

LEADS

Longitudinal Early-Onset
Alzheimer's Disease Study

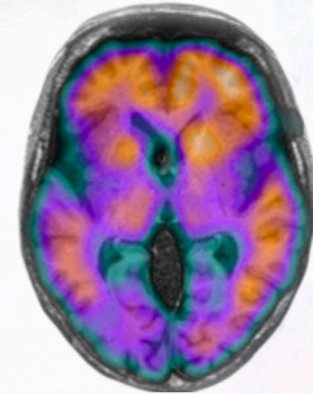


CONTACT

DONATE

“When it comes to ending
Alzheimer's disease,
time is of the essence.”

Mary Smith, Philanthropist



Longitudinal Early-Onset Alzheimer's Disease Study (LEADS)

The Longitudinal Early-onset AD Study (LEADS) is funded by the National Institute on Aging (NIA) to address several major gaps in Alzheimer's disease and related dementias research. LEADS is an observational study that will enroll and follow 500 cognitively impaired participants and 100 cognitively normal participants ages 40-64 years at approximately 15 sites in the United States. Clinical, cognitive, imaging, biomarker, and genetic characteristics will be assessed. The primary goal of LEADS is to develop sensitive clinical and biomarker measures for future clinical and research use. [Learn More.](#) [Join the Fight.](#)

LEADS Principal Investigators

Liana Apostolova



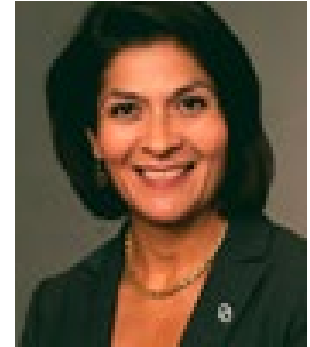
Gil Rabinovici



Brad Dickerson



Maria Carrillo



Study Goals

- ▶ Define early-onset Alzheimer's disease and all its variants
- ▶ Understand disease progression
- ▶ Derive important clinical, functional and biomarker metrics for clinical trials in the EOAD population
- ▶ Understand the impact and unique challenges of younger-onset Alzheimer's
- ▶ Identify resources available to assist individuals with younger-onset cognitive impairment



