NEW iDEAS
Imaging Dementia—Evidence For Amyloid Scanning

New IDEAS Study Close-Out Guide

Contents

FAQS ON STUDY CLOSURE 2

Announcement 2
Additional Context 2
What We Have Accomplished 3
Next Steps 3

FAQS FOR DEMENTIA PRACTICES 4

Registration-related Questions 4
Operational Questions 4
Insurance and Prior Authorization Questions 5
Regulatory and Site Termination Questions 5

FAQS FOR PET IMAGING FACILITIES 7

Operational Questions 7
Insurance and Prior Authorization Questions 7
Coinsurance Reimbursement Program Questions 8
Facility Termination Questions 8

FAQS FOR STUDY CHAMPIONS AND ALZHEIMER'S ASSOCIATION STAFF 9

Community-Engagement Activity Questions 9
Study Champion-Specific Questions 9
Alzheimer's Association Staff Questions 10

FAQs on Study Closure

Announcement

When was the Study-wide accrual closure date announced?

New IDEAS Study leadership announced the Study-wide accrual closure date on February 15, 2024. Read the New IDEAS Study Accrual Closure Memorandum. Please disseminate the memorandum and New IDEAS Study Close-Out Guide to Study stakeholders at your location.

When is the New IDEAS Study closing to new patient registrations?

The last day for dementia practices to register new patients in the New IDEAS Portal is Friday, March 1, 2024. The New IDEAS Portal will deactivate a practice's ability to register a patient at 11:59pmEST on that day.

Are all three race/ethnicity cohorts closing or just the "All Other Race/Ethnicity" cohort?

All race/ethnicity cohorts are closing to accrual, including patients who self-identify as Black/African American, Hispanic/Latinx and all other races and ethnicities. The reason for Study closure is independent of the Study's accrual goals.

Are all sites closing to accrual on the registration deadline or just certain sites?

All New IDEAS practices participating in the Study will be closed to patient registrations on Friday, March 1, 2024.

Additional Context

Who decided to close the New IDEAS Study?

After careful and thoughtful consideration, the New IDEAS Study leadership team made the decision to close the New IDEAS Study.

Why is the New IDEAS Study closing?

Study leadership determined that the best course of action for the Study is to close accrual study-wide, independent of accrual goals, after considering the feasibility of our protocol against new structural barriers presented by the retirement of the National Coverage Determination (NCD) on amyloid PET. Refer to the section below for details on how the retirement of the NCD has impacted the Study. Inclusivity and proper representation of all Medicare beneficiaries is important to the New IDEAS Study, and due to the Study's protocol inclusion criterion, "Medicare beneficiary with Medicare as primary insurance," the Study must consider the feasibility of our protocol against new structural barriers. Additionally, since the retirement of the NCD on amyloid PET means that the scans can now be obtained outside of participation in New IDEAS, there is a negative impact on recruitment efforts at participating practices and confusion for patients during the informed consent process. For these reasons, the Study Team felt there was an unfavorable risk-benefit tradeoff for patients if the Study continued, and the requirements to change these variables were outside our control as a Study Team.

How does the retirement of the National Coverage Determination on amyloid PET impact the New IDEAS Study?

The New IDEAS Study protocol was developed and approved as a Coverage with Evidence Development (CED) Study under the supervision of the Centers for Medicare & Medicaid Services (CMS). On October 13, 2023, CMS issued a public announcement 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, CED is no longer applicable to the Study, and Medicare contractors reserve the right to determine their own coverage policies. Recently, practices and facilities have brought to light several real-world complexities that impact Study patients and the ability to access a covered amyloid PET scan.

The new landscape for billing procedures and coverage of amyloid PET scans has proven to be inconsistent across insurance plans, namely Medicare Advantage (MA) plans. Among patients with traditional Medicare plans and select MA plans, the Study Team has seen successful reimbursement of scans post-NCD retirement. However, for some MA plans, we are unable to advise practices and facilities on a pathway to successful prior authorization in cases where plan-managed criteria for coverage have changed. In summary, we can no longer rely on the now retired NCD for justification of coverage. The Study Team is concerned that the 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.

