending. They are a mix of people from industry and some of the MRI and PET labs (Eric Reiman's lab, Paul Thompson's lab, Norman Foster's lab, Norbert Schuff's lab). The goal is to introduce some of the methods we have been using at UCD and also folks at UCSD to help people with analysis of ADNI data. People are asked to make sure they have a LONI account and can download files before the call. Danielle has circulated an agenda. If anyone has suggestions to add, that would help avoid confusion or frustration in working with the data, please send! We will talk about how to download data, show how to merge and get basic descriptions, how to fit random effects models and other summaries of change, how to use these to get sample size. We will then talk about how to get other covariates in (and how UCSD used this to estimate effects of biomarkers for improving study designs). We will finish up with cross validation, and, if time permits, the approaches we have used for comparisons across labs or modalities that take account of blocking by person.

This will be a web-based conference – we will have power points that people can see, and we will post those and handouts.

We hope this will encourage people to download and use the clinical and summary data. (We are not going to talk about processing the images themselves).

Laurel, Danielle and Bill were on a call yesterday with Mike Weiner and some FDA statisticians. The conversation yesterday with the FDA statisticians did not answer all of our questions. They referred questions about "techniques" (e.g. standardizing across imaging platforms via software and phantoms, developing data-driven ROI's by standard voxel-based approaches) to the CDRH. They are interested in the possibility of variance reduction via incorporation of pre-specified covariates but less keen on multiple comparison, data-driven, model-building approaches (they think of that as "just for fun" or for hypothesis generating). They said that it would take substantial evidence to be persuasive that a given marker (imaging or biomarker) could serve as primary endpoint, and referred to extensive discussions and literature on the surrogate marker discussions in cancer and elsewhere. Laurel will ask Mike to share minutes/ notes so that we will know who was on the call and a more detailed summary of what was said.

Laurel shared the draft version of the biostatistics aims for ADNI II and asked for feedback; we have plenty of time to edit, depending on results of ADNI I and on what other groups propose as aims. John thinks it looks great for now.

Budget issues: we have a 10% cut to the core for Year 5 to help save money for Year 6 no cost extension. Note that we have already saved a fair amount in Years 1 and 2 and set this aside and will get this for Year 6, too, as well as something from the supplement. One implication, though, is that we have virtually no funds for phone or travel. We propose to cut these calls to once a month. Everyone agreed on the 2nd Tuesday, same time. Laurel will send out a notice.

John followed up on the voxel-based analysis issues. We wanted to bring this up on the next call (how do we use the training set to generate ROI's) but there was not time. Laurel and Danielle will be discussing the cross validation issues on the training session, and a number of folks from labs are signed up, so we agreed to postpone consideration until we see if there is still a need after that session.

Next call: October 14, 10 AM Pacific time.