American College of Radiology™

NEW iDEAS
Imaging Dementia—Evidence For Amyloid Scanning

Alzheimer's Association and the American College of Radiology® (ACR®)

New IDEAS Study Update

March 20, 2024

6,061

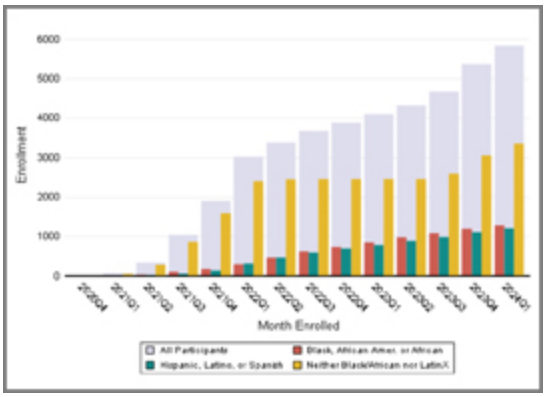
Total Patient Registrations:

1,315 Black/African American

1,258 Hispanic/Latino

3,488 All Other Race/Ethnicities

*Enrollment data represent unique registrations through March 7, 2024. Total patients **scanned** may not exceed 7,000 scans or exceed individual race/ethnicity cohort maximums.*



New IDEAS Surpasses 6,000 Patient Registrations

Thanks to activated dementia practices and PET imaging facilities, more than 4,600 registered participants have now received amyloid PET scans.

New IDEAS Study Leadership Announces Closure of Study

After careful consideration of numerous factors and evaluation of the risk-benefit tradeoff for

patients, Study leadership decided to end Study accrual on Friday, March 1, 2024, at 11:59pm ET. At that time, patient registration into the Study Portal was closed; this deadline was applicable to all race/ethnicity cohorts of the Study. This decision was difficult; however, Study leadership is confident that this is the best course of action based on the following factors:

- CMS retiring of national coverage determination (NCD) on amyloid PET, ending coverage with evidence development (CED) as a criterion for coverage of these scans.
- Recent increases in prior authorization denials of Study participants' amyloid PET scans, namely for patients with Medicare Advantage (MA) plans.
- Disconnect between the protocol and the real-world may jeopardize the relationship between the patient, practice and imaging facilities, and poses billing risks outside of the control of Study Team oversight.

Please read the full, official **Study Closure Memorandum and Study Close-Out Guide and Frequently Asked Questions** for more information and next steps for your dementia practice or PET imaging facility.

Next Steps

The American College of Radiology® (ACR®), which serves as the Study sponsor, will help facilitate close-out activities with participating dementia practices and imaging facilities through the remainder of the Study timeline. Sites and facilities should expect the following to occur:

- In the coming weeks and months, sites and facilities can expect to receive a personalized email from the operations team to touch base about outstanding data, individual timelines and additional closure procedures. Please review the **New IDEAS Study Close-Out Guide** for more detailed instructions.
- Dementia practice site principal investigators, or their designated staff, are responsible for submitting a termination report with the IRB after all study activities and data are complete. For Advarra IRB login support or CIRBI Portal technical assistance, please email **cirbi@advarra.com** or call 866-992-4724. Review instructions on how to **submit a termination report**.
- Facilities will be responsible for completing all contract-related data transfers, including form submissions in the New IDEAS Portal, image uploads to TRIAD and coinsurance reimbursement requests.
- Sites and facilities are encouraged to contact **newideas@acr.org** to expedite their close-out processes.

What We Have Accomplished

The New IDEAS accrual total is a testament to the collaborative efforts of participating dementia practices, community partners and volunteers who made the Study possible. Study leadership acknowledges that despite not meeting pre-specified cohort accrual goals, New IDEAS represents one of the largest datasets of its kind and is an important milestone in Alzheimer's research, prioritizing inclusion of patients who self-identify as Black/African American and Hispanic/Latinx — populations that share the greatest burden of dementia. The Study team is committed to seeing through the planned analyses and objectives of the Study, despite early closure to accrual. Updated Study accrual numbers are available on the **New IDEAS Recent Study Updates** webpage.

Thank You

Your commitment to patient care and research has been instrumental in the Study's accrual success. Study leadership is looking forward to sharing the study results with the greater scientific community and the research participants who complete the Study, as well as offering opportunities for investigators to access Study data in the future to explore their own research questions, advance the science and celebrate inclusive research.

We want to express our gratitude for your partnership and support of the New IDEAS mission to address important gaps in knowledge that will help advance the study and care of diverse groups of people with dementia. Your expertise and dedication have been invaluable throughout this process. While your involvement in this Study may be ending, we look forward to future opportunities for collaboration.

Beyond the New IDEAS Study

Beyond the scope of the Study protocol, practices should continue to provide culturally sensitive memory care, serve as advocates for their patients and allocate appropriate resources to stay engaged in their communities to increase access to memory care.

Guidance for Patients

Patients/Legally Authorized Representatives who consented to participate in New IDEAS but were not registered by the registration deadline should be contacted by the practice and notified about the Study's closure to accrual. Consider the following messages when communicating with patients:

- Patients who express interest in the Study after the registration deadline should be encouraged to consult with their memory care providers about best options for their clinical care plan and evaluation outside the scope of the New IDEAS protocol. The communication should describe options for continued clinical care at the practice with contact information for follow up.
- Practices are encouraged to include any additional practice-specific instructions (e.g., appointment duration, parking instructions, availability of language interpreters, etc.) to help patients understand what to expect when they visit the practice and to simplify the process for accessing memory care.
- For additional memory care and Alzheimer's support services, encourage patients to visit the Alzheimer's Association's **Community Resource Finder** or call the association's helpline at 800-272-3900.