What We Have Accomplished

Did the Study meet its pre-defined recruitment goals for each of the Study's cohorts?

Despite the leadership team's strong desire to achieve the study's pre-determined accrual goals, the protocol's pre-defined accrual goals were not met. However, the Study Team is committed to seeing through the planned analyses and objectives of the Study, despite early closure to accrual.

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. Additionally, the Study gathered substantial data and insight on novel recruitment and community engagement methodologies that will serve as a foundation for similar studies in the Alzheimer's space. The New IDEAS accrual total to date is a testament to the collaborative efforts of participating dementia practices, community partners and volunteers who made the Study possible.

Updates on Study accrual goals can be found on the New IDEAS Recent Study Updates webpage.

Next Steps

Who should I contact if I have questions about the Study closing?

Sites and facilities are encouraged to contact newideas@acr.org. The American College of Radiology, 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. 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 FAQs for Dementia Practices and FAQs for PET Imaging Facilities.

Study Champions and Alzheimer's Association staff, please review the FAQs for Study Champions and Alzheimer's Association Staff for more detailed information on community-engagement activities and contact information for study closure-related questions.

How can I learn more about the results of the New IDEAS Study?

After the accrual phase is completed, the New IDEAS Statistical Analysis Team will begin the analysis phase of the Study. Publications of New IDEAS research findings will be made publicly available online.

FAQs for Dementia Practices

Registration-related Questions

If a patient consented to participate but was not registered by the registration deadline, can they participate in New IDEAS?

No, patients must be registered in the New IDEAS Portal prior to the registration deadline of Friday, March 1, 2024 at 11:59pmET to be considered enrolled in the New IDEAS Study.

If a patient is registered prior to the registration deadline, but due to extenuating circumstances (e.g. prior authorization delays, patient travel, etc.) study timepoints are missed, can my patient be re-registered AFTER the registration deadline and still participate in New IDEAS?

No, patient re-registrations after the registration deadline will not be allowed, even if original registration occurred before the deadline. No exceptions will be made. Please ensure your practice staff are made aware of the new registration timelines to ensure timely submission of Study forms. If a site completes a patient re-registration prior to the registration deadline, the patient should complete all research activities as described by the Study protocol.

Will patients who are already registered be able to continue with the New IDEAS Study?

Yes, patients who were registered prior to the Study closure announcement and patients who are registered through Friday, March 1, 2024 should continue the standard activities outlined in the Study protocol. Imaging facilities should continue scanning patients referred to them through New IDEAS.

Can I still access the Data Collection tab in the New IDEAS Portal to complete Study forms after Friday, March 1, 2024?

Yes, starting Saturday, March 2, 2024, practices will no longer be able to register patients in the New IDEAS Portal. However, practice staff members and referring physicians will be able to access all other Study forms, including forms that need to be completed for patients on Study.

Operational Questions

If a patient/patient's legally authorized representative (LAR) consented to participate in New IDEAS, but the patient was not registered ahead of the registration deadline, should we notify the patient/LAR about the Study closure?

Yes, patients/LARs 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. The communication should describe options for continued clinical care at the practice with contact information for follow-up. We encourage practices 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 simplify the process for accessing memory care. Patients who express interest in the Study after the registration deadline should be encouraged to consult with their memory care providers on best options for their clinical care plan and evaluation outside the scope of the New IDEAS protocol.

Does the Study closure impact when my patients will receive their biosample kit?

No, patients will continue to receive their biosample kits after they complete the amyloid PET scan. Practice administrators will receive an automated notification from the New IDEAS Portal when the kit is shipped. Practice staff remain encouraged to help facilitate their patients through the collection process as needed.

How do I request replacement biosample (saliva and/or blood) kits for patients who did not complete the biosample collection or need a replacement?

Please email newideas-data@acr.org to request a replacement saliva or blood collection kit for patients who request a replacement. The New IDEAS Data Management Team will contact your site at the time of site close-out if there are any missing samples from your site.

Will patients continue to have access to transportation assistance through New IDEAS?

Yes, the Transportation Assistance Program through GoGo Grandparent will be available through the duration of the Study. Review how to schedule transportation assistance to the amyloid PET scan.

