Site Operations Toolkit

Thank you for advancing Alzheimer's and dementia research
to improve diagnosis, treatment, and care across all communities.

ALZ-NET Site ID: _____

ALZHEIMER'S NETWORK

ALZHEIMER'S ASSOCIATION®

ALZ-NET Site Operations Toolkit

CONTENTS

Welcome

Welcome to ALZ-NET

We are so pleased to have you join this important initiative and want to express our sincere gratitude for your participation. In this new era of treatment, your involvement is crucial to learning how the latest and future Alzheimer's therapies work in everyday settings.

ALZ-NET stands at the intersection of treatment and care, unleashing a powerful tool in the fight against Alzheimer's disease. By gathering and analyzing real-world data from people who receive FDA-approved Alzheimer's treatments, we can better understand long-term health and safety outcomes beyond controlled clinical trials.

Clinics like yours participating in ALZ-NET make it possible to harness real-world evidence from clinical care. Our collaboration is built on the goal of accelerating research, improving patient outcomes, and informing treatment and diagnostic practices for Alzheimer's disease. Your expertise and dedication are key to achieving this goal, and we are honored to have you as partners.

We developed this comprehensive toolkit to support your team. It will guide you through every step required to onboard your site, complete training, and carry out ALZ-NET activities. The following pages contain essential information, overviews of network systems and processes, and tips to help your site be successful with data collection.

The ALZ-NET Operations Team is here to support you every step of the way. Should you have any questions, require assistance, or wish to provide feedback, please do not hesitate to reach out.

We are excited to work together toward a future where all people affected by Alzheimer's and other dementia receive quality and equitable care. Again, thank you for your valuable contribution.

Sincerely,

ALZ-NET Principal Investigators

Maria Carrillo, Ph.D.

Chief Science Officer
and Medical Affairs Lead

Alzheimer's Association

Michael S. Rafii, M.D., Ph.D.

Medical Director,
Alzheimer's Therapeutic
Research Institute

Professor of Clinical Neurology
Keck School of Medicine

University of Southern California

Gil Rabinovici, M.D.

Edward Fein and Pearl
Landrith Distinguished
Professor in Memory
& Aging
Department of Neurology

University of California San Francisco

How to Use This Toolkit

This toolkit provides key information in a format that you can save and view offline. Within the content, links to additional resources and more detailed guidance appear where available.

Users can review the toolkit in its entirety or skip to a topic of interest. Topics within the toolkit are organized by phase of ALZ-NET participation, from startup through data collection.

The ALZ-NET Operations Team reviews and updates this toolkit regularly and will alert sites in the event of a major revision. The latest version can always be found on alznetproviders.org.

ABBREVIATIONS	
ALZ-NET	Alzheimer's Network for Treatment and Diagnostics
ACR	American College of Radiology
CED	coverage with evidence development
CITI	Collaborative Institutional Training Initiative
CMS	Centers for Medicare & Medicaid Services
eCRF	electronic case report form
EDC	electronic data capture
HSP	human subjects protection
HIPAA	Health Insurance Portability and Accountability Act
ICF	informed consent form
IRB	institutional review board
PI	principal investigator
RMS	Research Management System
TRIAD	Transfer of Images and Data

Ways to Stay Connected

VISIT THE WEBSITE

The ALZ-NET Providers website contains a wealth of up-to-date resources to help sites participate successfully in ALZ-NET.

Visit alznetproviders.org

ATTEND OFFICE HOURS

The ALZ-NET Operations Team offers Office Hours for sites twice a week:

Tuesdays
12–2 pm ET

Wednesdays
2–4 pm ET

Receive assistance for any questions related to ALZ-NET participation, from startup activities through data collection. No registration required. Questions? Email alz-net@acr.org or call 215-574-3181.

Join the Session

CONTACT US FOR HELP

For direct support, please contact the following teams based on your needs:

Contracts/Legal
alznet-contracts@acr.org

General Support

Advarra IRB
institutions@advarra.com
cirbi@advarra.com
886-992-4724

ACR Okta, RMS, and Medidata Rave
alz-net@acr.org
215-574-3181

Regulatory
alznet-regulatory@acr.org
215-574-3177

Data Management
alznet-data@acr.org
215-574-3216

TRIAD
triad-support@acr.org
703-390-9858

LET US KNOW

How to Update Site Contact Information

Our database includes the contact information submitted on the Staff Registration Survey.

Register New Staff
Use the Staff Registration Survey

Remove or Change Staff Information
Contact alz-net@acr.org

Have Feedback?

We want to make site participation in ALZ-NET as smooth as possible and welcome your feedback. We solicit input periodically via site surveys, or you can email alz-net@acr.org at any time with concerns or suggestions for improvement.

Startup and Training

Site Activation Flow Chart

All About Contracting

All About IRB

Training Index

Site Activation FAQs

Funding, Payment, and Billing Essentials

Consent Talking Points

Site Activation Flow Chart

Use this chart to track completion of the steps required for activation. The following pages will provide details about each of these steps.

We suggest starting these first since they can take longer.

