



**World Wide Alzheimer's Disease Neuroimaging Initiative  
Teleconference Minutes**

**May 5 / 6, 2016**

**1:00 am Eastern/ 12:00 am Central, May 6 / 10:00 pm Pacific, May 5**

**Attendees:**

Sandra Black	Colin Masters
Jim Hendrix	Chris Rowe
Takeshi Iwatsubo	Gustavo Sevlever
Gustavo Jimenez-Maggiora	Ana Luisa Sosa
Simon Lovestone	Mike Weiner
Richard Margolin	

**I. Roll Call and Welcome** Jim Hendrix welcomed the group to the meeting and reviewed the agenda.

**II. Progress Updates**

**a) Canada ADNI – Sandra Black**

**Medical Imaging Trials Network of Canada Amyloid Brain Project**

In this study, 150 patients from memory or stroke clinics with White Matter Hyperintensities (WMH) >10 cc will be compared to 150 matched patients from ADNI with minimal WMH will undergo 3T multimodal MRI, FDG and florbetapir PET at baseline and 2 years. Currently, contracts are in place with the sites and 25-30 subjects have been recruited. It is believed that people with White Matter disease have difficulty clearing amyloid due to edema. This study hopes to test this hypothesis.

**Brain Eye Amyloid Memory (BEAM) Study**

Study participants will undergo cognitive and functional testing, genetic testing, brain imaging (MRI, amyloid PET) and eye tests (eye tracking, Optical coherence tomography and lens amyloid over 4 years. Subjects will be recruited from the Toronto Dementia Research Alliance and include 65 amnesic/multidomain MCI, 65 AD, 65 LBD-PD, 65 subcortical VCI, and 60 normal controls.

**Ontario Brain Institute: Ontario Neurodegenerative Research Initiative (ONDRI)**

The ONDRI is a 5 year observational study of multiple neurodegenerative diseases across 11 centers in Ontario. The study will recruit 600 subjects with AD/MCI (150), ALS (90), FTD (60) PD (150), and VCI (150). The participants will undergo neuropsychological assessments, gait and ocular assessments, genomics and neuroimaging at baseline and every year with a telephone assessment every 6 month. Recruitment is expected to be completed in the fall of 2016.

**Canadian Consortium for Neurodegeneration in Aging (CCNA)**

The CCNA is an ambitious project that plans to recruit 1600 participants for a 5-year study that will look at wide variety of issues in 3 main themes of prevention,



treatment and quality of life. Biosamples (blood, saliva and CSF) will be collected from participants along with genetics data. The goal is to eventually make the data available in an open access form.

**b) NA-ADNI - Michael Weiner**

**ADNI-3 Update**

ADNI-3 will likely be funded at the \$60 to \$75 million range and start in August 2016.

There is concern about retention of ADNI-2 subjects and the recruitment of new subjects with competition from new interventional trials. There are at least 14 major US trials that are recruiting for prodromal AD.

The ADNI 3 study design is similar to ADNI 2 with the addition of a “financial capacity” scale. This is a complex functional instrument and requires a great deal of training for the person administering the test. Also new will be frequent Tau PET and MRI’s and online cognitive assessments. The baseline assessment is very extensive and includes a LP and multiple PET scans.

The selection of a platform for CSF analysis is the Cobas Elecsys assay system from Roche Diagnostics. The system is fully automated with a very high throughput and very low variability. The ADNI leadership is planning to rerun all available ADNI CSF samples in this system for consistency. The NIA controls all the CSF samples, however.

The Tau PET tracer selected for ADNI 3 is the Avid/Lilly ligand, AV-1451. Lilly has placed some restrictions on the use of the tracer by other companies. Genetech recently offered their Tau tracer to ADNI 3 but with similar restrictions. It is, therefore, unlikely that the Genetech tracer will be added to the study at this time.

**c) AIBL – Chris Rowe and Colin Masters**

Total recruitment to date is over 1800 participants where at least baseline data has been obtained. The 19-month follow-up has been completed with 400 participants. Recruitment is on-going to continue to enrich the study. There is also competition in Australia from pharma trials.

