ADNI 3 CLINICAL CORE PLANS

Paul Aisen
Ron Petersen
Mike Donohue
Mike Weiner

The aims of the ADNI3 Clinical Core will include:

- Oversight of ADNI3 clinical activities, data management, tracking and quality control, recruitment and retention of participants, regulatory oversight and financial management.
- Characterization of the cross-sectional features and longitudinal trajectories of cognitively normal older individuals and mild cognitive impairment.
- Study of the relationships among clinical/demographic, cognitive, genetic, biochemical and neuroimaging features of AD from the preclinical through dementia stages.
- Assessment of genetic, biomarker and clinical predictors of decline.
- Refinement of clinical trial designs, including secondary prevention, slowing of progression in symptomatic disease, and cognitive/behavioral management.

Key hypotheses of ADNI3 Clinical Core

- All or almost all normal participants with brain amyloidosis will show cognitive decline compared to those without amyloidosis, and will progress to MCI.
  - Confirmation of this hypothesis is critical to early stage trial design and regulatory support.

- MCI participants who are biomarker positive (amyloid and tau) will progress more rapidly than those who are negative

Other hypotheses

- Amyloid-related cognitive decline involves episodic memory, executive function and orientation across the spectrum of AD
- AD-related cognitive decline can be captured by unsupervised web-based testing
- Early stage AD cognitive decline predicts later functional and clinical decline
- Web-based registries will facilitate recruitment for ADNI (and therapeutic trials)

ADNI3 cohorts

- ADNI3 will carry forward roughly 300 normals (w/wo subjective concerns) and 300 MCI (EMCI+LMCI)
- ADNI3 will enroll modest numbers of new normal and MCI participants
- ADNI3 will follow MCI participants who progress to AD dementia

Possible adjustments to assessments

- Drop RAVLT, add FCSRT.
- Drop Boston Naming.
- Drop Clock Drawing.
- Add web-based cognitive testing.
- CFI instead of eCOG?

- Reaching a consensus will be challenging, but we need to begin the discussion even as we work on additional analyses.