QUESTIONS?

Join Office Hours

SITE AGREEMENT

Contact: alznet-contracts@acr.org

Submit template* for institutional review (MM/DD/YY) → Agreement executed (MM/DD/YY)

IRB APPROVAL

Contact: alznet-regulatory@acr.org

Execute IRB agreement
Refer to: IRB Guidance
(MM/DD/YY) →

Send ICF* changes to ALZ-NET (if needed)
(MM/DD/YY) →

Obtain Advarra IRB approval
(MM/DD/YY)

Complete these in any order. Please include your Site ID on all documents.

TRAINING AND REGISTRATION

Contact: alz-net@acr.org

For staff consenting and registering patients

PROTOCOL
Review protocol* and Training Module, send Acknowledgment Forms (Investigator and Support Staff) to ALZ-NET
(MM/DD/YY)

RMS
Create ACR Okta account, complete user registration
Refer to: RMS Training Module
(MM/DD/YY)

For staff entering data

MEDIDATA RAVE
Receive activation email, log in to register
Refer to: Medidata Rave Training
(MM/DD/YY)

For staff submitting images (if applicable)

TRIAD
Register for and install TRIAD
Refer to: Image Upload Instructions
(MM/DD/YY)

Once per site

PAYMENT Submit EFT Form and signed W-9 via Box (MM/DD/YY)

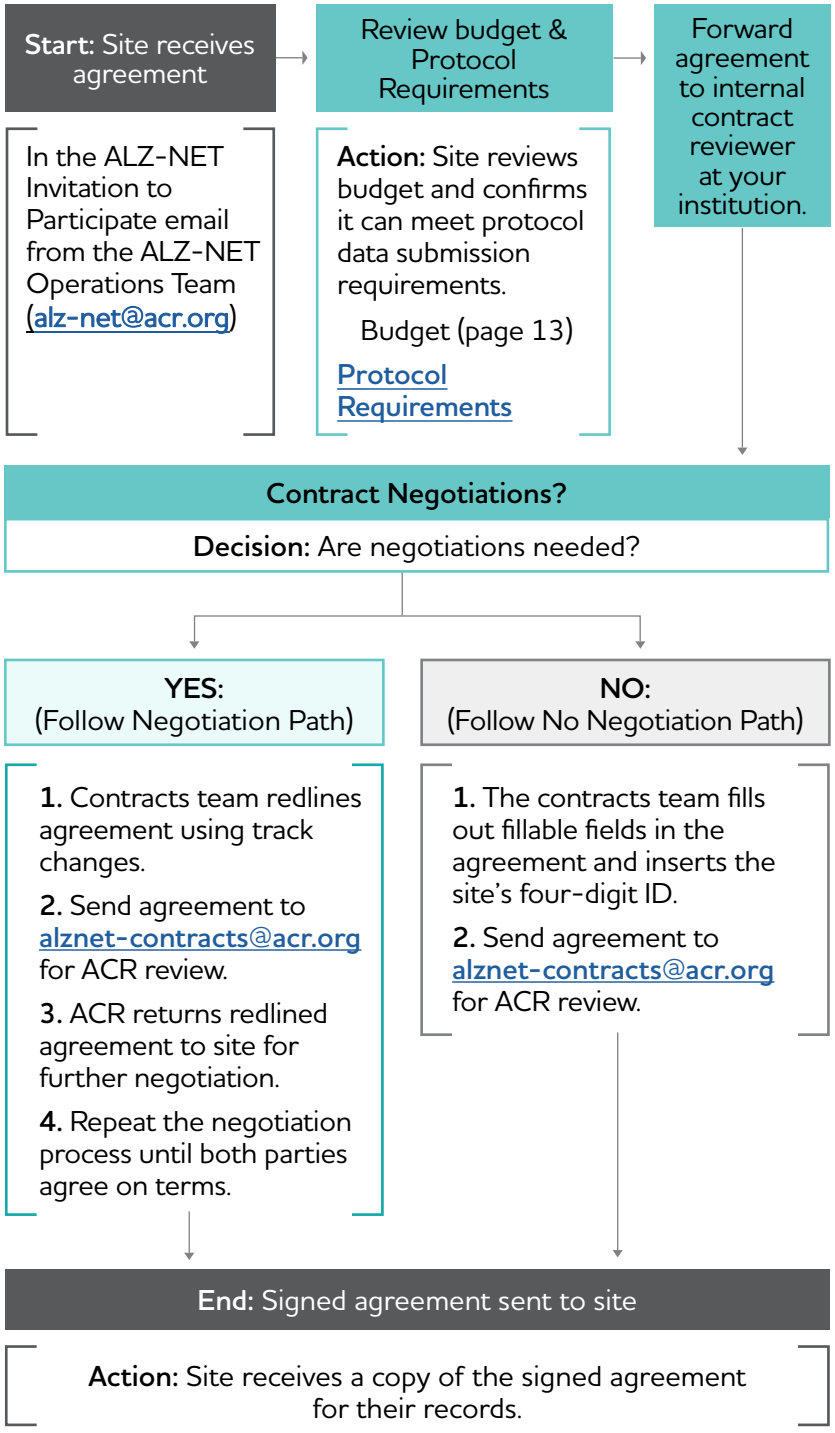
↓

Receive Activation Memo from alz-net@acr.org (MM/DD/YY) → **GO!** *Begin patient registration*

*Attached to ALZ-NET Invitation to Participate email sent by alz-net@acr.org.
EFT, electronic funds transfer; ICF, informed consent form

All About Contracting

PROCESS



CONTRACTS QUESTIONS

ALZ-NET Contracts Team

alznet-contracts@acr.org

Sites are encouraged to join ALZ-NET office hours to discuss any questions pertaining to the agreement.

