Clinical Trial Management System (CTMS) serves as the case registration application for ALZ-NET.
## Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Slides</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTMS Overview</td>
<td>Slide 3</td>
</tr>
<tr>
<td>Registering for an ACR Okta account</td>
<td>Slides 4-7</td>
</tr>
<tr>
<td>CTMS User Registration</td>
<td>Slides 8-15</td>
</tr>
<tr>
<td>How to Register a Patient</td>
<td>Slides 17-27</td>
</tr>
</tbody>
</table>
CTMS Overview

The Clinical Trial Management System (CTMS) will be used to register patients and confirm eligibility criteria.

CTMS can be accessed by clicking this link: https://clinicalweb.acr.org/ClinicalAcrin/faces/jsp/index.jsp

Accessing CTMS is a 2 Step Process:

- **ACR Okta** – This account is needed before creating a CTMS account. This will serve as your ACR ID.
- **ACRIN – Protocols** – This account is for access to CTMS only. Users that will be registering patients into CTMS must have access to this application.

*Please note that the preferred browser for using CTMS is Mozilla Firefox*
Creating an ACR Okta Account
Creating an ACR Okta Account

- Each user must have their own Okta Account. Ensure that the email being entered is a current email address.
- Passwords must be changed every 90 days.
- If you have participated in IDEAS/New IDEAS, you already have an ACR Okta Account, and may just log in directly. If you have issues accessing your account, please reach out to alz-net@acr.org
Creating an ACR Okta Account

1. Create your account and click “Register.”
2. Locate the ‘Welcome to ACR ID’ email in the email inbox you used to register and follow the one-time link to activate your account. Simply clicking on this link will activate your account (Note: check spam folder)
3. Return to the application’s home page (on previous slide).
4. Type in your username underneath Please Enter Your ACR Login (email address used to create ACR ID).
5. Set up Okta (two-factor authentication).
6. Return to the login portal and login with username and two-factor authentication.

Note: You will have to utilize a ‘multifactor authentication’ mechanism to log in each time. This is for security purposes.

Save your username and password. This is your ACR ID to be used across all ALZ-NET applications.

When you are done filling out the required fields, click ‘Register’
Logging into ACR Okta

ACR Okta will prompt to send a push to the mobile device that was registered with Okta. This is the multi-factor authentication. This is an example of what the prompt will look like.
CTMS User Registration
CTMS User Registration

Login with your email address. You must be logged into Okta before accessing CTMS.
CTMS User Registration

• After logging in with Okta, you will be directed to the CTMS homepage.
• To register for your ACRIN Account, please select **ACRIN – Protocols** and you will be redirected to create an account.
  • *Please note, if you have participated in IDEAS/New IDEAS, you **will still need to** create an ACRIN - Protocols account.
CTMS User Registration

The same web link that was used to create the ACRIN account will be used for logging in. **Please bookmark this page.**


Select **ACRIN- Protocols** under the ACTIVE section
Account activation is required for data center access on the ACRIN Web site. Also, radiologists who will provide data for imaging-related case report forms must obtain a Reader ID. To obtain account access or a reader ID, please supply all information requested.

* fields are mandatory

Cooperative Group: ACRIN - American College of Radiology Imaging Network

This is the page that will first appear when you are creating your User Profile. Select “ACRIN – American College of Radiology Imaging Network” and click ‘Submit’
<table>
<thead>
<tr>
<th>Field</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooperative Group</td>
<td>Select your institution from the drop-down menu</td>
</tr>
<tr>
<td>Primary Institution</td>
<td>Please select your prefix from the drop-down menu</td>
</tr>
<tr>
<td>Prefix</td>
<td>Enter your first and last name. Middle name is not required.</td>
</tr>
<tr>
<td>First Name</td>
<td>Enter your degree from the drop-down menu</td>
</tr>
<tr>
<td>Middle Name</td>
<td>Please enter your email and ensure that it is current and you have access to it.</td>
</tr>
<tr>
<td>Last Name</td>
<td>Leave the ACR Staff box unchecked.</td>
</tr>
<tr>
<td>Degree</td>
<td>Select No for Reader ID</td>
</tr>
<tr>
<td>Person Title</td>
<td>Please enter a phone number. This can be your practice office number</td>
</tr>
<tr>
<td>E-mail</td>
<td></td>
</tr>
<tr>
<td>ACR Staff</td>
<td></td>
</tr>
<tr>
<td>Do you require Reader ID?</td>
<td></td>
</tr>
<tr>
<td>Phone Number (USA Only):</td>
<td></td>
</tr>
</tbody>
</table>
User Registration Continued

Human Research Subject Protection Training Certificate is **required** for complete registration of your ACRIN – Protocols account. Examples of accepted certifications are CITI and NIDA.

If training is needed, ACR will cover the cost through affiliation with CITI. Users may affiliate with the American College of Radiology during their CITI registration process in order to complete the “Human Subject Research – Basic” course, free of charge.

