



# Medidata Rave Training

Medidata Rave serves as the Electronic Data Capture (EDC) application for ALZ-NET.

# Medidata Rave Overview

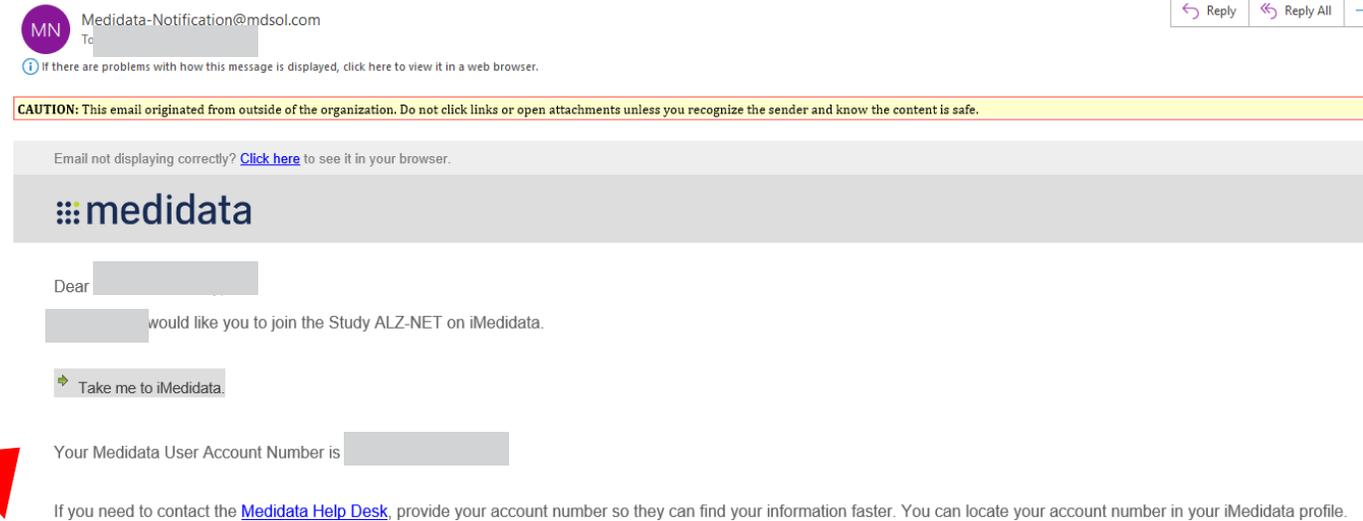
- Medidata Rave serves as the electronic data capture (EDC) for ALZ-NET.
- Each site staff member that will be entering in participant clinical data **must** have a Medidata Rave account to do so.
  - Your Medidata Rave account will be **unique** in that the login **cannot** be used for other applications used for ALZ-NET.

# Logging into Medidata – First Time User

Each user will receive an activation email from [Medidata-Notification@mdsol.com](mailto:Medidata-Notification@mdsol.com) after a member of the ALZ-NET Operations Team adds the user to their applicable site.

This is a *no-reply* email. If you have issues with Medidata registration, please email [alz-net@acr.org](mailto:alz-net@acr.org)

Click *Take me to iMedidata* to activate my account



# Logging into Medidata

<https://login.imedidata.com/login>

**Bookmark this page** and save your login information.

This login information is **unique** to Rave and **will not** grant you access to any other applications.