DID YOU KNOW?

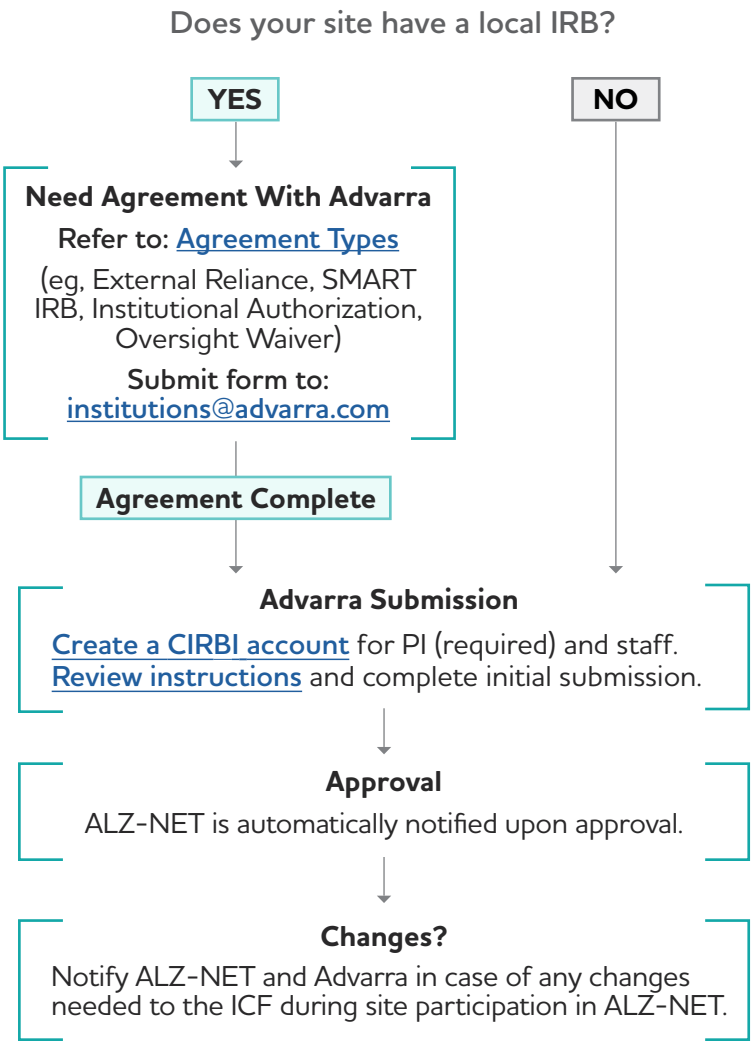
- ACR is the contracting entity for ALZ-NET and handles operations. The Alzheimer's Association is the sponsor of ALZ-NET.
- The funding schedule within the contract is non-negotiable.
- Contracts must be signed by the individual or authorized signatories for the institution.

CONTRACTING TIPS

- Start this process early! Contracting tends to be a rate-limiting step.
- Review the site payment plan to ensure feasibility.
- Confirm the site is capable of completing all protocol-related tasks before proceeding with contracting.
- Send your contracting team your site's four-digit ID provided in the email.

All About IRB

PROCESS



QUICK FACTS

All sites must use Advarra IRB as the IRB of record.

Local IRBs are not permitted to serve as the IRB of record for ALZ-NET, but they may need to review and acknowledge (per local policy) before a site can enroll.

Advarra IRB protocol number for ALZ-NET: Pro00064645

ICF TIPS

- Find the ICF template in your welcome email or CIRBI (IRB Issued Documents tab).
- The ICF does not contain a HIPAA section, so sites can add language or use a separate HIPAA form.
- Advarra does not require review of separate HIPAA forms, but sites can submit them if preferred.
- Any changes to the ICF require approval by ALZ-NET first.

ALZ-NET IRB QUESTIONS

ALZ-NET Resources
ALZ-NET IRB Guidance
alznet-regulatory@acr.org

Office Hours:
Tuesdays 12–2 pm ET
Wednesdays 2–4 pm ET

Advarra Resources
Advarra IRB Handbook
(on CIRBI under Reference Materials)

Help Desk (8:30 am–8:00 pm ET):
1-886-992-4724

institutions@advarra.com or
cirbi@advarra.com

Training Index

The table below outlines training that site staff need to complete during site activation. These trainings will equip the team with the necessary knowledge and tools to follow ALZ-NET protocol requirements and efficiently navigate the data systems used for enrollment and data collection.

