

**ADNI Biostatistics Conference Call  
Minutes 4 January 2005**

On call: Laurel Beckett, Danielle Harvey, Ron Thomas, Sarah Walter, Mike Biglan, Mike Weiner.

Away from call: John Kornak

Mike suggests that we forward information to Peter Snyder about our group and when we have calls and contact information, and let him pass this to the industry reps for biostat. They can then determine what level of participation they would like.

Ron introduced the ADNI team at the ADCS:

Coordinator: Sarah Walter.

Data coordination role: Devon Gessert.

Data systems role: Mike Biglan.

Statistician: Youyan Xu (just joined from NJ Cancer Center).

Ron will send contact information out to us and we can put on our web site.

The data collection document for the global summaries is complete. Danielle and Laurel are adding an overview of the analysis for the decisions for execution phase, and John will add a summary of the voxel-based analyses.

John is not on call but Danielle reported that he has been inquiring about summaries and whether there are additional analyses we can carry out. E-mail has been somewhat slow but phone call is planned. Paul Thompson has been very helpful

Conference call schedule: to members and Courtney. Jan 18, Feb 1, 15, March 1, 15.

Laurel to send an e-mail confirming schedule and call-in number. Use address [adni@biostat.ucsd.edu](mailto:adni@biostat.ucsd.edu) for Ron's group.

Mike: for Atlanta: brief summary of our progress, provide Danielle's document, analytic plans. And Ron would be welcome to add material and give a presentation.

Mike gave the date of the Miami meeting: April 11<sup>th</sup> from 8 to 12. Book quickly because it is Spring Break. We may not have enough data to make decisions at that point.

Mike summarized progress on accumulating scans: Somewhat behind original targets but not hugely. The big holdup is that the LONI hub is having IRB problems, completely related to miscommunication.

We want to be prepared to start analysis in February or March and be able to make decisions based on a snapshot. This may be based on part of data, not all; we may have to use interim summaries of the voxel-based.

Danielle sent Devon an interim list of the data points that we will need for analysis. We do not yet have boundaries for range checks. Mike says he thinks we are just doing right

hippocampal volume, not both. We can get a range from each site, and Devon can incorporate. Ron plans to do real-time range checks. Ron's group will take the lead on setting up a procedure for data corrections and queries, and a QC process with electronic submission of queries. Ron's usual process for data management is that, as soon as a record clears the QC process, it gets written out to a web-based FTP archive, for which analytic group will have permissions via secure connection.

Ron reports that the database is set up in preliminary form. There are five clinical sites and 3 labs that will be submitting data. The interface prototype is set up for the 3 labs but they are waiting to confirm what is to be captured. They need to hear back from Nick Fox. (Norbert and Anders have already replied.) It's not trivial because in some cases there is more than one scan per person but the database is set up to handle that. The 3 labs will provide the summary data on each scan, and the clinical sites will provide the data on each person (which are very simple; DOB, diagnosis, gender, education, MMSE). Ron should review this plan with Cliff Jack to make sure that the data capture reflects his understanding. The same portal is used but you get a different set of forms for analysis site than for the clinical sites. It hasn't been launched yet; Mike, Leon and Cliff should review before final launch. Ron will check with Devon when she gets back and gets it ready for approval, probably just a couple of days.

Mike asked what the posted analysis will look like. Danielle says preliminary tables and summaries can be posted; Laurel wants to make sure that we do not run into issues of bias from unblinding. Ron asked if LONI is going to post tracking information on accrual and completion of scans. It appears that there will be two web sites, one at UCLA and one at UCSD, both with portals for investigators and public, allowing queries based on scan data or clinical data. If it includes both, the databases need to be able to communicate. Ron would like to work with UCD to get the presentation together, especially easy to do if we are using R. LONI is primarily for display of imaging data but also hosting the web site for the whole project, including minutes.

Mike notes that discussion has focused on the MRI prep phase. The execution phase will be starting mid May and we can't lose sight of that. We need to start planning, including tracking, reports and imbalances. Ron has done this extensively and learned a lot of lessons; we should take advantage of his experience. Let's add this to agenda for future.

#### Action items:

1. Laurel: Forward information to Peter Snyder for the industry biostatisticians.
2. Danielle and Laurel: Finish writing up analytic plan for global summaries.
3. John: Write up first-stage analytic plan for voxel-based summaries.
4. Laurel, Danielle, John: Draft progress report, send with analytic plans for Atlanta. (Danielle's documentation on study design has already been sent.)
5. Laurel: Send out dates and number for conference calls through March 15.
6. Mike, Leon, Cliff: Test Ron's site as soon as it is ready for data entry.
7. Laurel, Danielle, Qian: Test downloading as soon as data available.
8. ADNI team at UCSD: Continue preparing for data, QC, documentation.