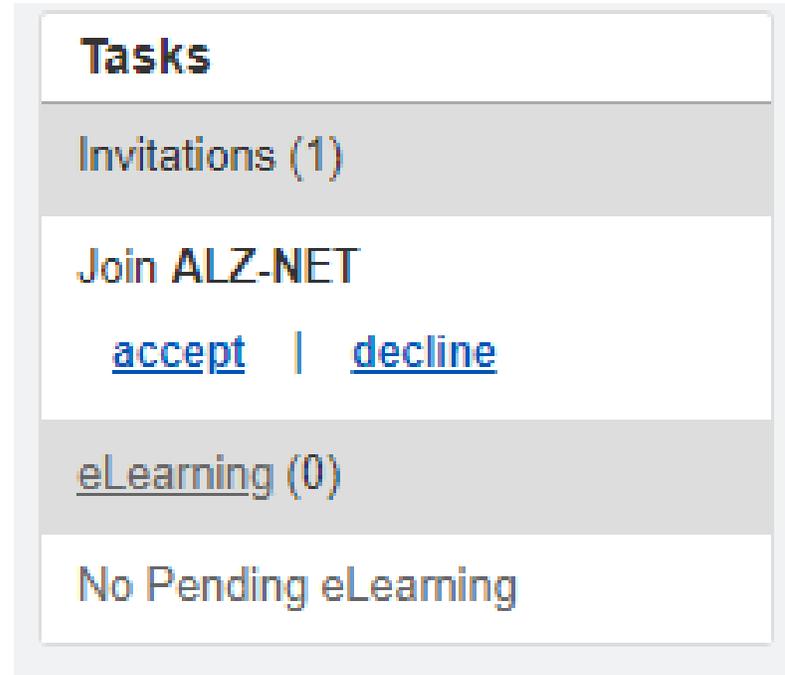
A screenshot of the Medidata login page. The page features the Medidata logo at the top left. Below the logo, the word "Welcome" is centered. The login form includes a "Username" field with the placeholder text "Enter username", a "Password" field with the placeholder text "Enter password" and a toggle icon, and a blue "Log In" button. Below the button, there are links for "I forgot my username or password" and "Activate pending account". At the bottom of the form, there is a language selector set to "English". Below the form, there is a link for "Help Documentation" and footer text: "Medidata Solutions, Inc., a Dassault Systèmes company", "Privacy Policy Terms of Use", and "Copyright © 1999-2022".

# Accessing ALZ-NET in Rave

Upon logging in, there will be a pending invitation on the right side of the screen.

Click '*accept*'

If a user has **not** completed the mandatory eLearning, it will be displayed in the eLearning section. The mandatory course for ALZ-NET is **Medidata Classic Rave EDC Essentials for Clinical Research Coordinators**. This must be completed in order to access the ALZ-NET EDC.



**Tasks**

Invitations (1)

Join ALZ-NET

[accept](#) | [decline](#)

eLearning (0)

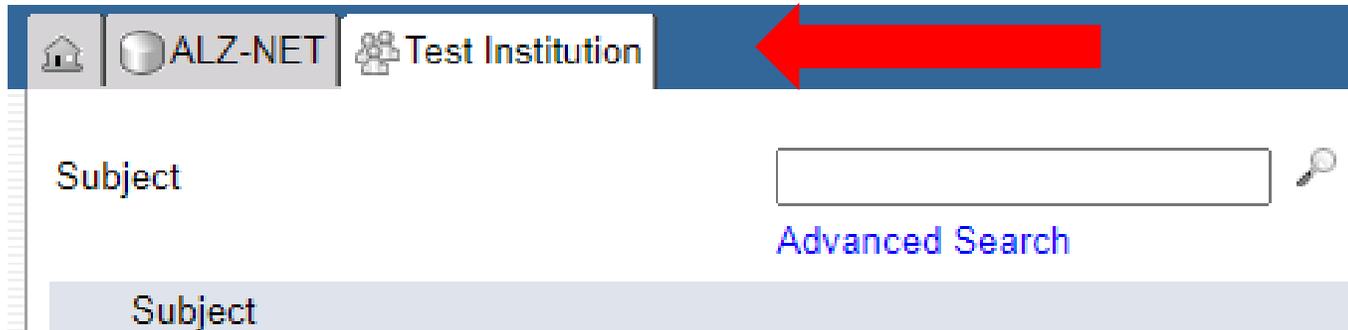
No Pending eLearning

# Medidata Rave Home Page

The screenshot displays the Medidata Rave Home Page interface. On the left is a sidebar with sections: 'Apps' (containing 'RAVE EDC', 'ACR', 'RAVE Modules', 'ACR') and 'My Information'. The main content area is titled 'Studies (3)' and features a search bar. Below the search bar, three study cards are shown, each with a database icon. The first card is for 'ALZ-NET' and includes links for 'Rave Modules' and 'Rave EDC'. A purple arrow points to the 'Rave EDC' link. The second card is for 'ALZ-NET (TST)' with a 'Rave EDC' link. The third card is for 'ALZ-NET (UAT)' with a 'Rave EDC' link.

If a user already has access to Rave, all studies they have access to will be listed. Please utilize **ALZ-NET** by clicking on *Rave EDC*

# Accessing ALZ-NET in Medidata Rave



After clicking on *Rave* EDC, you will be brought to this page. Your Institution name will be listed in the second tab, next to *ALZ-NET*.