DID YOU KNOW?

Sites can schedule a virtual protocol training by emailing alz-net@acr.org (include your team's availability and time zone).

Training	Description	Documentation required?	Prerequisites?	Est. time
Required for all staff consenting and registering patients				
Protocol Training	Provides an overview of ALZ-NET, affiliated studies, and site expectations. See also: Protocol Synopsis	Return investigator and staff acknowledgement forms to alz-net@acr.org.	None	30-60 min.
Human Subjects Protections (HSP)	Standard research training provided by your institution or an accredited body (free CITI course available).	Upload certificate (<3 y old) when registering for RMS.	None	Varies
Research Management System (RMS)	Introduces ALZ-NET's case registration application, including how to create an account and register patients.	No	Protocol Training, HSP training certificate	10 min.
Medidata Rave	Instructs staff on how to access ALZ-NET in Medidata Rave and enter patient information in the electronic data capture (EDC) system.	The EDC system records when the required eLearning is completed and grants access to ALZ-NET data entry.	ALZ-NET Medidata Rave account	30 min.
Required for staff submitting images (if applicable)				
TRIAD Image Submission	Guides staff on how to access TRIAD and upload brain images—for sites participating in image sharing.	No	ACR Okta account, TRIAD software installed	15 min.
Recommended for staff entering data				
eCRF (Baseline and Follow-up)	Describes how to complete the baseline and follow-up case report forms in Medidata Rave.	No—optional training.	RMS and Medidata Rave Trainings	30-45 min.

Site Activation FAQs

Our local IRB is pushing back about using Advarra. Can we use our local IRB?

No. All participating sites are required to use Advarra as the IRB of record for ALZ-NET. Local IRB stamp of approval or acknowledgement is allowed, but oversight of study conduct must be ceded to Advarra through a formal agreement.

Does ALZ-NET require the use of a delegation of authority log?

No. ALZ-NET uses the Staff Registration Survey to collect all required information on site investigators and staff. Site PIs are responsible for regulatory compliance and operations at their site. PIs are not required to complete assessments or enter data and can delegate these responsibilities if they wish.

What HSP training is required for site investigators and staff?

HSP training from an external organization or employer within the past 3 years is acceptable. A certificate of training completion is required. Site staff without a current certificate may complete the CITI HSP training ("Human Subject Research - Basic" course) free of charge by affiliating with the American College of Radiology during the CITI registration process.

Can our site receive group instruction to complete the ALZ-NET training?

ALZ-NET offers the option for sites to schedule a virtual protocol training. If interested, please email alz-net@acr.org with your team's availability and time zone. All other trainings are completed asynchronously via recordings or PDFs.

How long does it take for a site to become activated for enrolling patients in ALZ-NET?

Time to activation varies by institution and is dependent on local processes, but most sites are able to become active within 4 months. Sites experiencing challenges with activation steps may contact alz-net@acr.org or attend Office Hours for assistance.

How can I find a list of other clinical research sites participating in the ALZ-NET trial?

To find other participating sites, visit the site list on our website. This list is updated frequently to ensure you have the most current information and can easily connect with other collaborators.

Why aren't all our site staff receiving the ALZ-NET emails?

Ensure all site staff have been registered via ALZ-NET's Staff Registration Survey. If registered staff are not receiving the appropriate ALZ-NET communications, please contact alz-net@acr.org so we can update our records.

View more FAQs

Funding, Payment, and Billing Essentials

SITE COMPENSATION

ALZ-NET provides remuneration to help support time and resources spent on startup and data entry, as outlined in the table.

Once per site	
Site Activation	$2,500
10th Patient Registration	$5,000
Once per patient enrolled	
Case Registration and Baseline Submission	$300
Per each data submission	
Follow-up Submission	$150
Imaging Data Submission	$50

QUICK FACTS

For Medicare beneficiaries (Part B or C), enrollment in ALZ-NET permits coverage of traditionally approved monoclonal antibody treatments for Alzheimer's disease.

There is no direct cost for sites and clinicians to participate in ALZ-NET. Sites receive the usual payment and cost-sharing to administer treatment, plus compensation from ALZ-NET to support data entry.

ALZ-NET ClinicalTrials.gov Number: NCT06170268

Site Payments

Site payments are transmitted electronically via the details provided on the Electronic Funds Transfer Form submitted during site activation.

Payments are completed once a month for all site activity completed in the prior month. Sites can contact alz-net@acr.org for an itemized listing showing amounts paid by patient and type.

WHAT DO PATIENTS PAY?

There are no added costs to patients for taking part in ALZ-NET or its optional parts. All treatments and diagnostic procedures are charged to the patient's health insurer, as they would be without participating in ALZ-NET.

As with any medical service covered by insurance, patients are still responsible for any deductible or co-pays required for the service. Amounts for any co-insurance or co-pay are determined by the patient's insurance.

