ADNI 3
OVERVIEW

Michael Weiner, MD
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 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rollover Normals (NL)</td>
<td>225</td>
</tr>
<tr>
<td>Rollover MCI</td>
<td>305</td>
</tr>
<tr>
<td>Rollover SMC</td>
<td>85</td>
</tr>
<tr>
<td>New Normals</td>
<td>100</td>
</tr>
<tr>
<td>New MCI</td>
<td>200</td>
</tr>
<tr>
<td>New AD</td>
<td>100</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1015</strong></td>
</tr>
</tbody>
</table>