

Worldwide ADNI
November 28/29, 2006, 11:00PM CST
Teleconference Minutes

Attendance:

Bill Thies (US-Alzheimer's Assoc.), Maria Carrillo (US, Alzheimer's Assoc.), Pat Cole (Eisai/ISAB), Mike Wiener (UCSF), Leon Thal (UCSD), Tim Hsu (Eisai/ISAB), Martin Bednar (Pfizer/ISAB), Giovanni Frisoni (E-ADNI), Lars-Olaf Wahlund (S-ADNI), John Trojanowski (Penn), Anthony Gamst (UCSD)

Roll call and welcome by Maria. Teleconference began with a recap of the ISAB meeting in October which took place in Chicago. Giovanni summarized that as a result of that meeting, E-ADNI PIs, members of the ISAB and Alzheimer's Association representatives, and hopefully a member of the European commission will convene on Feb. 1st 2007 in London. The purpose of this meeting is to explore the fundraising options of an expansion of E-ADNI.

Giovanni Frisoni also gave an update on E-ADNI Pilot and the sequences are being installed now at all the sites. There were no problems installing the sites except Brescia where Mayo had to come in and install which caused a need to expand the budget by more than \$8,000 USD. The Alzheimer's Association was very responsive and approved this budget increase. All sequences should be loaded by the end of 2006. Volunteer trips are scheduled for December 15 to January 10th. The manual for the MR scanning has also been distributed and a TC was held with all the sites imaging core to finalize the imaging parameters.

The clinical core has defined the neuropsych battery which will be translated into the local language and all sites have agreed to use the USADNI protocol w/o the NART. The English version of the case report form has been distributed to centers and will be translated into the local language in some cases, others will use the English version and all will paste in the neuropsych.

Biomarker issues have been resolved, there was a TC on Aug 4 and Nov 11th to discuss the procedures for how samples are gathered, stored and shipped. The biomarker manual has been sent to all sites.

Giovanni as the Coordinator will be visiting all the sites within the next few weeks. The sites are the following:

- Rome
- Brescia
- Toulouse
- Munich
- Copenhagen
- Amsterdam
- Stockholm (S-ADNI)

Recruiting will start now, as soon as Case Report Forms have been adopted, should be within the week. Leon Thal mentioned that Sara Walter sent the database dictionary to Emma Reynish for use by E-ADNI. Giovanni says they do have this and have started using the database structure.

Leon Thal from US ADNI mentioned that he was pleased to see the degree of overlap between these WW ADNI efforts in the WWADNI Compatibility Spreadsheet that was circulated by the Alzheimer's Association. Data comparability should be possible among the projects.

S-ADNI reported by Lars-Olaf Wahlund that they have been incorporated into E-ADNI and therefore all sequences installed and are recruiting subjects currently.

A-ADNI sent a report via email stating the following:

The AIBL study has been officially launched with an excellent response from the public. Screening has begun but the imaging (MRI and PIB) will probably not get into full swing until February.

Leon Thal gave the US-ADNI overview and currently enrollment is at 600 with 75% of the enrollment completed. The study will close out enrollment within the next 3-6 months. There was a 6 month original delay in US-ADNI caused by the GE issue but now is on schedule.

Leon Thal also informed the group that the PIB study will be starting in April and the protocol is being distributed this week. Most subjects at that point will be receiving the PIB scan on year 1 or 2, baseline will be missed. This means that there may not be as many data points in the end and we may want to extend the study. There may also be a need to do longer follow-up on the PIB group. Extension of the study would allow for more PIB scans and as John Trojanowski pointed out, additional biomarker collection. Extending the study to a third time point will accomplish this and it may be required that a competitive renewal be submitted or funds may allow for the extension to take place.

Mike Weiner informed everyone that the FDDNP study will not be funded by Siemens. The primary reason they gave Gary Small is that there was no money in the budget.

J-ADNI sent a progress report via email. There were several questions raised by the group regarding funding status for this initiative.

