



ADNI Administrative Issues

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ADNI Administrative Issues

- ADNI Study Design
- ADNI Procedures
- Inclusion/Exclusion Issues
- Startup Requirements
- Subject Enrollment
- Online Database



ADNI Study Design

- Non-randomized natural history
- Non-treatment study
- 800 subjects: 200 normal controls, 400 individuals with MCI, and 200 subjects with mild AD
- 50 sites in the United States and Canada




ADNI Procedures

<u>Procedure</u>	<u>Subject%</u>
■ 1.5 Tesla MRI Imaging	100%
■ PET Imaging	50%
■ 3 Tesla MRI Imaging	25%
■ ApoE and genetic banking	100%
■ Biomarker Collection	100%
■ CSF for Biomarkers	20-50%

Inclusion/Exclusion Criteria

General Inclusion Criteria

- Hachinski less than or equal to 4
- Age between 55-90
- Stability of Permitted Medications (4 weeks)
- Geriatric Depression Scale less than 6
- Study partner with 10+ hr/wk contact, accompanies to visits
- Visual and auditory acuity adequate for neuropsychological testing
- Good general health with no diseases precluding enrollment.
- Women must be sterile or two years past childbearing potential
- Willing and able to complete a 3 year imaging study
- 6 grades education or work history
- Must speak English/Spanish fluently



**Inclusion/
Exclusion
Criteria
Subject
Group
Specific
Inclusion
Criteria**

Criteria	NL	MCI	AD
Memory Complaints	None.	Memory complaint that is verified by a study partner	Memory complaint that is verified by a study partner.
Memory Function	Normal memory function documented by scoring at specific cutoffs on the Logical Memory II subscale (delayed Paragraph Recall) from the Wechsler Memory Scaled - Revised (the maximum score is 25): a) more than or equal to 9 for 16 or more years of educatio	Abnormal memory function documented by scoring below the education adjusted cutoff on the Logical Memory II subscale (Delayed Paragraph Recall) from the Wechsler Memory Scale Ğ Revised (maximum score = 25): a) less than or equal to 8 for 16 or more years	Abnormal memory function documented by scoring below the education adjusted cutoff on the Logical Memory II subscale (Delayed Paragraph Recall) from the Wechsler Memory Scale Ğ Revised (the maximum score is 25): a) less than or equal to 8 for 16 or more
MMSE	24 - 30 Inclusive	24 - 30 Inclusive	20 - 26 Inclusive
CDR	CDR = 0 Memory Box Score = 0	CDR = 0 .5 Memory Box Score = 0.5	CDR = 0.5 or 1 Memory Box Score = 0.5 or 1
General Cognition	Cognitively normal, No Cognitive or ADL impairment	Cognition and ADL preserved such that a diagnosis of Alzheimer's disease cannot be made by the site physician at the time of the screening visit.	NINCDS/ADRDA criteria for probable AD.



Key ADNI Inclusion Criteria

- Commitment to Neuroimaging
- DNA for ApoE testing and banking
- Blood and Urine for Biomarkers
- Commitment to provide CSF samples (20-50% of study population)
- Not enrolled in other clinical trials



ADNI Start-up Requirements

- MRI Certification
 - Phantom Imaging*
 - Volunteer Imaging (after IRB approval)*
- PET Certification
 - Phantom Imaging*
- ADCS Site Personnel Certification
 - CDR, ADAS*