There will be a list of Subject IDs below that are enrolled at your Institution

# Entering Patient Information

ALZ-NET Test Institution 1314-KMD-001

Subject Enrollment

Visit	Date
Baseline	01 Jan 2022
6 Month Follow-Up	30 Jun 2022
12 Month Follow-Up	29 Dec 2022
18 Month Follow-Up	30 Jun 2023
24 Month Follow-Up	29 Dec 2023
3 Year Follow-Up	28 Dec 2024
4 Year Follow-Up	28 Dec 2025
5 Year Follow-Up	28 Dec 2026

Prior to entering patient information, please note that it is **recommended** that all data should be entered as soon as possible, and **no later than 14 days** after the folder date.

Once the Baseline visit is entered, the appropriate dates will be derived for all follow up visits. Folders will remain grayed out until the timepoint is reached.

If you have any questions regarding the data entry process, please email the **ALZ-NET Data Management Team** at [alznet-data@acr.org](mailto:alznet-data@acr.org)

# Entering Patient Information

The screenshot displays a web application interface. At the top, a breadcrumb trail shows the path: Home > ALZ-NET > Test Institution > 1242-001-SD. On the left side, a navigation menu is visible, with a red box highlighting the following items: 1242-001-SD, Enrollment Forms, Baseline, Medical History, Concomitant Medication, Adverse Events, ARIA Adverse Events, and TRIAD Submission Log. The main content area features a 'Subject Enrollment' link with a green checkmark icon, and a 'Visit' tab below it.

All tabs to the left must be filled out for each Subject ID. To fill out each section, click on the corresponding form.

When clicking on a section in the highlighted box, a new tab will open next to the Patient ID.

# Entering Patient Information



A screenshot of the Medidata RAVE web application interface. The top navigation bar includes a home icon, "ALZ-NET", "Test Institution", "1242-001-SD", "Enrollment Forms", and "Demography". A left sidebar menu shows "Enrollment Forms", "Demography", and "ALZ-NET Eligibility Checklist", with "Enrollment Forms" selected. The main content area displays "Subject: 1242-001-SD", "Page: Demography - Enrollment Forms", and a form field for "Subject Initials (LFM)". Below this is a label for "Date informed consent signed by patient or Legally Authorized Representative (LAR) (MM/DD)".

*Enrollment Forms* was selected. *Enrollment Forms* and *Demography* are automatically derived from data entered in CTMS during the case registration process. If any data is incorrect, contact the ALZ-NET Data Management Team.

# Entering Data in Medidata Rave

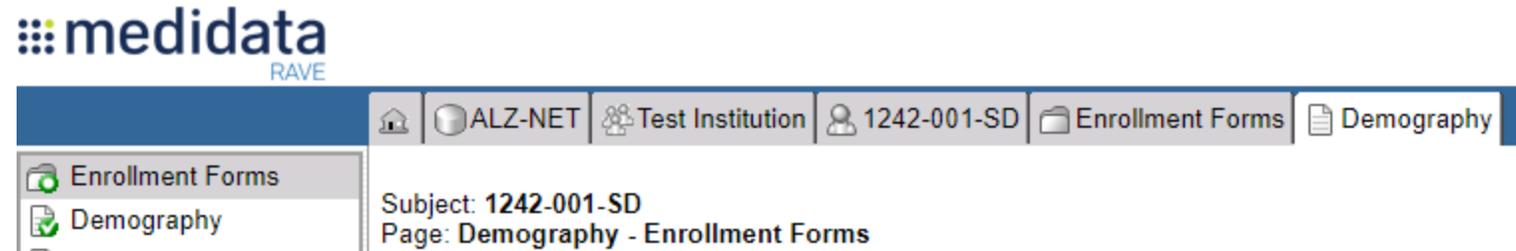
The screenshot shows the Medidata Rave interface. At the top left is the Medidata RAVE logo. Below it is a navigation bar with icons for Home, ALZ-NET, Test Institution, and Patient ID 1242-003-SD. A dropdown menu is open on the left, listing various data entry forms: 1242-003-SD, Enrollment Forms, Baseline, Medical History, Concomitant Medication, Adverse Events, ARIA Adverse Events, and TRIAD Submission Log. The main content area shows a 'Subject Enrollment' link and a 'Visit' table.