Continuing Best Practices for Recruitment and Retention in Future Studies

Dementia practice staff are encouraged to review resources provided by the **Trial Innovation Network** (TIN) **Recruitment Innovation Center** (RIC), an evidence-based center in innovative trial recruitment and retention methods, tools and strategies. The TIN and the RIC house free resources for the research community in the TIN Toolbox. These publicly available resources — created by the RIC and other research institutions — are intended to provide a variety of information that includes the best evidence-based recruitment information and some that may be evidence-informed. Researchers can access resources on the TIN Toolbox. Some example resources in the **TIN Toolbox** include:

- **Faster Together: Enhancing the Recruitment of Minoritized Groups in Clinical Trials**.
- **RIC Community Outreach Guide**.

- **RIC Community Informed Recruitment & Retention Plan Template**.
- **RIC Perceptions of Research Trustworthiness (PoRT) Scale**.
- **RIC Guidelines for Culturally Tailored Research Recruitment Materials**.
- **RIC Recruitment & Retention Materials Content + Design Toolkit**.
- **RIC Social Media Outreach & Recruitment Toolkit.**

New IDEAS Reminders for Study Participants

Patients registered by the deadline of March 1 should continue completing Study-related procedures, as outlined in the protocol. The New IDEAS Study Team developed numerous resources and programs to ensure that patients have the required information to complete study-related activities. Please share the following reminders with patients participating in New IDEAS:

- Contact the New IDEAS Patient Helpline for help with study-related tasks — practice staff should encourage patients to call 866-507-7254 or email **newideas-participant@alz.org**. Patients can also submit requests via the **New IDEAS Study Information Request Form**.
- **Review the Blood Draw Information Sheet** — This resource answers frequently asked questions about the blood draw and helps patients feel more comfortable donating blood for memory loss research.
- Utilize the **Transportation Assistance Program** to help patients travel to their amyloid PET scan.
- **Consider optional in-home blood collection services** that patients may choose instead of going into a local Quest Lab.
- Request a replacement saliva or blood kit — Patients who need new saliva and/or blood kits should contact their memory care doctor. Practice staff are encouraged to email **newideas@acr.org** to request replacement kits.

Amyloid PET Scan Billing Guidance for PET Imaging Facilities

The New IDEAS Study protocol was developed and approved as a CED Study under the supervision of the Centers for Medicare & Medicaid Services (CMS). On Oct. 13, 2023, CMS issued a **public announcement** that retired the NCD on amyloid PET and ended CED as a criterion for coverage of amyloid PET scans.

As a result, CED is no longer applicable to the Study, and Medicare contractors reserve the right to determine their own coverage policies. CMS released updated billing guidance in November regarding retirement of NCD 220.6.20 — Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease.

Please review the following billing updates:

- For all New IDEAS claims with a scan date of Oct. 13, 2023, or later, please remove the NCT number from box 19 and remove Q0 modifiers on the claim forms.
- Please review the following CMS transmittals and the MLN article release from November 2023: **R12364CP**, **R12364NCD** and **MM13429**.
- Use **Updated Sample Claim Forms** for scans conducted **after** Oct. 13, 2023, and **Sample Claim Forms** for scans conducted **before** Oct. 13, 2023.
- If your facility is currently experiencing issues with Medicare reimbursement or prior authorization requests for amyloid PET scans conducted through New IDEAS, please contact **newideas@acr.org** with the details.
- **The New IDEAS Coinsurance Reimbursement Program** remains active and in effect.

Support Services

A large multicenter national Study such as New IDEAS requires compartmentalized communication streams to respond in a timely, accurate manner. Below is a summary of Study email addresses, accompanied with a description of support services.

- **newideas@acr.org** — Primary Study email direct to the ACR Operations Team for topics and questions related to protocol specifics, trainings and IT operations.
- **newideas-data@acr.org** — Data-management–related topics and questions, such as data change requests and navigating the case report forms within the Study portal.
- **newideas-contracts@acr.org** — Contracting topics and questions specifically related to legal agreements for study participation.
- **newideas-regulatory@acr.org** — Regulatory topics and questions, such as informed consent review, assistance with Advarra IRB submissions, protocol deviations, etc.
- **newideas_recruitment@vumc.org** — Direct email to the Recruitment and Community Engagement Team for topics such as best practices and support with recruitment efforts.
- **newideasstudy.ces@med.unc.edu** — Study Champion inquiries, New IDEAS events and community engagement support.
- **triad-support@acr.org** — TRIAD image upload questions and/or requests for assistance.

Top Accruing Sites

Total Registrations to Date	Underrepresented Minority Participant (URMP) Registrations to Date
1) Baylor AT&T Memory Center (Dallas)	1) Center for Comprehensive Care and Research on Memory Disorders (Chicago)
2) Alok Bhattacharyya, MD (Fremont, CA)	2) Alok Bhattacharyya, MD (Fremont, CA)
3) Center for Comprehensive Care and Research on Memory Disorders (Chicago)	3) Center for Brain & Neuro (Fulton, MD)