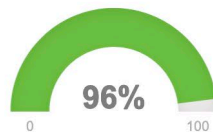
602 consented

43 in screening
445 completed BL

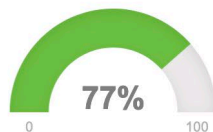
99 CN
332 EOAD
104 EOnonAD

6.2% PCA
5.7% PPA
7.6% Nonamnesic

Concordance visual Read vs. Quantification



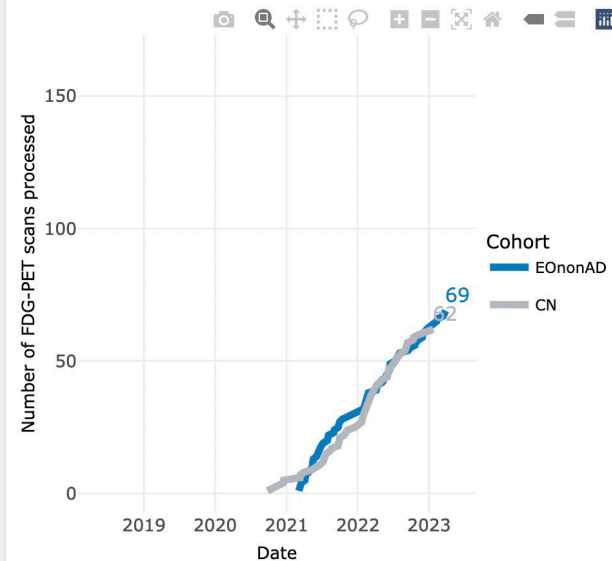
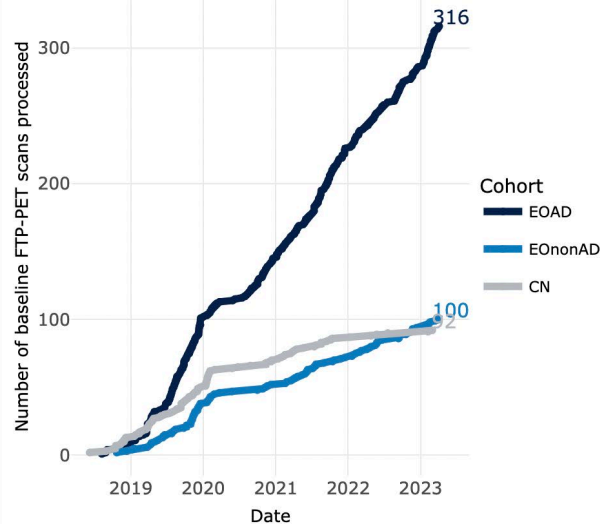
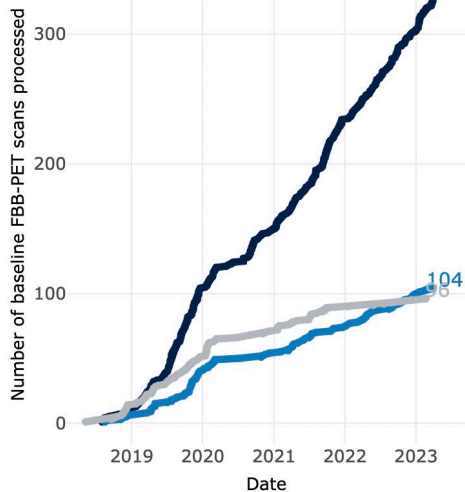
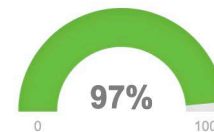
Rate Amyloid-positivity in PT



Rate Amyloid-negativity in PT



Rate Tau-positivity in EOAD



Schedule of Events

| Schedule of Events | Baseline | M12 | M24 | M36 | M48 + |
|---------------------------------------|----------|-----------------|-------|------------------|-------|
| Clinical Assessment | ▲ ● ◆ | ▲ ● ◆ | ▲ ● ◆ | ● ◆ | ● ◆ |
| Cognitive Assessments | ▲ ● ◆ | ▲ ● ◆ | ▲ ● ◆ | ● ◆ | ● ◆ |
| ADL Assessments | ▲ ● ◆ | ▲ ● ◆ | ▲ ● ◆ | ● ◆ | ● ◆ |
| Genetic Testing | ● ◆ | | | | |
| Blood Draw | ▲ ● ◆ | ▲ ● ◆ | ▲ ● ◆ | ● ◆ | ● ◆ |
| Lumbar Puncture | ▲ ● ◆ | ● ◆ | ▲ ● ◆ | ● ◆ | |
| 3T MRI | ▲ ● ◆ | ● ◆ | ▲ ● ◆ | ● ◆ | |
| ¹⁸ F-Florbetaben PET Scan | ▲ ● ◆ | ● | ● | ● ◆ | |
| ¹⁸ F-Flortaucipir PET Scan | ▲ ● ◆ | ● | ● | ● ◆ [#] | |
| FDG-PET Scan | | ◆ ^{\$} | ▲ | | |

▲ CN

● EOAD

◆ EOnonAD

* If LP in CN is unsuccessful at baseline, participants can be re-approached and LP collected at Month 12

Only amyloid-positive EOnonAD will receive a tau PET scan at mo 36

\$ FDG PET scan for EOnonAD will take place at their next visit



LEADS-TU: Scientific rationale

- ▶ Strengths:
 - ▶ **The cohort** – aggressive disease course, less co-pathology
 - ▶ Well-characterized with layers and layers of omics
 - ▶ Collecting meaningful trial run-in data
 - ▶ EOAD participants are eager to participate

