ADNI biostat conference call, 29 August 2006

On the call: Rob Croop, Sarah Walter, John Kornak, Mike Weiner.

Sarah updated us on enrollment. Anthony Gamst did a projection that suggests enrollment would be complete sometime during 3rd quarter of 2007 (earlier if the current trends continue, later if they flatten out some as cells fill up.) As of today there have been 818 screened, 433 randomized. August has been slow (36); best month was May with 75. Right now there are 150 normal, 197 MCI, 86 AD.

The last MR call had both PET and MR folks. John reports that there are still some issues to be settled but that there will be both an ROI (a priori) approach and a cross validated test/ training approach. There is also a back-up plan that will have a single test and single training sample set for those who do not have sophistication or randomization tools to do cross validation on multiple sets. There is still some disagreement on how much emphasis should be on a priori regions and how much on novel regions identified through exploratory approaches.

Rob asked whether the FDA had given any feedback yet. Mike is trying to get their statisticians involved to give feedback, but so far we have not met. We hope to get more feedback on our document and to get them more engaged. Rob encouraged us to get FDA involved in both design and analysis for both biomarkers and imaging. Mike is working to get a specific person. Once we get an initial contact we can share the draft document. Laurel suggested inviting the person to our planned workshop on statistical analysis, also.

Mike says in quite a few weeks the grad warped and intensity-corrected images will be posted. Processing will begin by October, we hope, and we shouldn't expect to see lots of data before the New Year. We will continue to work on methods and set up mechanisms to download. Mike says the interface will be quite different. We can either work directly through the LONI website and download ADCS data or work through ADCS. Mike prefers that we work through LONI as that is the way the rest of the world will work. The interface is not yet available for anyone. It is supposed to come up (Phase I) in first part of September. We need to work with Karen Crawford and Anthony Gamst to make sure we can get everything we want through LONI website. Art and Karen will set up some teleconferences so we can test out the website as soon as it goes up. We can also report on this in October.

There will be some interesting challenges in days to weeks; the MRI phantom data, for example. There is a phantom in every single scan and there is a summary produced for every scan. We will have 55 sites, patients with baseline images, some with longitudinal images, and one phantom for every image. We can look at sources of variation: site, scanner, over time. Unfortunately due to complications with Anders Dale grad warp, this is delayed, but we can examine this for potential QC issues. We can use to help develop control charts. There are at least 450 scans already so we will have a lot of data. There are also PET phantoms. What variables should we follow for developing QC?

We also need to ask Karen and Anthony about access to neuropsych data, which variables should be available, what is currently used in clinical trials. LONI is also going to need to have this information to develop interface. Leon and Ron can give us guidance about the key clinical variables to put on the interface. Who at ADCS would be the best person to talk to? We can report on this in two weeks.

Action items:
1. Find out from Cliff what variables we should look at for phantom QC, make sure those get into LONI interface for us.
2. Ask Leon and Ron about key clinical variables to put on interface; same as trials or different (much wider range of function than in typical trial). Work with Karen and Anthony to ensure access through LONI interface.
3. Beta testing of LONI interface when it becomes available in September.
4. Work on expanded version of analytic plan that includes the a priori ROI approaches, cross validated exploratory approaches, and test/ validation sample for those who need a simplified strategy. Target dates: draft version out by mid September, revised out by end of September, and to be presented at October meetings.

Next call: 12 September at 10 AM Pacific time.