Select ALZ-NET, which is Protocol Number **4709**
User Registration Continued

☐ By checking the “I agree” box at the end of this statement, I agree to keep my account and/or reader ID confidential and not to allow its use by anyone else and that the use of my account is the legally binding equivalent of my traditional handwritten signature.

Requestor Name: ___________________________  Date: 9/22/2022

After agreeing to the statement above, type your full name in the Requester Name box. The date will auto-populate. Then, click Submit.
When your account is approved and activated, you will receive an email from websupport@acr.org. Please note that account activation may take up to 1-3 business days.
How to Register a Patient in CTMS
How to Register a Patient in CTMS

If you are not already logged in, sign in with your ACR Okta email address.
How to Register a Patient in CTMS

Your site ID number (Inst No) that was provided via email by the ALZ-NET Operations Center will be displayed here.
How to Register a Patient in CTMS

To add a new patient, click ‘Patient Registration’

All other tabs are not applicable to ALZ-NET. The only tab necessary for navigating CTMS is Patient Registration
How to Register a Patient in CTMS

The Study Number for ALZ-NET is **4709**. Then, click ‘Register’ to continue the registration process.
Patient Registration

1. Name of person registering case

2. Name of treating clinician

3. Date informed consent signed by patient or Legally Authorized Representative (LAR) (MM/DD/YYYY)

4. Date of protocol version for which informed consent was obtained

6. Informed consent provided by:
   - Patient
   - Legally Authorized Representative

7. If provided by LAR, what is their relationship to the patient?

8. In what language was the consent form completed?
   - English
   - Spanish
   - Other language, specify

9. If other language, please specify

10. Has consent been provided for the patient to be contacted about other research studies investigating Alzheimer’s disease for which he or she may be a candidate?
    - No
    - Yes

11. Patient’s Country of Residence
    - USA
    - CA (Canada)
    - Other

12. Patient’s Year of Birth

13. Patient’s sex assigned at birth
    - Male
    - Female
    - Unknown

14. Patient’s self-reported identification of gender
    - Female
    - Male
    - Other Gender Identity, Specify
    - Prefer not to answer
    - Transgender Female
    - Transgender Male

15. Other gender identity, specify

Please use the date of the most current IRB approved version of the ALZ-NET protocol.
When the form is complete, click ‘Submit’
Patient Registration

Inclusion/Exclusion Criteria

1. Patient or patient’s legally authorized representative (LAR) (e.g., spouse or legal guardian) has the ability to understand the purpose and risks of ALZ-NET and provide signed and dated informed consent and authorization to use protected health information (PHI) in accordance with national and local patient privacy regulations.  
   - No
   - Yes

2. Patient is at least 18 years of age at the time of informed consent.  
   - No
   - Yes

3. Patient has a diagnosis of MCI or dementia with clinical suspicion of Alzheimer’s disease (AD) or contributing pathology and 1) is being evaluated for treatment or 2) will be initiating treatment or 3) has already initiated treatment with novel FDA-approved AD therapies in real world clinical practice.  
   - No
   - Yes

4. If treatment is initiated at time of consent, patient meets appropriate label requirements and treatment follows appropriate use recommendations for novel FDA-approved AD therapy/therapies.  
   - No
   - Yes
   - Not applicable

5. Patient’s treating clinician has made the decision to provide clinical care or treatment prior to patient consent and independently of the purpose of ALZ-NET.  
   - No
   - Yes

Answer all questions by clicking either ‘Yes’ or ‘No’ and click Submit
Completing Patient Registration

Patient Registration Confirmation

Study Number
Institution Number
Case Number
Rave Patient Id
Participant Initials
Treatment Arm

4709 - ALZHEIMERS NATIONAL REGISTRY FOR TREATMENT AND DIAGNOSTICS
9999 - Test Institution
26
4709-26
N/A

Treatment Arm is not applicable to ALZ-NET. All patients will have Treatment Arm listed as ‘N/A’

You will be receiving copies of the Registration form you submitted and the Patient Calendar via E-Mail.

Our records indicate that your current E-Mail?address is @acr.org

If this is incorrect, Please contact websupport@acr.org

After clicking Submit, an email will be sent to your email address on file. Please keep records of the Case Number and Rave Patient ID noted on this page.
Hello,

This message is Confirmation of New Case Registration for the ACRIN Study # 4709 and Case # 25. Please find the attached A0.

Thanks,
WebSupport

Note:
This information E-mail is Auto generated by the WebPilot Server On Apr 14, 2023 (Greenwich Mean Time). Replies will not be checked on this server, so please send your Queries to HQ directly for prompt response.

DISCLAIMER:
This message contains privileged confidential information which is not to be disclosed. If you are not the intended recipient of this message please contact websupport@acr.org and destroy this message as well as all existing copies and attachments.
A0 Form Confirmation

This is the attachment on the confirmation email. Here, the patient and physician name can be viewed as well as other specifics of the patient registration. This can be saved for your records.