

ADNI CLINICAL COORDINATING CENTER

RON PETERSEN

LEON THAL

RON THOMAS

CONSULTANTS

MARILYN ALBERT

RON THOMAS

JOHN MORRIS

PIERRE TARIOT

DAVID SALMON

STEVE DEKOSKY

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ADNI - Clinical Core

- Lead by Leon Thal, Ron Petersen and Ron Thomas
- Responsible for:
 - Inclusion, exclusion criteria
 - All measures
 - Collection of all data
 - Data basing at UCSD

Study Design

- MCI (n = 400): 0, 6, 12, 18, 24, 30, 36 months
- Mild AD (n = 200): 0, 6, 12, 18, 24 months
- Controls (n = 200): 0, 6, 12, 24, 36 months
- Clinical, MRI (1.5 T) at:
 - MCI - All except 30 months
 - AD - All except 18 months
 - NI - Baseline, 6 months, then yearly
- FDG PET at same timepoints in a 50% subset
- 3.0 T MRI at same timepoints in a 25% subset
- Blood and urine at Baseline then yearly for biomarkers
- Immortalized cell lines at baseline
- CSF at Baseline and yr 1 in a 20% subset

MILD COGNITIVE IMPAIRMENT ORIGINAL CRITERIA

- **MEMORY COMPLAINT**
- **MEMORY IMPAIRED FOR AGE**
- **NORMAL GENERAL COGNITIVE
FUNCTION**
- **NORMAL ACTIVITIES OF DAILY
LIVING**
- **NOT DEMENTED**