Any costs incurred would exist whether a patient is participating or not. However, for Medicare beneficiaries, participation in ALZ-NET permits the coverage of certain drugs.

Patients will not receive any compensation for participating in ALZ-NET.

- CMS Patient Fact Sheet: Medicare Coverage for Alzheimer's Drugs

BILLING

Send ALZ-NET's billing guidance to the billing team of the provider administering treatment.

Registration in ALZ-NET must occur prior to a patient receiving coverage for an approved therapy. Include the ALZ-NET NCT number on the claim submission form.

If a patient is enrolled in one registry but wants to switch to ALZ-NET, register the patient in ALZ NET and update the NCT number on the claim submission form.

Save ALZ-NET patient registration confirmation emails to provide as documentation in the event of a CMS audit.

Disclaimer: Every reasonable effort has been made to ensure the accuracy of this information. Nevertheless, the ultimate responsibility for correct coding and billing lies with the user. ALZ-NET makes no representation, warranty, or guarantee that these resources are error-free or that the use of these resources will prevent differences of opinion or disputes with payers. ALZ-NET will bear no responsibility or liability for the results or consequences of the use of these resources.

BILLING RESOURCES

See ALZ-NET's Medicare Reimbursement Information for:

- Medicare billing guidance
- Example claim submission forms (for treatment and imaging)
- CMS reimbursement rates
- Coding details
- Links to articles, fact sheets, templates, and more

Consent Talking Points

This handout covers some common patient questions about ALZ-NET participation to assist site staff during the informed consent process. These talking points are not intended to be a script. All scripts used in patient conversations must be IRB approved.

What is a registry?

Registries are common tools in clinical settings. They have helped gather information on patient outcomes for decades.

Registries collect health information, such as details from office visits and patient medical records. Sometimes registries collect imaging and specimens. They gather information from many patients over time. This helps answer questions such as:

- Does a treatment meaningfully improve health outcomes?
- How well does a treatment work for patients in broad community practice?
- How do treatment benefits and harms change over time?

Registries have strong privacy protections. They also follow laws and regulations that apply, such as HIPAA.

Why does ALZ-NET ask for personal information, including social security number?

Personal information includes your name, address, social security number, health insurance number, and birth date. It also includes contact details like phone number and email address.

ALZ-NET asks for these so researchers can request information from your health insurer. Your insurer may have more details about your medical care than your memory care provider. ALZ-NET may also use the information to contact you, if you agreed.

How is my information protected?

ALZ-NET takes extra care to protect your information. Once you join, ALZ-NET uses a number to identify your health data. It stores your name and other personal information separately.

Only trained and approved staff can see your personal information. ALZ-NET staff may only access these details for certain purposes such as requesting your health insurance claims. When ALZ-NET shares your health data for research, it will not share your name or personal information.

Refer to the ICF for more details.

Consent Talking Points

This handout covers some common patient questions about ALZ-NET participation to assist site staff during the informed consent process. These talking points are not intended to be a script. All scripts used in patient conversations must be IRB approved.

What is the role of the Alzheimer's Association in ALZ-NET?

The Alzheimer's Association sponsors the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET). Dr. Maria Carrillo, the Association's Chief Science Officer and Medical Affairs Lead, serves as a Co-Principal Investigator of ALZ-NET alongside Drs. Gil Rabinovici and Michael Rafii. The Association also plays a key role in overseeing ALZ-NET and guiding data analysis and interpretation.

What is ACR's role in ALZ-NET?

The American College of Radiology (ACR) serves as the Operations Center for ALZ-NET, offering expertise and guidance to ALZ-NET investigators on imaging-related matters.

Enrollment and Data Collection

Power of ALZ-NET Data

ALZ-NET Data Collection 101

Data Systems Overview

System Registration

RMS Quick Reference Guide

Medidata Rave Quick Reference Guide

TRIAD Quick Reference Guide

Image Submission Best Practices

Data Collection FAQs

Power of ALZ-NET Data

ALZ-NET enables responsible sharing of de-identified data, brain imaging, and biospecimens with the research community to support data insights and emerging science that can inform care and benefit patients.

Data submitted by ALZ-NET sites will help answer these questions and many more…

ALZ-NET Data Collection 101

Quality, consistent data are critical to building a usable ALZ-NET dataset that can fuel new discoveries to improve care. With the rapidly transforming landscape of Alzheimer's treatments, longitudinal real-world data are more important than ever. This handout introduces the fundamentals of ALZ-NET data collection. The rest of this section contains details on data entry.

ESSENTIAL RESOURCES

Summary Table of Data Elements
Provides an overview of the mandatory and optional data elements that should be collected.

eCRFs

eCRF packets are available for download as reference. Sites enter data electronically via ALZ-NET data systems. A patient's electronic medical record may serve as source documentation for ALZ-NET, as an alternative to paper source documentation. Consult your institution's local guidelines regarding source documentation requirements.

