ACR®
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NEW
IDEAS
Imaging Dementia—Evidence
For Amyloid Scanning

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

New IDEAS Study Update

Mar 10, 2023

145

Activated Dementia Expert Sites

Find a Dementia Site

121

Activated PET Imaging Facilities

Find an Imaging Facility

4,065

Total Patient Registrations:

42% Black/African American cohort

39% Hispanic/Latino cohort

82% All Other Race/Ethnicities cohort

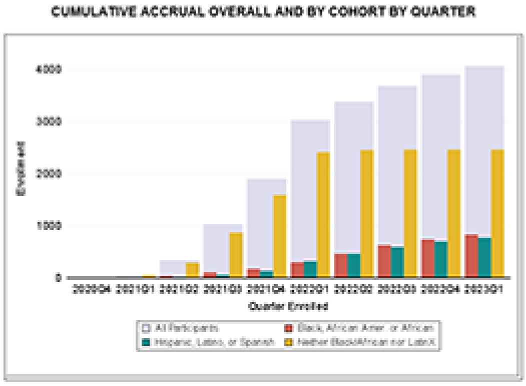
Note: The temporary enrollment pause on the "All Other Races/Ethnicities" cohort will be lifted when both Black/African American and Hispanic/Latinx cohorts reach 75% (n=1,500 each) of the cohorts total accrual goals.

Building on the dataset from the original IDEAS study, the New IDEAS Study has now enrolled more total patients who self-identify as Black/African American and Hispanic/Latinx than took part in the original IDEAS Study. Forty-two percent (n=832) of enrolled New IDEAS Study patients are Black/African American, while 39% (n=771) are Hispanic/Latinx.

Of the 11,409 patients included in the **IDEAS study final dataset** for the aim 1 analysis, only 3.8% (n=431) patients self-identified as Black/African American and 4.0% (n=453) patients self-identified as Hispanic/Latinx.

The New IDEAS Study plans to enroll 2,000 patients into each cohort by the end of study enrollment. Study leadership is thrilled to achieve this important milestone and commends all participating dementia practices for striving to meet study goals. Inclusive and diverse patient participation aims to ensure that the research findings from New IDEAS are generalizable to Medicare beneficiaries across the country and representative of patients within races/ethnicities that are disproportionately affected by Alzheimer's disease.

Garrett Davis, Carl Hill, MD, and Peggye Dilworth-Anderson, MD, discuss the importance of underrepresented communities' participation in clinical trials on stage during the intermission of "Unforgettable" at the Wilshire Ebell Theatre in Los Angeles in January. "Unforgettable" showcases the importance of early detection and the effects of caring for a loved one with Alzheimer's. **Attend a showing of the play in a city near you** and help spread the word about New IDEAS.



New IDEAS Surpasses 4,000 Patient Registration Milestone

Thanks to the activated dementia practices and PET imaging facilities, more than 3,200 registered participants have now received amyloid PET scans.

New Study Initiatives — March 2023

The New IDEAS Study Team is excited to announce new study-wide initiatives, including transportation assistance to the amyloid PET scan, in-home blood collection services and updates to the study protocol inclusion criteria for more inclusive research.

1. **Study Protocol and Informed Consent Form Amendment** — The Study Team received approval for a protocol and Informed Consent Form (ICF) amendment on March 1, 2023. Sites should look for email communication from the Study Team and

Advarra Institutional Review Board (IRB) with additional details and next steps and check the New IDEAS Study Updates webpage for additional study updates.

2. **Transportation Assistance to the Amyloid PET Scan Appointment** — The New IDEAS Study Team received community feedback that a common barrier to participation in New IDEAS is transportation to participating PET facilities. Practices should expect updates from the Study Team on a new transportation assistance program to help patients get to their amyloid PET scan visit. In the interim, facilities that provided documentation indicating they offer transportation assistance are marked with the statement, "(Note: Transportation Assistance Provided)" on the **Facility Finder**. Practice staff should encourage patients to call 866-507-7254 or email **newideas-participant@alz.org** to learn about transportation options in their communities.

3. **Optional In-Home Blood Collection Services** — The New IDEAS Biorepository for saliva and blood remains a priority to aid future research of Alzheimer's disease biomarkers. Protocol and ICF changes include an optional in-home blood draw that patients may choose instead of going into a local Quest Lab.

