

ADNI Biostatistics Conference Call Minutes 1 February 2005

On call: Danielle Harvey, Ron Thomas, Sarah Walter, Mike Biglan, Devon Gessert, Youyan Xu, John Kornak, Robert Croop, Mike Weiner.
Away from call: Laurel Beckett

A draft of the numerical summaries analytic plan for the Prep Phase has been sent to LONI to be posted on the ADNI website. John has written up a draft for the voxel based analyses that will be distributed to Colin Studholme, Gene Alexander, and Paul Thompson for comments. A conference call with this group will be set up for the coming week to discuss the strategies for the analyses. John also suggested a monthly conference call with this group to discuss issues that arise in the voxel based analyses.

Robert Croop, from Bristol-Myers Squibb joined the call for the first time and provided us with a little background. He is a neurologist by training and has been in the pharmaceutical industry since 1991. He has been involved with various Phase 3 trials, with the development of treatments for Alzheimer's disease, and has worked with statisticians at BMS. He is mainly interested in CNS compounds. He also updated us on the industry group's interest in having at least one representative on each conference call. He all mentioned that he may invite statisticians or database managers from BMS to join the conference calls if there is something on the agenda that may be of interest.

Sarha updated the group on the status of the ADCS website. They are still waiting to get feedback from Anders on the measures that he will be collecting and the layout of the form for the data that he will be submitting to ADCS. The group had a training meeting with all clinical sites except for UCSD and UCD, although times had been set for UCSD and UCD to get the training for inputting the clinical and scan data (DOB, education, MMSE, diagnosis, scan type, platform, date of scan, Tesla strength). Sites have had access to a demo site and have been able to practice entering data. Later today, the clinical database will be released. The forms for the analytic sites are almost done. The BSI forms are ready to go, so they are just waiting on Anders to give feedback. They have also received and incorporated ranges for hippocampal volumes and BSI.

The reports available from the ADCS website were also discussed. There are currently two reports available: enrollment history and enrollment summary. In addition, a tracking report can be created which can include the QC status of the scans from Mayo, scans by AD/control, along with a possible link with LONI. Ron also mentioned that if there are summaries that will be helpful, it is fairly routine and easy to generate, for example, real-time reports that could be made available. We just need to let his group know what we would like to have available. They also mentioned a tool for accessing a csv file of the data, which we will be using to get the analytic data sets.

Rob Croop asked about industry access to the ADCS website and internal reports on the data. This issue has not been fully addressed by the Executive Committee, so the ground

rules need to be clarified and will be discussed at the next Executive Committee conference call.

A call with Mike Weiner, Mike Biglan, Karen Crawford, and Ron Thomas will be set up to discuss a time-line and the process for linking the ADCS and LONI websites.

Scans have been collected at Mayo and UCSD. Hopkins and UCD are expected to start this week. It's not clear what scans will be done at Boston, so this needs to be clarified. UCSD is picking up some of the scans (ones that were scheduled to be done at MGH). This change has already been incorporated into the ADCS website. Danielle will talk to Cliff to find out other changes in the acquisition sites so that the Prep Phase Imaging Summary document can be updated.

Mike Weiner gave a brief summary of the meeting in Atlanta and said that the majority of the meeting focused on the clinical protocol. It is expected that this protocol will take a minimum of 3 months to get through the various IRBs, so the beginning of the Execution Phase will not be until May 15 at the earliest. He expressed very strong support for the ADCS website and encouraged all of those present at the Atlanta meeting to look into the capabilities of the website and the reports that can be generated.

In preparation for the Execution Phase, it was mentioned that the numerical summaries analyses from the Preparation Phase would lead and influence models that can be developed during the Execution Phase. For the voxel-based analyses, John has had some time to think about possible methods, although he needs the data from the Prep Phase to do some testing of his ideas, particularly in the area of comparing the VBM and TBM analyses. Danielle mentioned that the graduate student working with her and Laurel, Qian Weng, will be doing some methodological work this summer to develop some strategies for handling the imaging data that will be obtained during the Execution Phase.

It is unclear at this time when the meeting will take place that will determine the final protocol for the Execution Phase. Mike Weiner said that the Prep Phase would not slow down the start of the Execution Phase and his understanding of this phase was to see if Anders' new sequences were better than the default sequences generated by the machines. We will go with the default sequences unless there is sufficient data to support the use of Anders' sequences.

Ron asked about the Biostat Methodology Conference and said that we should begin to think about when to have it. It was determined that it should be after the Prep Phase is done so that people would have more ideas and time to discuss.

Ron also mentioned that the development of the ADCS database for the Execution Phase is well underway.

Agenda items:

1. Conference call to be set-up with voxel-based analysis sites (John)
2. Write-up a proposal for industry access to the ADCS website and reports. (Ron)

3. Conference call to be set-up with Mike Biglan, Karen Crawford, Ron Thomas and Mike Weiner to discuss linking ADCS and LONI databases (Ron)
4. Update the Prep Phase Imaging Summary document (Danielle)
5. Think about time for Biostat Methodological Conference (all)
6. Write a summary document for Execution Phase (Danielle)