- ALZ-NET Baseline Case Report Form
- ALZ-NET Follow-Up Case Report Form

DATA SOURCES

All data must be entered into ALZ-NET's EDC systems. Acceptable sources of the data that sites enter are:

- Patient electronic or paper medical records
- Physician notes from patient encounters
- Data provided by patients and caregivers

ALZ-NET VS CMS REGISTRY

ALZ-NET qualifies as a Coverage with Evidence Development (CED) study, providing a pathway to Medicare coverage for FDA-approved anti-amyloid Alzheimer's therapies. This means patient registration into ALZ-NET fulfills the evidence-gathering requirement for Medicare coverage, and **you only need to enter patient data into one system**.

See Funding, Payment, and Billing Essentials for more information.

FORMS AT-A-GLANCE

Baseline and Follow-up

- Reporting period and patient status
- Medical history
- Vital signs
- Concurrent studies
- Lifestyle data
- Patient characteristics
- Copathology
- Additional measures
- AD diagnosis
- Novel therapy
- Clinical imaging submission

Patient Level

- Concomitant medications
- Adverse events
- ARIA adverse events
- TRIAD submission log

REQUIRED VS OPTIONAL DATA ELEMENTS

The ALZ-NET protocol was created with the intention to balance the need for gathering data to answer important questions against the realities of busy real-world clinical practice.

All forms listed within the Summary Table of Data Elements must be submitted within the ALZ-NET EDC. The forms listed as optional (o) have yes/no lead-in questions that control whether the entire form becomes available for completion or not.

IMAGING DATA

Imaging studies submitted to ALZ-NET must be exams conducted as part of routine clinical care, such as Amyloid PET, Amyloid PET/CT, Amyloid PET/MR, Tau PET, Tau PET/CT, Tau PET/MR, or MRI brain scans. Radiology reports for each uploaded image must also be submitted via TRIAD in PDF format. Once a scan is submitted to TRIAD, key details are automatically transferred to the ALZ-NET database, and the scans are archived at the ACR CRI. Refer to the TRIAD Quick Reference Guide on page 23 for training resources and submission instructions.

MISSING DATA

Sites are required to submit data on all forms no later than 30 days after the close of a data entry time point for each patient. After the 30-day window, open forms will be included on the site's missing data report, which is distributed monthly.

DATA REVIEW PROCESS

Sites receive a monthly data report with overdue forms and open queries. The report comes via an automated email from noreply@mdsol.com with the subject "ALZ-NET (A4709) Monthly Reports - site 6XXX".

The email contains an Excel file with 4 tabs:

- Forms SUMMARY
- Queries SUMMARY
- Forms OVERDUE
- Queries OPEN

For guidance on how to navigate to and answer queries, please refer to the Medidata Rave Training module or email alznet-data@acr.org.

DID YOU KNOW?

While site staff should make a reasonable effort to capture and submit all required data elements, the system does allow for "unknown (UNK)" to be entered for many of the questions, including full or partial dates.

Data Systems Overview

RESEARCH MANAGEMENT SYSTEM (RMS)

Purpose	Case registration application for ALZ-NET. Users confirm eligibility and enroll patients in this system.
Access	Who: Any site staff who register patients How: ACR Okta account
Reference	RMS Training
For Help	Email alz-net@acr.org or call (215) 574-3181

Visit RMS

MEDIDATA RAVE

Purpose	Electronic data capture application for ALZ-NET. Users enter patient data via forms in this system.
Access	Who: All site staff entering patient data How: Unique login for this application (created via an activation email)
Reference	Medidata Rave Training
For Help	Email alz-net@acr.org

Visit Medidata Rave

TRANSFER OF IMAGES AND DATA (TRIAD)

Purpose	Image submission software for ALZ-NET. Users upload imaging studies and accompanying reports to the ACR Center for Research and Innovation.
Access	Who: Site staff who submit images How: ACR Okta account after installing TRIAD software
Reference	Image Submission Instructions and TRIAD User Guide
For Help	Email triad-support@acr.org or call 703-390-9858

Visit TRIAD

System Registration

Complete the following steps to register for ALZ-NET data systems. Each user must have their own account.

RMS

1. Visit acr-patientregistration.acr.org. Create your ACR Okta account first and click "**Register**."
2. Locate the "**Welcome to ACR ID**" email (check spam folder) and use the activation link.
3. Type your username under "**Please Enter Your ACR Login**" (email address used for ACR ID).
4. **Select** "**ALZ-NET**" as the Group.
5. Select your institution name, which will have ALZ-NET at the end. You can also search by your Site ID. Enter the **Protocol Number for ALZ-NET: 4709**.
6. You will receive an email once the ALZ-NET Operations Team approves your account.

MEDIDATA RAVE

1. Once the ALZ-NET Operations Team adds you to your site, you will receive an email from Medidata-Notification@mdsol.com. **Click the link in it to activate your account**.
2. **Log into Medidata Rave** and accept the pending invitation on the right side of the screen.
3. **Complete the mandatory eLearning course**, "Medidata Classic Rave EDC Essentials for Clinical Research Coordinators," if not already done.