4. **Protocol Amendment: Removal of Inclusion Criterion, "English or Spanish Speaking"** — Per the feedback of New IDEAS sites, the inclusion criterion "English or Spanish speaking" for the purposes of informed consent will be removed for participation in New IDEAS, effective on the date of IRB approval for the associated protocol amendment. All questions or concerns should be directed to the New IDEAS Regulatory Specialist at **newideas-regulatory@acr.org**.

First Social Media Campaign in Chicago and Houston

Thanks to our partnership with the Alzheimer's Association, in January 2023, the New IDEAS Study launched its first social media pilot campaign in Houston and Chicago. The campaign performed exceptionally well, and the Study Team is looking forward to launching another campaign across additional cities in our community-engaged metro regions.

Resources for Minority Recruitment and Engagement

Study leadership assumes that all participating sites are actively demonstrating their commitment to the study by engaging in specific efforts to recruit and enroll patients throughout the enrollment pause on the "all other races and ethnicities" cohort. Review the **Temporary Enrollment Pause Memorandum** and **FAQ** to learn more.

How to Help New IDEAS Meet Accrual Goals

1. Request additional printed recruitment materials using the **New IDEAS Printed Recruitment Materials Request Form**:
   - The New IDEAS Recruitment and Community Engagement Team developed a comprehensive suite of recruitment and informational materials to help promote diversity and inclusion, and to authentically reach the study's underrepresented patient populations.
   - Multiple versions ensure the study materials are both culturally sensitive and easily understood by all patients.

2. Obtain Patient Navigation Assistance Card for your site (**See example**):
   - Patient Navigation Assistance Cards help new patients understand what to expect when they visit a dementia practice and simplify the process for

accessing healthcare.
    - Complete the **patient navigation assistance survey** for your site. Study Champions will disseminate your practice's card into the community to answer common questions about your practice.

3. Complete a site interview with the New IDEAS Recruitment Support Team by sending an email to **newideas_recruitment@vumc.org** to request assistance with enhancing minority recruitment efforts at your site.

4. Learn best practices for minority recruitment and engagement by viewing resources in our **Recruitment Toolkit**.

5. Ensure that your site has a copy of your ICF translated into Spanish.
    - All participating dementia practices should have received a translated version of their IRB-approved ICF. This translation was paid for by the study, free of charge.
    - Please log in to your site's **Advara IRB CIRBI Portal** to access and download the translated, approved document. If you have not received a translated version or need a copy of the ICF in a language other than English or Spanish, please contact the New IDEAS Regulatory Specialist at **newideas-regulatory@acr.org**.

6. Help increase awareness among primary care providers (PCPs) in your area of the dementia disparities among Black and Latinx patients and the potential value of amyloid PET imaging.
    - Share PCP contacts with the Study Team to let them do the outreach for you. Complete a brief **PCP Engagement Survey** to share information with the team about PCPs who may be interested in learning more about New IDEAS.
    - Contact PCPs in your area directly using the following email templates:
        - **Template 1**
        - **Template 2**

7. Refer volunteers to New IDEAS Study Community Engagement Specialists by providing them with this email address: **Newideasstudy.ces@med.unc.edu**. Volunteers can serve as Study Champions in the community-engaged metropolitan areas as defined in the Study Protocol and **Study Champion FAQ sheet**.

8. Share the names of local community organizations or businesses with the Study Team to help us identify potential partnerships or locations for increasing study awareness. Have an organization in mind? Complete this **short form**.

9. Connect with your local Alzheimer's Association chapter and attend community meetings. Email **newideas@acr.org** to learn how to obtain support from your local chapter.
    - The New IDEAS Study Team is leveraging a robust national network of the Alzheimer's Association and partnering with chapters involved in minority communities to form local, community-based recruitment teams.
    - Local, community-based recruitment teams will disseminate recruitment materials to trusted churches, social, civic and cultural groups in Black and Latinx communities.

10. Share your feedback for additional Study Team support.

  - Feedback from participating sites, facilities and community stakeholders is important to our team. We invite you to connect with the New IDEAS Operations Team to discuss new, innovate ways to meet our study goals and increase access to care. Email us at **newideas@acr.org**.

How to Increase Biosample Retention

The New IDEAS Study Team expects site staff to have ongoing consent discussions with patients about their commitment to completing the saliva collection and optional blood draw. Here are additional ways sites are increasing their biosample retention to meet study goals:

1. Track sample shipments and send email reminders to patients:
    - Practice staff can now view tracking information for patient saliva and blood shipments in the New IDEAS Portal. Reminder notifications will be sent to practice staff when kits are shipped to patients.
    - Practice staff should identify and notify patients who have not yet completed the biosample collection process. To view patient status, click on the Biosample Tab by Case ID in the New IDEAS Portal.
    - For increased patient awareness, the New IDEAS Study developed a patient-facing **email template** for practices to share with patients when biosample kits are mailed. Practice staff members are encouraged to reach out to patients when kits are shipped.