The screenshot shows the Medidata RAVE interface for the 'Vital Signs - Baseline' form. The top navigation bar includes Home, ALZ-NET, Test Institution, Patient ID 1242-003-SD, Baseline, and Vital Signs. The left sidebar lists various data entry forms, with 'Baseline' selected. The main content area displays the form instructions: 'Form Instructions: Data elements below must be collected by authorized site staff during standard of care clinical visit.' The form includes sections for 'Assessment Date', 'Was height performed?' (with a 'Height' input field), 'Was weight performed?' (with a 'Weight' input field), and 'BMI (derived)'.

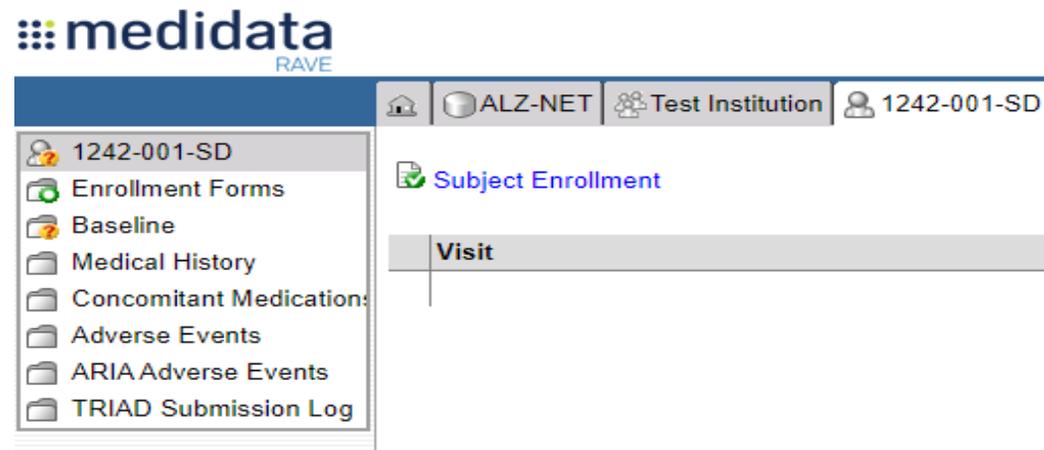
To enter information into a different form, click the Patient ID and navigate to the next form of choice.

# Entering Patient Information

To see what forms are outstanding, click the patient ID tab.



The full list of forms that need to be completed will be listed on the left side of the screen.

