## New IDEAS Study SCHEMA

| Time Point | Participant Events | Data Collection |
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| **T1 (Visit 1)** | Clinic Visit with dementia specialist: Participant screened for eligibility, consented and referred for Amyloid PET Scan | Registrar: Submit Case Registration Form and Socio-demographic Form |
| **T2** | NOTE: Dementia Specialist must submit the pre-PET clinical assessment form electronically **within 7 days of registration or the case automatically cancels** and the patient must be entirely re-registered. | Dementia specialist: Submit Pre-PET Form within 7 days of Case Registration |
| **T3 (Visit 2)** | Amyloid PET Scan<br>• Scan cannot begin until AFTER T2 – receipt of Pre-PET form<br>• Scan must be completed within 60 days of T2 | Imaging Facility Staff: Submit Scan Completion Form within 7 days of the day of scan<br><br>Radiologist/Nuc. Med. Phys.: Dictate report and complete PET Assessment Form. Note: same physician must interpret scans and complete assessment. |
| **T4** | Time point at which Dementia specialist discloses results of the Amyloid PET scan. This is a standard of care appointment. Adjustments to patient management may be made if appropriate.<br>THIS IS NOT THE POST-PET VISIT | No data collection is associated with this time point |
| **T5 (Visit 3)** | Clinical visit with Dementia specialist: Clinical visit to assess participant's status, assess whether changes to management made at T4 have been implemented (i.e. adherence to and tolerance of treatment), and to gather data for Post-PET form.<br>This visit should take place approximately 90 days after PET scan, but no less than 60 days and no more than 120 days. | Dementia specialist: Submit the Post-PET form<br><br>Post-PET form requests status update for each item that had been planned as of the Pre-PET and any new items added since the PET scan. |

Dementia Specialist

Radiologist / Nuc. Med. Phys.

Data collection by onsite study staff

## TIPS FOR WORKING WITH POTENTIAL STUDY PATIENTS

» Best to verify eligibility **BEFORE** presenting the study to a patient.
  - If needed, order structural imaging and lab tests while patient is in the clinic and verify eligibility once results are available before discussing study enrollment.

» Allow sufficient **TIME** for patient and any caregiver to read the consent form or other information (e.g., patient brochure) *before* being asked to sign.

» Use **OPEN ENDED QUESTIONS** to assess understanding of the consent – if the potential subject lacks capacity, seek the consent of a legally authorized representative, such as those named in a durable power of attorney.

» Data collected about the patient regarding their race, ethnicity, gender, and socio-demographics must be **SELF-REPORTED** by the participant or caregiver themselves.

» **DISCUSS** the psychological ramifications of knowing one's amyloid status. Anyone who is likely to be negatively affected by knowing their amyloid status should not be enrolled.

» **REVIEW** required follow-up visits. (Disclosure visit shortly after the PET scan, and visit 90-days following the PET scan).
  - Consider scheduling these visits once date of PET scan is known.

» **DISCUSS** Medicare reimbursement. Be prepared to provide an estimate of out-of-pocket costs. Traditional Medicare plans (Part B) provide 80% of payment; the other 20% may be provided by supplemental insurance plans or self-pay. Medicare Advantage plans (Part C) may have a co-pay or require pre-authorization. Encourage patients to contact their specific plan to learn more. Note: Costs may depend on the type of PET facility (Hospital-based vs. Independent).

NEW iDEAS

Imaging Dementia—Evidence For Amyloid Scanning

# New IDEAS: Imaging Dementia — Evidence for Amyloid Scanning Study:

*A Study to Improve Precision in Amyloid PET Coverage and Patient Care*

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| **Directed by** | Alzheimer's Association® |
| **Sponsored and Managed by** | American College of Radiology |
| **Advised by** | Centers for Medicare & Medicaid Services |
| **Clinicaltrials.gov ID** | NCT04426539 |
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alzheimer's association®

**Learn more at: www.IDEAS-Study.org**

## STUDY OBJECTIVES/SPECIFIC AIMS

The New IDEAS Study is an observational, open-label, longitudinal cohort study designed to address the requirements of the CED provisions of the NCD on beta-amyloid PET. Building on the initial Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) study, New IDEAS will evaluate the association between amyloid PET and patient-centered outcomes in an expanded and more **ethnoracially and clinically diverse** group of Medicare participants presenting with cognitive impairment.