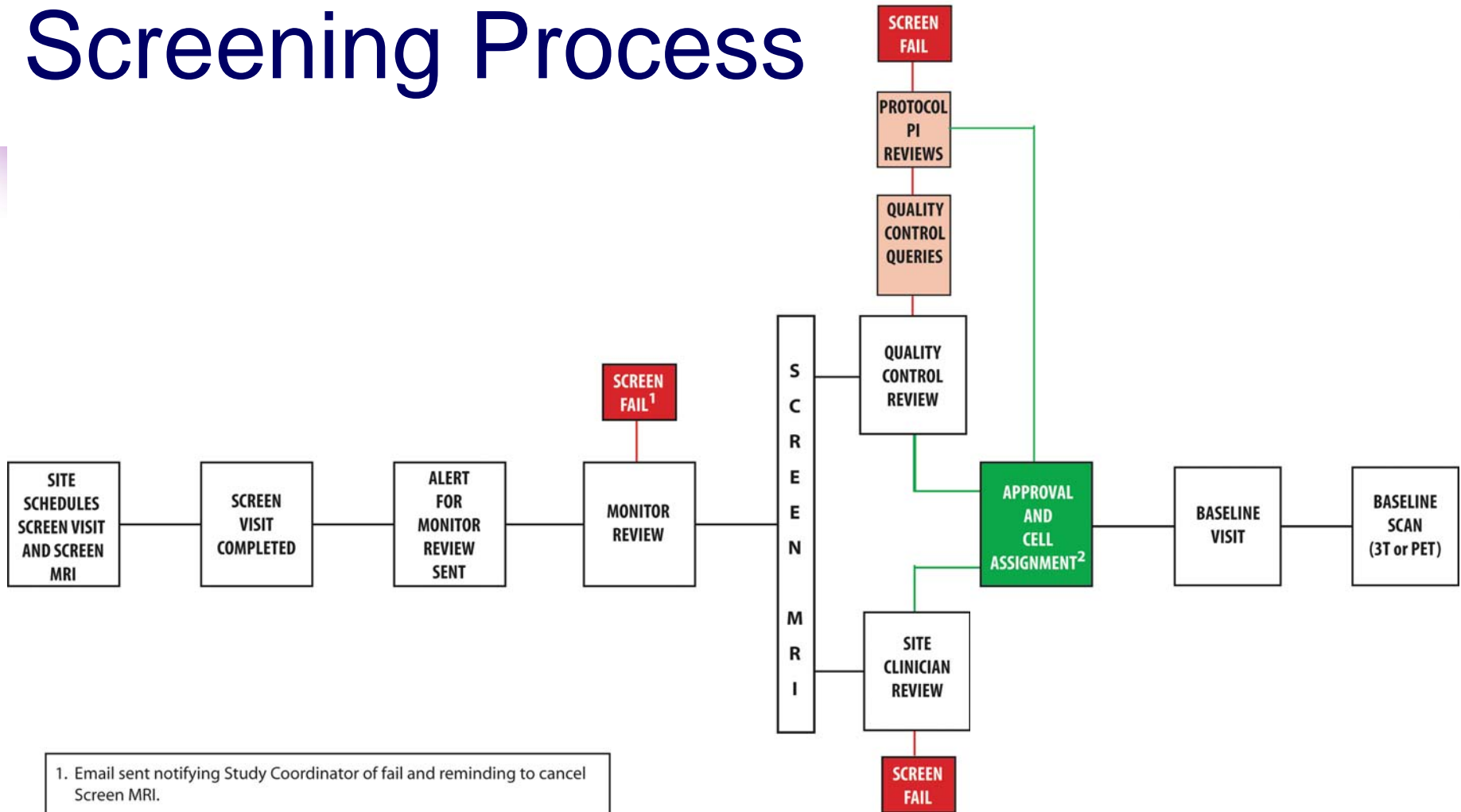
Sites must complete all certifications *prior* to scheduling screening visits!



Subject Enrollment

- Each site is expected to enroll 16 subjects (4 AD, 4 NL, 8 MCI)
- Enrollment could be limited if sites do not recruit a minimum of 20% to LP.
- Subject allocation to sub-studies (MRI and PET) will depend on site's capabilities, subject's consent, and centralized subject allocation.

Screening Process



1. Email sent notifying Study Coordinator of fail and reminding to cancel Screen MRI.
2. Cell assignment incorporates APOE results. If subject consents to both PET and 3T, cell assignment will notify site which scan to schedule for Baseline.

Online Databases: Data Management

- Enter and Manage own data
- Resolve queries in real time
- Reports on Site Performance
- Reports on overall Study Progress

QuickTime™ and a
TIFF (Uncompressed) decompressor
are needed to see this picture.

Project Menu > Site Menu > ADNI Subject Menu > Visit Menu

Subject: 1-aaa

Required CRF's for each visit:

Screening Visit

View PDF

Baseline Visit

View PDF

Registry

Registry

Participant Demographic Information

Vital Signs

Study Partner Demographic Information

Neuropsychological Battery

Medical History

Neuropsychiatric Inventory Q



ADCS ADNI Team

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