



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

New IDEAS Study Update

December 11, 2024



6,061

Total Patient Registrations:

66% Black/African American

63% Hispanic/Latino

100% All Other Race/Ethnicities

Note: Enrollment data represent unique registrations through March 1, 2024. Total patients scanned may not exceed 7,000 scans or exceed individual race/ethnicity cohort maximums.

Thanks to the collaborative efforts of dementia practices and PET imaging facilities, more than 4,900 patients received an amyloid PET scan through New IDEAS. The New IDEAS Study Team applauds the fantastic work completed by the larger New IDEAS Study network. Your participation and commitment to patient care and research has been instrumental in the study's accrual success.

Final Study Timelines and Program Closures

Please review the following important timelines and instructions for smooth closeout of study activities and contact the New IDEAS Operations Team at newideas@acr.org with any questions.

End of Participant Enrollment

After careful consideration of numerous factors and evaluation of the risk-benefit tradeoff for patients, study leadership ended study accrual on Friday, March 1, 2024, at 11:59pm ET. At

that time, patient registration into the study portal closed, and this deadline applied to all race/ethnicity cohorts. Please read the full, official **Study Closure Memorandum**.

Site and Facility Closeout

ACR®, the study sponsor, will continue to help facilitate closeout activities for both dementia practices and imaging facilities. Please review the following important reminders regarding closeout:

- The New IDEAS Operations Team will contact you regarding outstanding data, individual timelines and additional closeout procedures.
- 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**.
- As you review or reconcile payments received, please review the finance tab in the portal and reach out to newideas@acr.org with any further questions.
- 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.

Coinsurance Reimbursement Program Closure

PET imaging facilities have until June 1, 2025, to submit and reconcile any remaining coinsurance reimbursement forms in the study portal. The program closure date, which is more than one year from the last service date of the scan completed as part of the study, allows sufficient time for facilities to complete the billing and submission cycle.

- The study sponsor will pay for coinsurance amounts that Medicare beneficiaries participating in the study would otherwise owe for Medicare-reimbursable amyloid PET scans provided during the study, regardless of financial need.
- Coinsurance amounts associated with the amyloid PET scan (including technical, professional or global charges) and/or fixed copayments not covered by patient supplemental insurance are reimbursed under this program.
- Unmet beneficiary deductibles and coinsurance or copayments associated with dementia expert visits are not reimbursed under this program.
- 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.
- **Read the full updated policy**

Biosample Collection Program Termination

Patients participating in New IDEAS consented to providing a saliva sample and may have consented to providing a blood sample. Final biosample kits are expected to ship to participants by the end of 2024.

- Patients should be instructed to complete these study activities as outlined on the study informed consent form.

- The final date to request replacement kits is Dec. 31, 2024. Please contact newideas@acr.org if your patient needs a replacement kit or has not received their original kit shipment.
- Participants will have until June 1, 2025, to return their biosamples. Samples received after that date will be destroyed and not included in the biorepository and no payment will be made.
- As a reminder, your practice will not submit a termination report to the IRB until you've shipped all patients their biosample kits, including any replacement kits.

Study Wrap Up — Updates for the Next Phase

New IDEAS Data Analyses

In 2024, the New IDEAS Study Team devised two working groups to collaboratively work on data analyses and publications. The Primary Analysis working group focuses on key findings associated with the study's aims and objectives. The Social Determinants of Health working group uses data from New IDEAS to estimate associations between social determinants of health with Amyloid PET positivity status as well as changes in management for a cohort of Medicare beneficiaries with cognitive impairment. All study results will be shared broadly with sites and communities, and published on the [Recent Study Updates](#) webpage.

Learning From Our Partners

The New IDEAS Recruitment and Community Engagement Teams are actively working to learn from the New IDEAS Study partners to improve recruitment and community engagement strategies in future projects.

- **New IDEAS Recruitment Experience Interviews** — Vanderbilt University Medical Center will use a multi-methods approach to evaluate the New IDEAS Study site recruitment experience. Their approach includes a qualitative research plan that aims to explore overall views, facilitators, limitations and areas of improvement for recruiting into the New IDEAS Study. Semi-structured interviews will take place with participating sites through June 2025.
- **New IDEAS Focus Groups With Community Partners** — The University of North Carolina Chapel Community Engagement Specialist Team will conduct focus groups with New IDEAS Study Champions, Alzheimer's field offices and other partners to gather focused feedback about their experiences during the study process and supplement the knowledge gained through Alzheimer's community-engaged work.

IDEAS Study Program Data Requests

The IDEAS Study program, which includes the IDEAS Study and New IDEAS Study, is committed to providing academic and industry investigators the opportunity to access study data for purposes consistent with IDEAS Study program goals. This may include ancillary research studies, technology development and educational initiatives.

IDEAS Study Data

IDEAS Study data elements available for use are viewable on The Global Alzheimer's

Association Interactive Network platform. **Explore data**. To request study data, please review and submit the Laboratory of Neuro Imaging IDEAS **Data Use Agreement**.

New IDEAS Study Data

After all study data is collected, it will be processed for data access requests by the New IDEAS Study Team. **Watch for updates** regarding study data availability.

- All requests will be evaluated for relevancy and contributions to diverse, equitable and inclusive science by the New IDEAS Research and Publications Committee.
- The **New IDEAS Data Sharing and Publication Policy** provides information and guidelines for individuals and corporations wishing to request access to clinical or image data archived during the New IDEAS Study.
- Please email **IDEAS-ResearchPub@acr.org** with any questions or concerns.

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**.
- **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.
- **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 no later than Dec. 31, 2024.

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)

New IDEAS: Imaging Dementia — Evidence for Amyloid Scanning

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