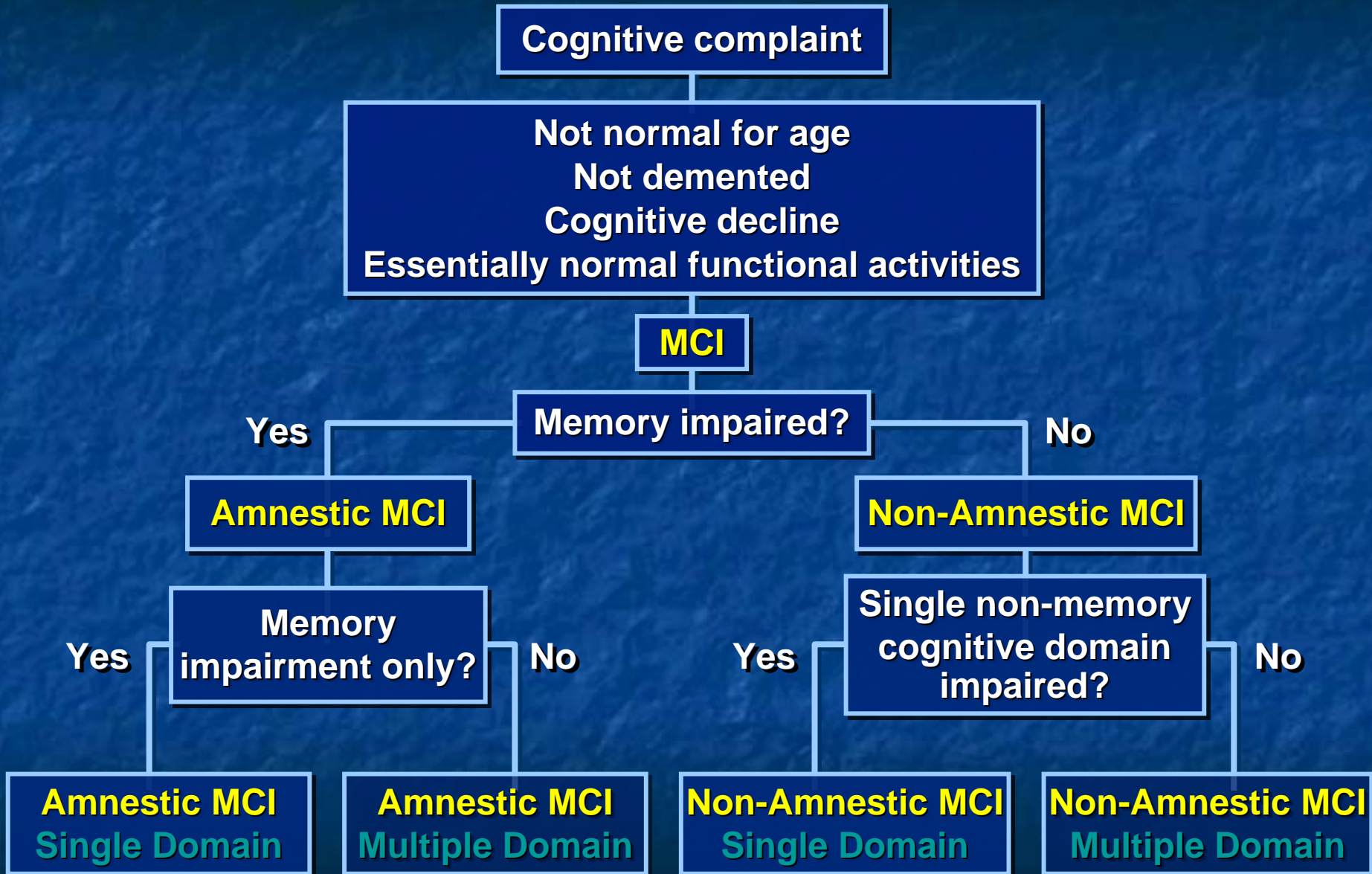
MCI DEFINITION

- Amnestic
- Multidomain with an amnestic component
 - Allow in?
 - How to define?

MCI DOMAINS

- **MEMORY**
- **LANGUAGE**
- **ATTENTION/EXECUTIVE**
- **VISUOSPATIAL**

Mild Cognitive Impairment



GENERAL INCLUSION CRITERIA

- MCI-amnestic per ADCS protocol
 - CDR 0.5
 - MMSE 24-30
 - WMS cutoffs by education
 - ?add multidomain MCI
- Normal
 - MMSE 24-30
 - CDR 0
- Mild AD
 - MMSE 18-26
 - CDR 0.5-2

Subject Evaluation

- Baseline/screening eval and q 6 mo.
 - Labs, Apo E
 - Hamilton(S)
 - Beck
 - MMSE
 - ANART
 - ADAS-cog
 - NPI
 - CDR
 - ADL
- Neuropsych(B and q 6 mo)
 - Logical Memory(S)
 - AVLT
 - BNT
 - Trails A &B
 - Symbol digit
 - Clock drawing
 - Category fluency

ADNI VS UDS(ADC)

- ADNI
 - Baseline
 - Logical Memory
 - Hamilton
 - ANART
 - Q 6 months
 - AVLT
 - BNT
 - Trails A & B
 - Symbol digit
 - Clock drawing
 - Category fluency
 - ADAS-cog
 - MMSE
 - Beck
 - NPI
 - CDR
 - ADL

 - UDS
 - Logical memory 1 and 2 (done once)
 - Digit span F & B
 - Digit ordering
 - Category fluency(animals, fruits, vegetables)
 - Trail A & B
 - Digit symbol
 - MMSE
- Items in red not in ADNI but could be added.
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- Is exec functioning adequately tested?