2. Communicate effectively with your patients during informed consent discussions by providing important reminders:
    - Saliva collection is a part of the main study protocol for New IDEAS. Therefore, all study participants will receive saliva collection kits in the mail after completing the amyloid PET scan. Please remind patients that collection and return of saliva samples is a required task of study participation.
    - Participants who consented into optional blood collection will receive a combined collection kit in the mail.
    - Results of apolipoprotein E (APOE) analysis will not be provided to the patient or to their care provider. However, patient participation in the biorepository will help researchers learn more about conditions that cause changes in memory and thinking. It will also help researchers understand how to better diagnose, treat and prevent memory loss.
    - Patients, family members and caregivers should contact the New IDEAS Study Patient Helpline at 866-507-7254 or **newideas-participant@alz.org** if they need assistance with the saliva collection process or help scheduling a blood draw appointment.

3. Establish drop-in hours for saliva collection at your site:
    - Identify a few days and times during the week when your practice staff are available to assist patients with their saliva kit shipments. Patients should be encouraged to bring their kits to the practice for assistance when help is needed. The post-PET visit is a great way for patients to receive assistance during already scheduled visits to the office.

4. Request replacement kits for your patients:
    - The New IDEAS Study biorepository coordinator can work with your practice to ship a replacement kit to patients who may not have received or misplaced their kits, or to those who completed their sample collections incorrectly. Email

newideas@acr.org to request replacement kits for your patients.

5. Request a demonstration kit:
    - The New IDEAS Study Team can supply your site with demonstration kits for informed consent discussions with your patients to further explain what to expect upon receipt of the kits. Email **newideas@acr.org** to request your demonstration kits.
6. Schedule a site training with the New IDEAS Operations Team:
    - Contact **newideas@acr.org** to review best practices for biosample collection at your site and improve your current processes to meet study goals.

Adhering to Coinsurance Reimbursement Program Policy

- To participate in New IDEAS, all active imaging facilities must review and comply with the **New IDEAS Coinsurance Reimbursement Policy**, implemented Jan. 1, 2022.
- Please review full program details in the **Coinsurance Reimbursement Training Module**, and find answers to frequently asked questions in the **Coinsurance Reimbursement Program FAQ**.
- To remain active in New IDEAS, PET facilities must complete all items on the PET Facility Checklist within the Program **Operational Training Module** (see Slide 15).

Medicare Reimbursement and Billing Guidance

- **Important Amyloid PET Scan Exclusion Criteria Clarification**
  Patients with histories of amyloid PET scans or who received scans in the original IDEAS Study are not eligible to participate in New IDEAS. The current CMS coverage limit for amyloid PET is one scan per patient lifetime.
- **Prior Authorization and/or Medicare Reimbursement Issues**
  If your facility is currently experiencing issues with prior authorization requests or Medicare reimbursement for amyloid PET scans, please contact the New IDEAS Operations Team at **newideas@acr.org**.
- **PECOS Requirement**
  All participating referring dementia providers and radiologists/nuclear medicine physicians must be enrolled in the Medicare Patient Enrollment Chain and Ownership System (PECOS). This is a requirement set forth by the study protocol and CMS to bill for the services provided to Medicare beneficiaries.
- **Facilities Denying Medicare Advantage Plans**
  Imaging facilities must accept the referral for a Medicare Advantage (MA) participant if the facility is contracted with that patient’s plan. In general, providers who accept Medicare cannot add restrictions that would discriminate against Medicare beneficiaries (42 CFR § 489.53).

  If a provider accepts an MA plan, it cannot discriminate by selectively accepting referrals for Medicare patients. However, providers are not required to accept all Medicare Advantage plans. Any provider who violates this condition of participation can be reported to the CMS and their respective MA plan.

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 for the ACR Operations team. 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 study legal agreements for 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)	1) Alok Bhattacharyya, MD (Fremont, CA)
2) Baylor AT&T Memory Center (Claudia Padilla, PI; Dallas, TX)	2) Center for Comprehensive Care and Research on Memory Disorders (Chicago, IL)
3) Center for Comprehensive Care and Research on Memory Disorders (Chicago, IL)	3) Andrew Lerman, MD (Miami, FL)

New IDEAS - Imaging Dementia - Evidence for Amyloid Scanning

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