



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

New IDEAS Study Update

Dec. 21, 2023



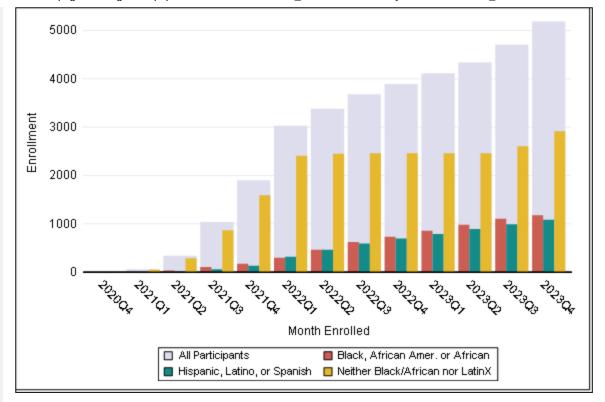




Note: Enrollment data represent unique registrations through Nov. 28, 2023. Total patients scanned may not exceed 7,000 scans or exceed individual race/ethnicity cohort maximums.

New IDEAS Surpasses 5,000 Patient Registrations

Thanks to activated dementia practices and PET imaging facilities, more than 4,000 registered participants have now received amyloid PET scans.



Year in Review: 2023 New IDEAS Community Engagement Activities

New IDEAS served as a catalyst for increasing awareness about memory loss, the need for memory care and bringing communities together to address the challenges posed by Alzheimer's and dementia. Notably, the New IDEAS Community Engagement Team:

- Attended 79 community events spanning eight community-engaged metro areas.
 Events included educational seminars, health fairs, community walks and Alzheimer's
 Association-led initiatives, like the Unforgettable play and Walk to End Alzheimer's.
- Trained 32 New IDEAS Study Champions on best practices for conducting community outreach on the importance of minority participation in research. Notably, 41% of all Study Champions speak Spanish, which is imperative to successful engagement of Spanish-speaking communities. Additionally, five Champions are students, who were trained as part of the Student Champion initiative launched summer 2023.
- Distributed more than 750 recruitment materials in English and Spanish to community organizations and at in-person events. The most frequent recipients are family members of potential participants, followed by caregivers, healthcare providers, community partners, potential participants and "other," which include potential student Champions and community members.
- Partnered with 17 organizations to increase study awareness and minority participation in research.



A Study Champion at the Community of Neighbors Health & Wellness Seminar near Dallas.

Thank You to Our Collaborators

We are grateful to the organizations below for their integral support as we pursue inclusive research through community engagement. Each organization plays a crucial role in breaking down barriers, fostering community connections and promoting inclusivity in research. We express our sincere appreciation for your partnership and look forward to continued collaboration.

- Alter Program
- AME Church
- BDS Healthy Aging Networks, Inc.
- Blue Door Neighborhood Center
- Comcast
- Coppin State University
- First Baptist Church
- Howard University
- Latino Providers Network

- Melanin Minded LLC
- National Black Nurses Association
- National Council of Negro Women
- Potter's House
- Saint Matthew AME Church
- Salvation Army Kroc Centers
 - Texas Southern University
 - 100 Black Men of Long Beach, Inc.

Connect With Us and Expand Our Network

Do you know of an organization interested in partnering with New IDEAS to promote more diverse and inclusive research? Connect them with our New IDEAS Community Engagement Specialists and expand our community network. Email **newideasstudy.ces@med.unc.edu**.

How to Support New IDEAS Champions in Your Community

1. Refer a Student to Become a New IDEAS Student Champion

Do you know an undergraduate or graduate school student interested in pursuing a career in social media/marketing or curious about Alzheimer's research? The New IDEAS Student Champion program aims to increase awareness of New IDEAS among younger generations. Student Champions will design and implement social media campaigns to increase attendance at Study Champion events. Students interested in

research will conduct literature reviews, prepare policy briefs and receive exposure to data visualization. Email **newideasstudy.ces@med.unc.edu** to learn more.

Share Information About Your Practice at a Community Event in Your Area
 Use the Alzheimer's Association Community Resource Finder to identify programs
 and events in your area to share information about your practice.