Will patients continue to have the option for in-lab or in-home blood collection if they consent to complete the optional blood collection?

Yes, patients will have the option to complete the optional blood draw in-lab through Quest Diagnostics or in-home through ExamOne. Patients who consent to the optional blood draw will receive their blood draw kit with instructions after they complete their amyloid PET scan. Learn more about giving a blood sample for New IDEAS.

Will patients continue to have coverage of their amyloid PET scan coinsurance through the Coinsurance Reimbursement Program?

Yes, the Coinsurance Reimbursement Program will remain active through the duration of the Study. Please review the Coinsurance Reimbursement Program Policy for more information.

Will the patient-facing helpline still be available to patients who need assistance with Study-related activities?

Yes, the Patient-facing helpline managed by the Alzheimer's Association will be available to patients through the duration of the Study. Patients, family, and caregivers are encouraged to call 866-507-7254 or email newideas-participant@alz.org.

Insurance and Prior Authorization Questions

Who should I contact if I have concerns about Medicare Advantage plan denials?

If your site or facility is experiencing prior authorization denials for amyloid PET scans through New IDEAS or has concerns about Medicare Advantage Plan reimbursement for amyloid PET scans conducted in New IDEAS, please contact newideas@acr.org.

Who should I contact if I have billing questions related to New IDEAS amyloid PET scans?

Please review the Medicare Reimbursement guidance found on our study website for more information on billing, and direct any questions to newideas@acr.org.

Are prior authorizations for the amyloid PET scan required for patients participating in New IDEAS?

Yes, if a practice or facility identifies that a patient's insurance plan requires prior authorization before the amyloid PET scan, the prior authorization needs to be obtained before the patient can receive the scan. Please review New IDEAS Medicare Advantage Plan Guidance and Frequently Asked Questions

Regulatory and Site Termination Questions

Who should I contact for instructions for site close-out?

Please email the American College of Radiology, Study sponsor, at newideas@acr.org for site-specific close-out instructions. The New IDEAS Data Management Team will review existing data and create a summary report of pending items, including informed consent form review, missing data forms, and pending biosample kits. Sites may be contacted by the New IDEAS Data Management Team to set up a close-out

meeting to review data management requests. Once all data queries have been addressed, the site will receive an invitation to complete an exit survey and instructions to submit a termination report to Advarra IRB.

If my site did not register or consent any patients in New IDEAS, can I close-out my site?

Practices that did not register any patients in the New IDEAS Portal should submit a termination report to Advarra IRB. Please contact newideas@acr.org with any questions.

If my site consented patients but did not register any patients in the New IDEAS Portal, how do I close-out my site?

Practices that consented patients but did not register any patients in the New IDEAS Portal should contact their patients to notify them of the Study closure. The site should submit a termination report to Advarra IRB after all patients are notified. Please contact newideas@acr.org with any questions.

If my site received IRB approval, but was never activated for participation in New IDEAS, how do I close-out my site?

Sites that received IRB approval but were never activated to enroll patients into the Study should submit a termination report to Advarra IRB.

Who is responsible for closing out my site with Advarra IRB?

Dementia practice site principal investigators, or their designated staff, are responsible for submitting a termination report with the IRB. For Advarra IRB log in support or CIRBI Portal technical assistance, please email cirbi@advarra.com or call 1-866-992-4724. Review instructions on how to submit a termination report.

If my site was planning to participate in New IDEAS, but was not activated ahead of the Study closure announcement, will it be activated ahead of the registration deadline?

No, sites that were not activated for accrual into New IDEAS ahead of the Study closure announcement are not eligible to be activated prior to the registration deadline. Sites who received IRB approval but were not activated should submit a termination report to Advarra IRB.

When will my site contract be terminated by the American College of Radiology?

The American College of Radiology will issue your site a contract termination notice when all data are submitted in the New IDEAS Portal, your site receives termination approval notice from Advarra IRB, and all practice payments are fulfilled.

Where can I find resources on best practices for recruitment and retention for future studies?