Emailed progress report is as follows:

I update you about our funding situations. On Nov 22, Takeshi and me with Dr. Kuwano went to a meeting organized by the Ministry of Economy, Trade and Industry. The audience is from big industries including pharmaceutical companies. We got a favorable response, and it is my feeling that we are able to get a support from the Ministry of Economy next year. I think that it is absolutely required to have a support from the Ministry of Health also, because J-ADNI is a kind of clinical trial (we use patients for the study). Thus, we should send our proposal to the Ministry of Health as well, the deadline

of which is Dec 11. With both supports, J-ADNI will start next year. Without a support from the Ministry of Health we would face big difficulties to launch J-ADNI.

Giovanni Frisoni also wanted to inform the group that the strategy for expansion for E-ADNI was to approach the European Commission which has funding bodies from different sources. The EC has many funding mechanisms and lines of research, two of these include the collection of new data and the building up of infrastructure. Bruno Vellas in collaboration with Giovanni will be talking to people at the EC. Giovanni will be meeting with someone at the EC that is in charge of making funding decision for infrastructure, the same person involved in the funding of the NIR, Neuroimaging Repository feasibility study. This meeting will take place on Friday in Brussels. Bruno Vellas will meet with the person who is in charge of research money at the EC in charge of research dollars and will bring Letters of Intent from as many of the 30 centers possible who have agreed to join full scale E-ADNI. In this letter of intent, the centers will state that they will co-fund with institutional funds the E-ADNI projects in their centers. This letter has been obtained from four centers already and more will hopefully be collected. The funding will go towards indirect expenses which in Europe include salaries for the PIs and personnel involved, these are infrastructure expenses. There will be a meeting at the AD/PD conference in Salzburg on the 14th of March which will discuss E-ADNI expansion and Giovanni asked that Leon Thal and Mike Weiner consider attending to encourage the centers to participate fully. This meeting will be sponsored by the EADC (European Alzheimer's Diseases Consortium) and the EADC will make E-ADNI one of its future projects.

The EFPIA (European Federation of Pharmaceutical Industries & Associations) may also be useful to have at either the Salzburg meeting or the London meeting in Feb. Emma Reynish may have a contact and Maria Carrillo at the Association will work with Emma to talk to someone from EFPIA and see if they can attend one of these meetings.

Philanthropy in Europe has not been extensively examined, John Trojanowski pointed out there were some groups that might be approachable such as one in Tubingen. Giovanni stated that most philanthropy in Europe would not be interested in funding something that involved multiple countries, most are interested in funding within their country only but he will look into this avenue as well.

Anthony Gamst spoke to the group about data integration. The most important detail about integration is data comparability which it appears the WW-ADNIs have. The next step can be managed in two different ways. The first is that the data is collected and then after collection integrated into a database, this will require funding. The second possibility is to centralize data to the extent possible in a central location from the beginning so that all data is collected in one place and is integrated from the start. This option would require funding also.

Leon thought stated these were good points to be thinking about now but what about the language issues. Anthony Gamst thought that the data integration could handle the multiple languages, there are examples of that happening now in the US.

Another issue to be discussed is training. Leon Thal mentioned that this should be considered for full-scale E-ADNI or J-ADNI. This would involve bringing together a group of people that would be trained on the use of the instruments so that collection of data is as standardized as possible, the goal is to improve the quality of the data collected. J-ADNI may not have started yet, as the CRFs were just sent to them this month.

Tim Hsu asked if there was a particular center that is being used now for data integration in US-ADNI, Anthony replied that UCSD and the ADCS are providing that service now and that this center could be expanded for WW-ADNI use. Mike Weiner suggested that Anthony have more direct contact with Bruno Vellas and Emma Reynish about the database that will be located in Brescia for the E-ADNI pilot and future E-ADNI expansion. Sharing the same center could also result in a lower cost if other studies utilized the UCSD informatics center.

Anthony concluded with the suggestion that the UCSC informatics center could be replicated in Europe so that data analysis could be managed locally. This seemed to be the best option.

TC was concluded at 12:10 CST.

Next TC scheduled for January 30th/31st, 2007.