Breaking Barriers: Webinar Recap on Best Practices for Recruiting Black/African American and Hispanic/Latinx Patients Into New IDEAS

The New IDEAS Recruitment and Innovation Team at Vanderbilt University Medical Center hosted a live, one-hour webinar that included principal investigators and clinic staff from sites performing exceptionally well in the enrollment of Black/African American and Hispanic/Latinx participants into the New IDEAS Study.

The discussion-based webinar provided the audience with an opportunity to hear firsthand from sites about effective strategies and challenges faced in recruiting these priority populations into the study. A live Q&A session was held at the end of the webinar for continued discussion. We appreciated your participation!

If you missed it, you may watch the **full webinar on demand**.

Recruitment Tips for Success in New IDEAS

Our panelist discussion resulted in three key themes for best practices to recruit patients into New IDEAS. Here are a few actions that your site can take to become a top performing recruitment location:

1. Communication

- Involve family members and caregivers in the conversation around New IDEAS.
 For example, encourage family members to attend appointments, share printed study information sheets for patients to bring home to review with their families and provide the patient-facing website for easy accessibility to family members who cannot attend appointments.
- Ask proactive staff members to follow up on patient concerns/questions and address reservations. Also encourage them to complete a study protocol training with the New IDEAS Operations Team to ensure they are comfortable conducting the study and answering patient questions. To set up a site training, email newideas@acr.org.
- Ensure your site offers a Spanish-speaking staff member. If Spanish-speaking staff members are not available, consult institutional interpreter services.

2. Organizational techniques

- Create checklists for tasks to be completed.
- Follow up on insurance and copay issues. Please contact newideas@acr.org
 with any ongoing insurance concerns, including prior authorization denials or
 insurance eligibility checks.

3. Instilling patient confidence

- Present a positive narrative to the patient and weave research into the discussion
- Reassure patients by addressing their vulnerabilities and providing them with a sense of empowerment.

Your feedback is important to us. If you watched the webinar, please complete this **brief** survey to help our team better understand what topics to cover in 2024.

For more information on recruitment of minoritized populations in clinical trials, consider taking this free course created by the Vanderbilt Recruitment Innovation Center: **Faster Together, Enhancing the Recruitment of Marginalized Communities in Clinical Trials.**

Impact of CMS Removal of CED Criterion for Amyloid PET Scans on New IDEAS Study

The New IDEAS Study protocol was initially approved as a coverage with evidence development (CED) study under the supervision of the Centers for Medicare & Medicaid Services (CMS). CMS issued a **public announcement** Oct. 13 that retired the national coverage determination (NCD) on amyloid PET and ended CED as a criterion for coverage of amyloid PET scans. As a result of the retirement of the NCD, the CED is no longer applicable to the New IDEAS Study.

Please review the following important information:

- The New IDEAS Study remains active and is enrolling new patients.
- The New IDEAS Coinsurance Reimbursement Program remains active and in effect.

Actions for Participating Dementia Practices:

The Study Sponsor has obtained IRB approval for a patient-facing notice that explains the CED changes in lay terminology for all IRB-approved sites. Approval letters can be found in the **Advarra IRB CIRBI Portal**. Upon receiving site-level approval for the patient-facing letter, sites must:

- Log in to the **CIRBI Portal**, and download the patient-facing letter from the "IRB-Issued Documents" section.
- Disseminate the letter to already consented patients awaiting PET scans and those interested in participating.
- File a copy of the document in the protocol folder.

Actions for Participating Imaging Facilities:

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 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.
- 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.

New IDEAS Reminders for Study Participants

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.
- 3. **Schedule optional transportation assistance to the amyloid PET scan appointment** In March 2023, the study received IRB approval for a Transportation Assistance Program to help patients travel to their amyloid PET scan.
- 4. Consider optional in-home blood collection services The study also received IRB approval for an optional in-home blood draw 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.

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) Alok Bhattacharyya, MD (Fremont, CA)	Center for Comprehensive Care and Research on Memory Disorders (Chicago)
2) Baylor AT&T Memory Center (Dallas)	2) Alok Bhattacharyya, MD (Fremont, CA)
3) Center for Comprehensive Care and Research on Memory Disorders (Chicago)	3) Andrew Lerman, MD (Miami)

New IDEAS - Imaging Dementia - Evidence for Amyloid Scanning

50 S. 16th St., Suite 2800 | Philadelphia, PA 19102

© 2023 New IdeasStudy. All Rights Reserved.

View in web browser

Opt out from IDEAS e-newsletter