TRIAD

1. **Install** the TRIAD software on computers within the institutional firewall or network that staff will use for submitting images.
2. Visit the TRIAD website and click "**Login with ACR ID**." Use your ACR Okta login details.
3. Click on "**Site User**."
4. Enter your "Site Name." You can also search by your Site ID. The **ALZ-NET Trial Number is 4709**. Click "Continue."
5. Review the information for accuracy, then click "**Submit**." *(Note: Your Site Name should have "ALZ-NET" next to it.)*
6. You will receive an email within one business day once the ALZ-NET Operations Team approves your account.

TIPS

Bookmark the login page for each data system.

If you encounter any issues, email for assistance: alz-net@acr.org.

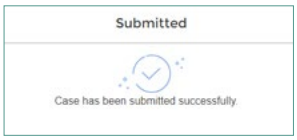
RMS Quick Reference Guide

Use this system to confirm eligibility and register patients into ALZ-NET.

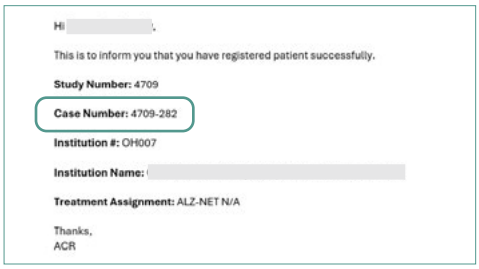
REGISTERING A PATIENT

Estimated time to complete: 10-20 min.

1. Log into RMS.
2. Click the "**New Patient Registration**" box.
   - To see enrolled or incomplete patient registrations, click "View Subjects for applicable study."
   - If you start a patient registration but don't finish it, you can retrieve it by clicking "Incomplete Registration" on the next screen.
3. **Complete and submit** the required information.



4. Registration complete.
   - You will receive a confirmation email. Save this email for your records.
   - The Patient ID (Case Number) will now be available in Medidata Rave to begin entering data.



IMPORTANT LINKS

Login at:
acr-patientregistration.acr.org
Use ACR Okta account

RMS Training

TIPS

Do not use your browser's back button during registration. This will log you out of RMS.

You have 7 calendar days from the initial registration date to complete a patient enrollment, or your progress will be deleted.

NEED HELP?

Contact alz-net@acr.org or 215-574-3181

Medidata Rave Quick Reference Guide

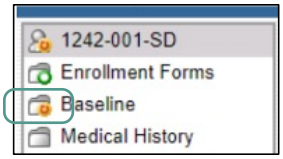
Use this system to enter participant clinical data for ALZ-NET.

ENTERING PATIENT DATA

Estimated time to complete: 30-60 min. for baseline
20-40 min. for follow-up

1. On the Medidata Rave homepage under ALZ-NET, **click on** "**Rave EDC**" to access your site's enrolled patients.
2. Click a Subject ID and navigate to the desired form.
3. Complete the form and **click** "**Save**" at the bottom of the page before proceeding.

4. Click the **Subject ID tab** to view which forms are outstanding or completed.
   - Select the next form to complete.
   - If a form has a field that contains an error or was left blank, a yellow icon will appear next to it. Return to the form to correct.



5. After entering the Baseline visit, follow-up visits will appear but will be grayed out until their time. Complete them **no later than 14 days** after the date shown.

IMPORTANT LINKS

Login at:
login.imedidata.com/login
Use Medidata Rave login

Medidata Rave Training
eCRF Training

TIPS

Baseline data must be entered within 14 days of patient registration.

Enrollment Forms and *Demography* are read-only because the data come from RMS (as entered during patient registration).

NEED HELP?

Contact the ALZ-NET Data Management Team: alznet-data@acr.org.

TRIAD Quick Reference Guide

Use this system to submit imaging studies and reports to ALZ-NET.

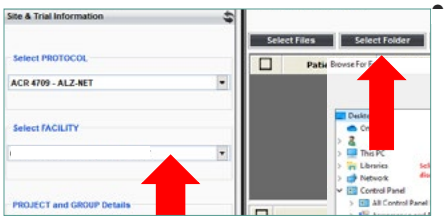
SUBMITTING IMAGING STUDIES

Estimated time to complete: 5–30 min. (average 15 min.)

1. Select image files following the procedures based on how TRIAD is configured on your network:

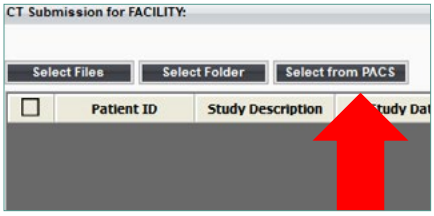
   If image files are on **CD or an internal network location**:

   - Choose your site from the "Select FACILITY" drop-down menu
   - Then click "Select Folder" to choose the image file



   If image files are on the **scanner console or internal PACS destination**:

   - Click "Select from PACS" to choose the image file



2. Images ready for submission will appear in a list. Select the images you want to submit and **click** "**Move to Submission Queue**."
3. Select the Subject ID and Image Code (submission type).