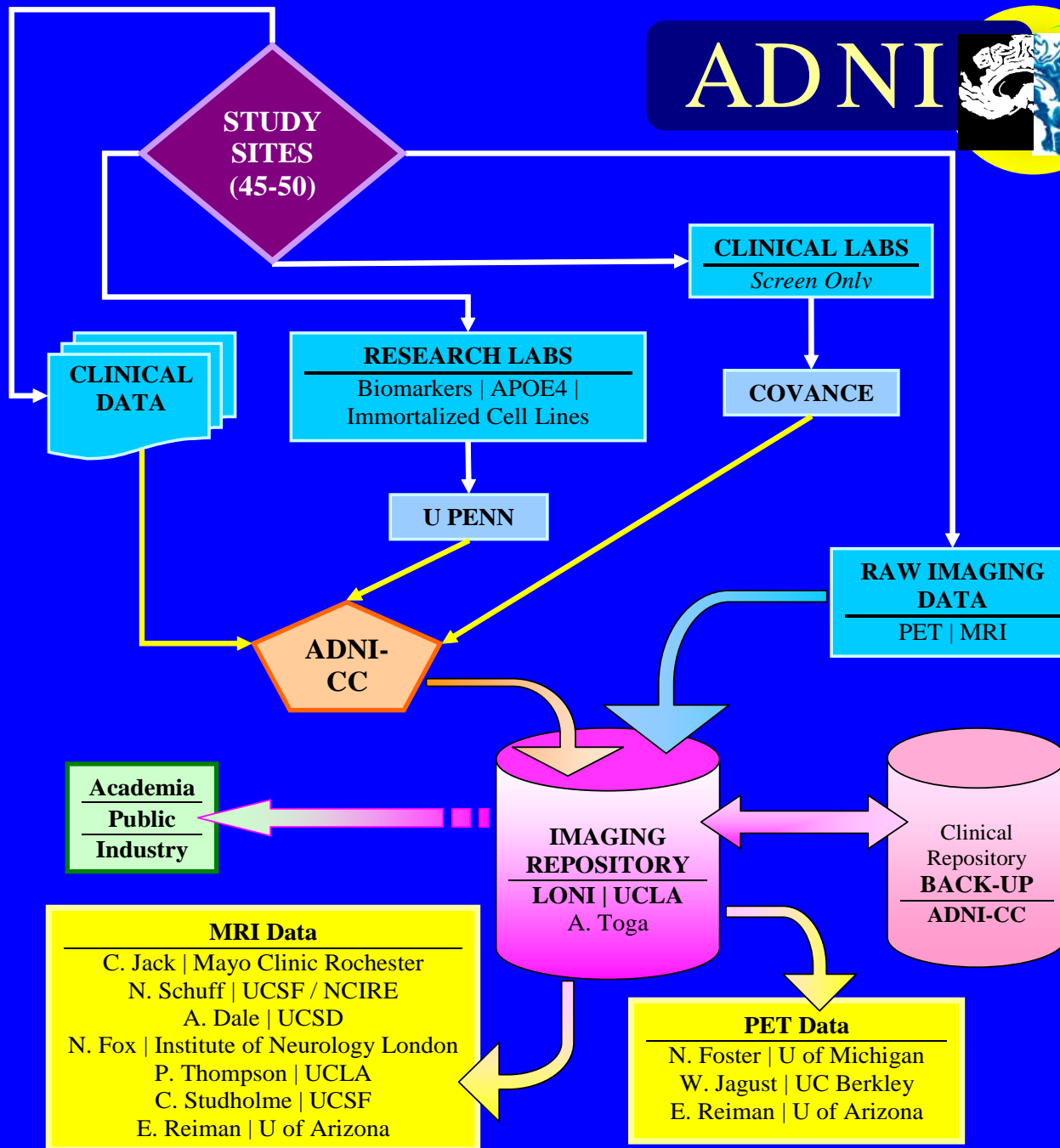
Site Selection

- 50 primary sites selected + 10 back-ups
- Major requirement: demonstrated ability to recruit MCI subjects for trials
- 41 of these sites participated in ADCS MCI trial and enrolled 525 subjects in 20 months
- Also need acceptable 1.5 T MRI
- Some sites will provide 3.0 T and PET

Linkage of Data Bases

- Clinical Data housed at ADCS/UCSD
- Imaging Data housed at LONI
- Data to be exchanged for back-up
- Need to “link” clinical and imaging data for public access, data analysis etc.
 - Ron Thomas and Art Toga

ADNI



PAYMENT SCHEME

- Recruitment funds
 - Available
 - Recruitment-700k
 - Retention-300k
- Direct payment for procedures
 - MRI-\$100-site, \$600-facility = \$700/MRI (\$875T)
 - PET-\$100-site, \$1500-facility = \$1600/PET (\$2000T)
 - LP-\$100-patient, \$250-site = \$350/LP (\$437.50T)
- 25% indirect added to each of above

PAYMENT SCHEME(2)

- Direct cost for patients
 - Failed screen-\$500/subject (\$625T)
 - MCI-8 visits-inc \$800 subj payments=\$6800 (\$8500T)
 - NL-8 visits-incl \$800 subj payments=\$6150 (\$7688T)
 - AD-6 visits-incl \$600 subj payments=\$5040 (\$6300T)
- 25% Indirect added to each of above

RECRUITMENT

- \$700k-recruitment
- \$300k-retention
- Methods
 - Central
 - Paid ads
 - Media stories
 - ADEAR
 - Groups-AARP, AA
 - Local
 - Tailored to the local site

RETENTION

- Call subject if a 6 month visit is not occurring
- Thank you notes after each visit
- Birthday cards?
- Newsletter on study progress
- Compensation
 - Direct payment for visit and imaging studies
 - Gifts, certificates(ie like S&H green stamps?)

DISCUSSION

- How long will it take for sites to obtain IRB approval?
- Can sites recruit 800 subjects with 50 sites=16 subjects in 12 months(1.3 subjects/month)?
- Should we enroll multidomain MCI?
- Can sites perform LP's on a 20% subset?
- Can we maintain no more than a 10%/year drop out rate?
- Do we need to add better measures of executive functioning?
- Should we align with the UDS?