Dementia practice staff are encouraged to review resources provided by the Trial Innovation Network's Recruitment Innovation Center (RIC), an evidence-based center in innovative trial recruitment and retention methods, tools, and strategies. The Trial Innovation Network (TIN) and the RIC house and 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 here. Some example resources in the TIN Toolbox include:

- Faster Together: Enhancing the Recruitment of Minoritized Groups in Clinical Trials.
- Recruitment Innovation Center (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

FAQs for PET Imaging Facilities

Operational Questions

How does the Study registration deadline impact my facility?

The registration deadline is specific to patient registrations that are completed by the participating dementia practices. Facilities should continue standard Study operations and schedule patients for amyloid PET scans within 60 days of receipt of the Study enrollment authorization notice, sent via email to the facility administrator.

Should my facility continue to scan patients who are already assigned to my facility in the New IDEAS Portal?

Yes, PET imaging facilities should continue to scan patients who are assigned to them in the New IDEAS Portal once they receive email confirmation that the patient is authorized to receive a scan through the New IDEAS Study.

What is the last day for patients to receive a scan through New IDEAS?

The last day for a patient to receive a scan through New IDEAS is 60 days from the submission of the last Pre-PET form. Facilities will receive confirmation emails with dates for each patient registered when they are authorized to receive a scan through the Study.

Insurance and Prior Authorization Questions

Should my facility continue to bill Medicare for patients who complete scans through New IDEAS?

Yes, PET imaging facilities should continue to bill Medicare for New IDEAS Scans. Scans completed prior to October 13, 2023 should follow Sample Claim Form guidance here. Scans completed after October 13, 2023 should follow Updated Sample Claim Form guidance here.

Who should I contact if I have concerns about Medicare Advantage plan denials?

If your site or facility is experiencing prior authorization denials for amyloid PET scans through New IDEAS or has concerns about Medicare Advantage Plan reimbursement for amyloid PET scans conducted in New IDEAS, please contact newideas@acr.org.

Who should I contact if I have billing questions related to New IDEAS amyloid PET scans?

Please review the Medicare Reimbursement guidance found on our study website for more information on billing, and direct any questions to newideas@acr.org.

Are prior authorizations for the amyloid PET scan required for patients participating in New IDEAS?

Yes, if a practice or facility identifies that a patient's insurance plan that requires prior authorization before the amyloid PET scan, the prior authorization needs to be obtained before the patient can receive the scan. Please review New IDEAS Medicare Advantage Plan Guidance and Frequently Asked Questions

Is it appropriate for my facility to issue a patient an Advanced Beneficiary Notice prior to the scan?

No, patients participating in New IDEAS are only responsible for the unmet deductible associated with their amyloid PET scan. New IDEAS participants should not be receiving a bill for their scan or the tracer used. If there are concerns about facility reimbursement or incorrect patient billing, please contact newideas@acr.org.

Coinsurance Reimbursement Program Questions

Should my facility continue to submit Coinsurance Reimbursement Requests for patients who were left with coinsurance after completing the scan?

Yes. The Coinsurance Reimbursement Program will remain active through the duration of the Study. Please review the Coinsurance Reimbursement Program Policy for more information.

What is the last day for my facility to submit requests for the Coinsurance Reimbursement Program?

PET Imaging facilities should continue to submit coinsurance reimbursement requests. The Study Team will communicate any updates if anything changes to the reimbursement request timeline.

Facility Termination Questions

Who should I contact for instructions for facility closure?

Please email newideas@acr.org for instructions for facility closure. 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.

When will my facility contract be terminated by the American College of Radiology?

The American College of Radiology, the Study sponsor, will issue your facility a contract termination notice when all data are submitted in the New IDEAS Portal and images are uploaded to TRIAD. Additionally, the sponsor will confirm Coinsurance Reimbursement Form submissions are completed and reimbursement requests have been fulfilled, as applicable.

If my facility was planning to participate in New IDEAS, but was not activated prior to the study closure announcement, will it be activated in the future?

No, facilities that were not activated prior to the announcement will not be eligible for activation for New IDEAS prior to registration deadline.

FAQs for Study Champions and Alzheimer's Association Staff

Community-Engagement Activity Questions

When is the last day I should share information about the New IDEAS Study?

Study Champions and Alzheimer's Association Chapter staff should continue to share New IDEAS Study information through Thursday, February 29, 2024. However, individuals interested in participating should be made aware that the last day to enroll in the New IDEAS Study is Friday, March 1, 2024.

