ADNI 3 OVERVIEW

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PI ADNI

OVERALL GOAL OF ADNI

- To validate biomarkers for clinical AD trials
- To standardize biomarkers for clinical AD trials
- To optimize biomarkers for clinical AD trials
- AD trials include Phase 2 (POC) and Phase 3
- To provide all the data to those designing trials
- To help create a world wide network for AD trials
- Ultimately to facilitate development of of a surrogate biomarker outcome measure: tau?

ACCOMPLISHMENTS OF ADNI (21 months left)

- Amyloid phenotyping with PET and CSF
- Standardized methods for MRI, PET, and cognitive measurements
- Provided data for designing trials
- World wide network of clinical sites
- Pilot tau study about to start
- Pilot on-line cognitive testing hopefully to start.

ADNI 3 AIMS

- Continued followup of ADNI subjects
- Enrollment of new controls, MCI, early AD
- Computerized cognitive testing
- Baseline and longitudinal tau PET
- State of the art MRI; helpful for phase 2
- Amyloid PET and FDG PET
- CSF analysis
- Genetics and Neuropathology
- Standardization of all methods

WHAT IS UNIQUE ABOUT ADNI 3

- ADNI 3 will be the only large multisite observational and longitudinal study of AD using:
  - clinical/cognitive assessments
  - MRI: Conventional and Advanced
  - lumbar puncture collection of CSF
  - amyloid PET, tau PET, FDG PET
  - genetics. Plasma/serum banking
  - all data is available without embargo on LONI
  - ***No other study provides this!***

STUDY DESIGN AND BUDGET

- The design process has just begun
- Some possible scenarios are presented for discussion
- The balance of subjects is to be determined:
  - Carrying some subjects forward; enrolling new
  - Controls, MCI, AD Current ratio is 1:2:1
  - This issue will be discussed in depth in Clinical Core discussion

Summary of ADNI III Subjects

Rollover Normals (NL)	225
Rollover MCI	305
Rollover SMC	85
New Normals	100
New MCI	200
New AD	100
Total	**1015**