AIBL is also participating in A4/A5 and is recruiting 150 MCI and 120 health controls for this study. The study is using Solanezumab and JNJ-54861911, the BACE inhibitor from Janssen. Participants that screen fail for A4 are brought back into AIBL in a pre-AD cohort to explore possible primary prevention.

Like Korea, AIBL has no government funding since 2013. The current sources of funding are from philanthropic organizations and pharmaceutical companies.

Other AIBL Highlights:

- AIBL is working on the conversion from SUVR to the centiloid scale.

- AIBL is recruiting 150 subjects for Tau imaging and is planning an 18 month follow-up.
- GWAS and SNP analysis are underway.
- AIBL data is now available via GAAIN.

**d) Japanese ADNI - Takeshi Iwatsubo**

Data from J-ADNI spanning 2008-2014 was released in January 2016 via the NBDS database for open access worldwide. J-ADNI 2 is suspended until the summer but has secured 3 years of funding and is hoping for an additional 3 years. The ADCS-J is working to build a trial ready cohort similar to the EPAD efforts. There is also an effort to develop a predictive algorithm to support the building of the trial ready cohort. The data is will be gathered for this effort in the next 6-12 months.

**e) EPAD – Simon Lovestone**

Simon provided an update on the progress made to build the infrastructure and steps needed to establish a cohort for EPAD Trials. The goal is to establish an EPAD registry with 24,000 people. From this group a predictive algorithm will be used to select 6,000 people that fit the criterial for the readiness cohort.

- EPAD is designed to allow for adaptive trials.
- FDA and EMA have also been in communication with EPAD as they move forward.
- The UK Biobank is a source of samples from 17,000 people of which over 2000 have memory issues. This is another source of valuable data in building the predictive algorithm.
- The people in the readiness cohort will be given cognitive assessments, APOE genotyping, CSF analysis and possibly PET imaging and this data will be used in further refining the selection of trial participants.
- The registry has recently entered their first patient into the cohort.
- The first candidate therapeutic has been selected for a trial but has not yet been announced publicly.
- The EMIF software will allow researchers to access data on the cohorts. The participant selection tool is being developed in collaboration with Art Toga. The data generated from EPAD will eventually be linked to GAAIN.
- The Longitudinal Cohort Study is the most ADNI-like. It will maintain a study cohort of 6,000 participants and will include clinical measures, fluid and imaging biomarkers. The RBANS instrument will be used and the primary neuropsychological assessment tool. Imaging will include both structural and functional MRI. Amyloid PET is proposed but not yet confirmed for the study.
- EPAD is working to link their efforts to the global research community via GAP (Global Alzheimer's Prevention). Paul Aisen's proposal for a similar trial-ready cohort in the US failed to receive a fundable score in the last grant review.

**f) Argentina ADNI - Gustavo Sevlever**

Gustavo provided an update on Arg-ADNI. He reported that 46 of the 56 subjects with baseline data (CSF A $\beta$ -tau, FDG and PiB PET) have been followed for 30 months. They are also planning 54 month follow-up that will include Tau PET (AV1451). The group has also begun enrolling for DIAN in Argentina.

**g) Other ADNI Efforts**

Seong Yoon Kim was unable to participate on the call but provided the following update via e-mail.

**Korea-ADNI (K-ADNI):**

At the end of last year, the K-ADNI project was declined for a renewal of annual government funding due to several reasons;

- Building the infrastructure took longer and was more expensive than expected.
- The lack of infrastructure led to insufficient achievements in K-ADNI for the last 3 years.

K-ADNI researchers are seeking for multiple sources of private funding for data collection on the built platform.

Finally, Seong Yoon Kim has had to step down from his leadership of K-ADNI due to some health problems.

**III. Planning for July Face-To-Face Meeting - Jim Hendrix**

Jim discussed the planning for the WW-ADNI meeting at AAIC on July 22, 2016 in Toronto. The meeting will be half-day devoted to WW-ADNI. Following the WW-ADNI meeting will be a GAP meeting.