What should I do with leftover New IDEAS materials (e.g. flyers, posters, etc.)?

Any leftover New IDEAS materials should be recycled. Any materials created by the Alzheimer's Association without the New IDEAS logo can continue to be shared at Alzheimer's Association-led events.

What should I do if I have a New IDEAS event scheduled after February 29, 2024 or plan on attending an event after that date to share information about New IDEAS?

If you are hosting a New IDEAS event or attending an event with plans to distribute New IDEAS materials after February 29, 2024, please contact New IDEAS Community Engagement Specialists, Timothy Simmons and Andrea Mendoza at timothy_simmons@med.unc.edu and andrea_mendoza@med.unc.edu for additional event-specific instructions.

Where and when should I return my tablet that I used at New IDEAS community engagement events?

Chapter offices and Study Champions who have UNC tablets should send the tablets to the following address by May 31, 2024.

Shikira Flounory
333 S. Columbia St.
319B MacNider Hall
Campus Box 7240
Chapel Hill, NC 27599

Where should I direct individuals who are interested in learning more about memory care options after the Study ends?

Individuals are encouraged to talk to a memory care provider about memory care options after the Study ends. To locate a memory care provider and other medical services related to memory care, visit the Alzheimer's Association's Community Resource Finder or call the Association's 1-800 Helpline at 1-800-272-3900.

Study Champion-Specific Questions

What are my Study Champion responsibilities after February 29, 2024?

While Study Champions will no longer be able to share New IDEAS-related information or host New IDEAS community events, Champions will 1) work with UNC Community Engagement Specialists to make sure all New IDEAS events and material distributions are entered in REDCap and 2) complete close out and process evaluations.

Student Research Champions should continue their work as scheduled.

What will happen to my stipend?

Pending successful completion of close-out activities between March and May, the final stipend Champions receive will be delivered in May and June 2024.

Will Study Champion check-ins continue?
Check-ins will continue as scheduled until the completion of data collection and evaluations.

Should I still submit previous distribution and event tracking logs?
Yes, Study Champions should submit previous logs and ensure all their distribution and event tracking logs for all activities are entered in REDCap.

Will the end of the Study affect my role as a volunteer for the Alzheimer's Association?
No, Study Champions who are also Alzheimer's Association volunteers can continue their duties as volunteers for the Alzheimer's Association.

Can I continue community collaborations/partnerships that I have established?
Yes, Study Champions are encouraged to continue any collaborations or partnerships that they have established in their community. Champions should connect the partnering organization with their local Alzheimer's Association staff partner for further resources and support.

How do I identify my Alzheimer's Association staff partner?
If you do not have or know your Alzheimer's Association staff partner, please contact New IDEAS Community Engagement Specialists, Timothy Simmons and Andrea Mendoza at timothy_simmons@med.unc.edu and andrea_mendoza@med.unc.edu. They can help you get connected with your local Alzheimer's Association chapter.

What can I do to continue to raise awareness of Alzheimer's disease and other forms of dementia?
Champions are encouraged to connect with the local Alzheimer's Association office and become an Alzheimer's Association volunteer if they are not already. To learn more about the Association's volunteer opportunities visit alz.org/get-involved-now/volunteer.

Who should I reach out to for additional questions?
Study Champions can reach out to New IDEAS Community Engagement Specialists, Timothy Simmons and Andrea Mendoza at timothy_simmons@med.unc.edu and andrea_mendoza@med.unc.edu.

Alzheimer's Association Staff Questions

Who should I reach out to for additional questions concerning New IDEAS Study Champions?
For any questions concerning Study Champions, Alzheimer's Association chapter staff members should contact New IDEAS Community Engagement Specialists, Timothy Simmons and Andrea Mendoza at timothy_simmons@med.unc.edu and andrea_mendoza@med.unc.edu.

Who should my chapter staff members reach out to for additional questions about New IDEAS?
Alzheimer's Association chapter staff members involved in the New IDEAS Study should contact Chris Weber at cweber@alz.org and Beverly Berry at bmberry@alz.org for additional questions.