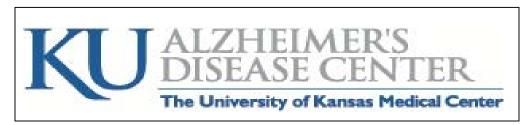
### How Centers Use Biomarkers

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#### **Disclosures:**

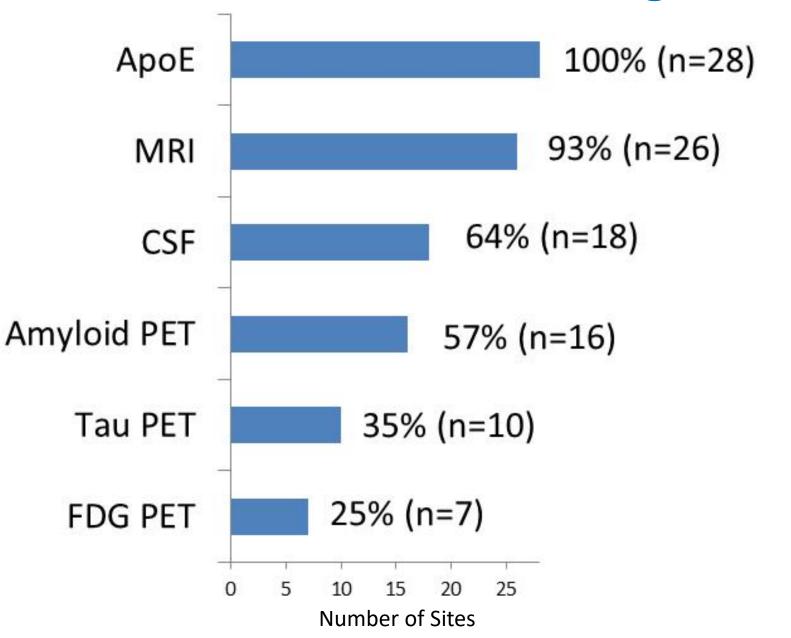
- Research funding from the NIH and Lilly.
- Clinical trial support from Lilly, Avid Radiopharmaceuticals, Toyama Chemical Company, Merck, Biogen, AbbVie, vTv Therapeutics, and Janssen.
- Speaking or consulting with Grifols, Lilly



# **Summary of Findings**

- All centers are using biomarkers
  - Little uniformity in approach or purpose
- Funding is creative; heavily leverage other projects
  - Few centers exclusively fund via P30/50 support
  - Very little clinical or standard-of-care activity
- Few use biomarkers diagnostically
- Significant barriers but enormous opportunity to leverage the ADC network

## What biomarkers are being used?



#### MRI

- 26 sites capture MRI data on clinical cohort
  - 11 sites scan entire cohort
    - One time (n=3)
    - Annually (n=1; cases only)
    - Every 2 years (n=4)
    - Every 3 years (n=2)
    - Every 4 years (n=1)
  - 9 select subsets for standardized scanning
  - 6 leverage other study data
- <u>Funding</u>: Most leverage multiple funding sources (none the P30/50 exclusively)

#### CSF

- 18 sites with diverse approaches
  - 3 sites have required LPs
    - Required at entry then optional annually; every 2 years; and every 3 years
  - 8 have standard optional LPs
  - 7 capture CSF via other studies
- 3 sites bank with NCRAD
- Funding: multiple funding sources for majority;
  2 sites use P30/50 funds exclusively

# **Amyloid PET**

- 16 sites collect amyloid PET
  - 2 sites image all participants uniformly (yearly or every 3 years)
  - 1 site images 50% every 3 years
  - 13 sites capture some amyloid PET data on subsets via other projects
- Funding: all sites use multiple funding sources (none use P30/50 exclusively)

## Tau PET

- 10 sites are collecting tau PET
  - Most sites (n=7) capture data from other projects
  - 2 sites image entire cohort longitudinally (annually or every 3 years)
  - 1 site images a subset a single time
- Funding: multiple funding sources or non P30/50 fundings

### FDG PET

- 7 sites
  - 1 center captures FDG PET on all participants annually
  - 6 sites capture data opportunistically through other projects one time (n=1), every 3 years (n=1) or irregularly (n=4)
- Funding

Combined funding sources or non P30/50 sources

# Biomarkers for Diagnosis?

- 19 sites report using biomarkers to support diagnosis
  - MRI most commonly used
    - Reviewed at consensus conferences, often "when available" or "as requested"
    - Several report occasional use of CSF, ApoE, FDG PET
  - Most lack a uniform approach incorporating biomarkers
  - Several explicitly keep clinicians blinded

#### What Biomarker Activity is Flowing to NACC? Data as of March 1, 2017

|              |       | Biomarkers |            |
|--------------|-------|------------|------------|
|              | Total | Assessed   | % Assessed |
| Normal       | 7738  | 311        | 4.0%       |
| Impaired/MCI | 3045  | 256        | 8.4%       |
| Demented     | 4270  | 628        | 14.7%      |

# Barriers

- FUNDING
- Non-uniformity
  - Lack of shared questions
  - Variable approaches
  - Analytics
- Infrastructure

- Nomenclature/Semantics
  - "Mixed Dementia" is not enough
  - Need new clinical concepts
  - Need new tools / vocabulary to capture and classify the complexity

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