### Aim 1:

To compare 12-month claims-derived health outcomes in amyloid PET-positive versus amyloid PET-negative individuals presenting with MCI and dementia in the entire study cohort of diverse Medicare beneficiaries.

### Aim 2:

To describe the association of amyloid PET findings with changes in patient management and 12–month claims-derived health outcomes among Blacks/African Americans, Latinx/Hispanics and Whites/Caucasians presenting with MCI and dementia.

### Aim 3:

To describe the association of amyloid PET findings with changes in management and 12-month claims-derived health outcomes in individuals presenting with typical (progressive amnestic) versus atypical clinical presentations of MCI and AD dementia.

### Additional Objectives:

**A.** Biorepository – To collect and bank plasma and DNA from a practice based sample of cognitively impaired patients.

**B.** Image Repository – To collect and archive amyloid PET scans for use in future research

## INCLUSION CRITERIA

Note: All inclusion required tests and procedures are considered standard practice.

- Medicare beneficiary.
- Meets clinical criteria for Mild Cognitive Impairment (MCI) or Dementia as defined by the 2018 National Institute on Aging – Alzheimer's Association Research Framework.
- Head MRI and/or CT within 24 months prior to enrollment.
- Clinical laboratory assessment (CBC, standard blood chemistry profile, TSH, vitamin B12) within 12 months prior to enrollment.
- Able to tolerate amyloid PET required by protocol, to be performed at a participating PET facility.
- Neuropsychiatric syndrome can be classified into "clinically typical" or "clinically atypical" categories.
  - Clinically typical – memory-predominant presentation of MCI and dementia in whom the clinical course and progression are highly suggestive of AD as the underlying cause
    - Insidious onset of symptoms over months to years, not sudden over hours or days.
    - History of worsening condition by report or observation
    - Initial and most prominent cognitive deficits are impairment in episodic memory. A diagnosis of dementia, impairment in another cognitive domain is required.
  - Clinically atypical - underlying AD is considered a possible cause of MCI and dementia, but are not "clinically typical" because they have one or more of the following features:
    - Primary symptoms not related to memory
    - Presence of significant co-morbidities that can contribute to cognitive decline.
    - Course of clinical progression is atypical
    - Clinical Course has mixed features of AD and non-AD dementing illnesses

## EXCLUSION CRITERIA

- Normal cognition or subjective complaints that are not verified by cognitive testing.
- Knowledge of amyloid status, in the opinion of the referring dementia expert, may cause significant psychological harm or otherwise negatively impact the patient or family.
- Amyloid or tau status already known to patient or referring clinician based on prior amyloid imaging or cerebrospinal fluid analysis.
- Current or previous enrollment in an anti-amyloid therapeutic trial.
- Scan is being ordered solely based on a family history of dementia, presence of apolipoprotein E (APOE) 4, or in lieu of genotyping for suspected autosomal mutation carriers.
- Scan being ordered for nonmedical purposes (e.g., legal, insurance coverage, or employment screening).
- Cancer requiring active therapy (excluding non-melanoma skin cancer).
- Hip/pelvic fracture within the 12 months prior to enrollment.
- Body weight exceeds PET scanner weight limit.
- Currently pregnant or planning to become pregnant within 90 days of registration.
- Life expectancy less than 24 months based on medical co-morbidities.
- Residence in a skilled nursing facility.

**For information about Medicare reimbursement for eligible study participants visit: www.Ideas-Study.org**