4. Click "**Submit**."
5. Submit radiology reports using this same process. ***Radiology reports must be PDFs***.

IMPORTANT LINKS

TRIAD Support
Image Submission Instructions
TRIAD User Guide

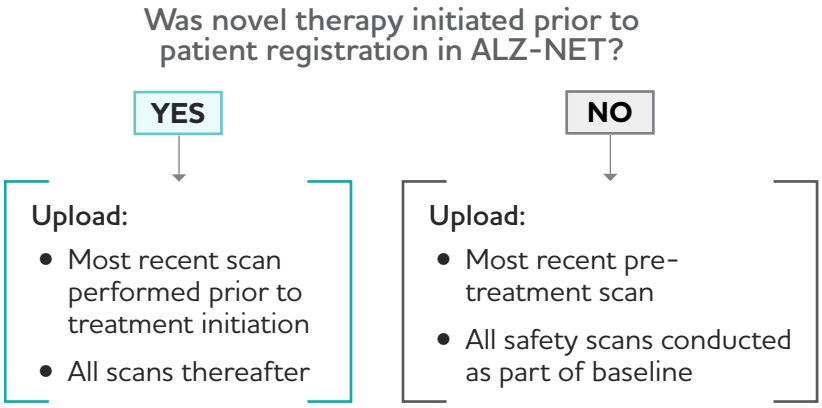
NEED HELP?

TRIAD tech support is available Monday through Friday, 8 am–5 pm ET:
703-390-9858
triad-support@acr.org

Image Submission Best Practices

ALZ-NET is focusing on MRI, amyloid PET, FDG-PET, and tau PET scans. Radiology reports associated with each uploaded image are also required to be uploaded via TRIAD.

BASELINE IMAGES



Does the baseline in ALZ-NET need to match the baseline of treatment?

No. Baseline may include images taken over several months, reflecting doses administered before registering in ALZ-NET.

IMAGE BEFORE AND AFTER TREATMENT

After the baseline images, continue to upload any subsequent images taken during the patient's ALZ-NET participation.

NO REDACTION NEEDED

The TRIAD system removes personal identifying information from image files on the local machine before submission. TRIAD replaces Patient Name and Patient ID fields with the trial-specific ALZ-NET Case ID Number.

Radiology reports do not need to be redacted because patients agreed to the sharing of personal information with ALZ-NET by signing the ICF. However, some institutions may have their own requirements for de-identification prior to submission.

RESOURCE

Please share with your site staff to support consistency in reports:

Brain MRI Reporting Template for Emerging Alzheimer's Therapeutics

NEED HELP?

For questions about imaging expectations for ALZ-NET, contact:

Rebecca DiGati, CMNT Senior Imaging Services Specialist: rdigati@acr.org or 215-574-3175

Data Collection FAQs

I already have a Medidata Rave account. Can I use this for ALZ-NET?

Yes. Provide the email address used for your Medidata Rave account in the Staff Registration Survey or email alz-net@acr.org. The ALZ-NET Operations Team will add a user profile for each provided email address. For existing Medidata Rave users, an invitation to access the ALZ-NET EDC will appear in Medidata Rave.

I registered my account in Medidata Rave. Why do I not see ALZ-NET?

When initially invited to join ALZ-NET in Medidata Rave, an eLearning module must be completed. Please ensure that the eLearning has been completed. If ALZ-NET is still not showing up, please contact the ALZ-NET Operations Team at alz-net@acr.org.

I didn't get a Medidata Rave activation email, so I can't log in—what do I do?

ALZ-NET uses the Staff Registration Survey to collect information on which applications site staff need to access. Users will receive an activation email from Medidata-Notification@mdsol.com. Check that the activation email didn't go into a spam folder. If registered staff did not receive the activation email, please contact alz-net@acr.org.

Our site has new staff. How do we get them access to the ALZ-NET data systems?

Complete the Staff Registration Survey and indicate which applications site staff need to access. To expedite the process, please also email alz-net@acr.org after submitting the registration survey. The ALZ-NET Operations Team will process the request and initiate account access.

I am receiving a query in Medidata Rave that I do not understand how to close. How can I fix this?

For questions regarding queries in Medidata Rave, please contact alznet-data@acr.org.

Does the PI have to do the assessments for ALZ-NET?

PIs are not required to complete assessments or enter data and can delegate these responsibilities if they wish.

Is there a certain version of the Mini-Mental State Examination (MMSE) and the Montreal Cognitive Assessment (MoCA) that should be used?

No, there is no preference for version number. Please use the version that is used in everyday practice at your site.

Does a patient need to be seen every 6 months for ALZ-NET?

Not necessarily. Patients should be seen by their clinician per the standard care that would be provided by the site, even if the patient was not enrolled in ALZ-NET. The data collection time points outlined by the ALZ-NET protocol are just time intervals in which data should be entered, not a mandatory visit schedule.

View more FAQs

Acknowledgments

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ALZHEIMER'S NETWORK
ALZHEIMER'S ASSOCIATION

ALZ-NET Partnering Organizations

ALZHEIMER'S ASSOCIATION
American College of Radiology
ASNR American Society of Neuroradiology
School of Public Health BROWN UNIVERSITY