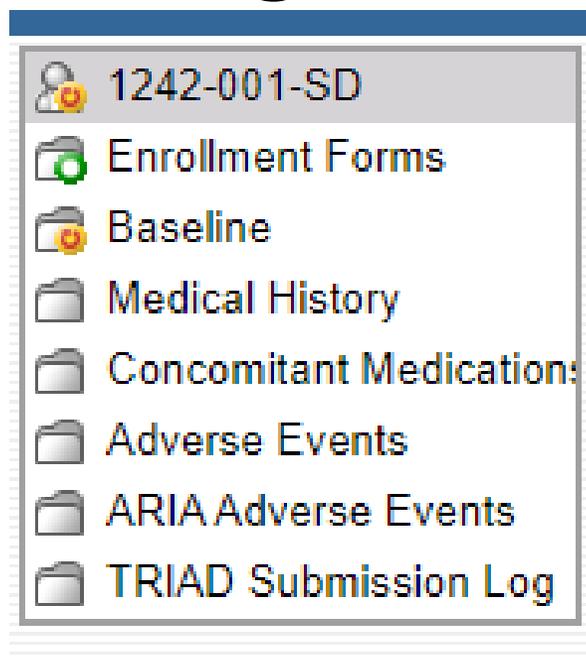


# Accessing ALZ-NET in Medidata Rave

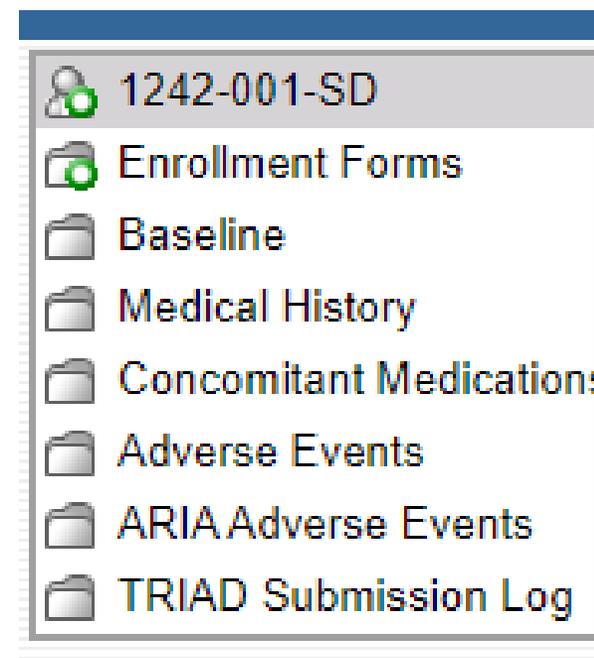
Click 'Save' at the bottom of each page to ensure that all entered information has been saved before moving to the next section.



# Entering Patient Information



If data is not entered correctly, a yellow icon with a red arrow will appear. This indicates that there is a field that is either blank or contains an error. Please go back and make the necessary corrections to complete the form.



After completing each section, click on the Subject ID tab, which will show which sections are completed and which ones are outstanding.

# Entering Patient Information – Medical History

Medical History is entered at each visit

ALZ-NET Test Institution 1242-001-SD Medical History Medical History

Subject: 1242-001-SD  
Page: Medical History - Medical History

Assessment Date  ...

Please enter Assessment Date and Save the page. Then complete the questions that appear below.

#	Medical History Term	If autoimmune disorders, cancer, or other CNS disease, please specify	Did this medical condition occur/ Is this medical condition occurring?	Start Date	Ongoing	End Date?	Coded Medical History Term <i>(derived)</i>	
1	Atrial fibrillation							<input type="radio"/> <input type="checkbox"/>
2	Cardiac Arrhythmia							<input type="radio"/> <input type="checkbox"/>
3	Congestive heart failure							<input type="radio"/> <input type="checkbox"/>
4	Ischemic heart disease							<input type="radio"/> <input type="checkbox"/>
5	Down syndrome							<input type="radio"/> <input type="checkbox"/>
6	Chronic liver disease							<input type="radio"/> <input type="checkbox"/>
7	Autoimmune disorders, specify							<input type="radio"/> <input type="checkbox"/>
8	Multiple sclerosis							<input type="radio"/> <input type="checkbox"/>
9	Chronic infection							<input type="radio"/> <input type="checkbox"/>
10	Diabetes							<input type="radio"/> <input type="checkbox"/>
11	Dyslipidemia							<input type="radio"/> <input type="checkbox"/>
12	Cancer, specify							<input type="radio"/> <input type="checkbox"/>
13	Cerebrovascular disease (without stroke)							<input type="radio"/> <input type="checkbox"/>
14	Chronic headaches							<input type="radio"/> <input type="checkbox"/>
15	Epilepsy							<input type="radio"/> <input type="checkbox"/>
16	Other central nervous system disease, specify							<input type="radio"/> <input type="checkbox"/>
17	Parkinson's disease							<input type="radio"/> <input type="checkbox"/>
18	Seizure disorder							<input type="radio"/> <input type="checkbox"/>
19	Stroke							<input type="radio"/> <input type="checkbox"/>
20	Transient ischemic attack							<input type="radio"/> <input type="checkbox"/>

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Paginate 1 2 Save Cancel

# Entering Patient Information – Concomitant Medications

ALZ-NET Test Institution 1242-001-SD Concomitant Medications Concomitant Medications

Subject: 1242-001-SD  
Page: Concomitant Medications - Concomitant Medications

Currently viewing line 1 of 1.  
Click here to return to "Complete View".

Apply to Record

Concomitant medication name

Indication  Adverse Event  
 ARIA Adverse Event  
 Medical History  
 Other

Dose

Units

Frequency

Route

Start Date

Ongoing  Yes  
 No  
 Unknown

End Date

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Save Cancel

Please log all medications that the enrolled patient is taking.  
**\*Note** that this information can be entered on an ongoing basis

# Entering Patient Information – Reporting an Adverse Event

ALZ-NET Test Institution 1242-001-SD Adverse Events Adverse Events

Subject: 1242-001-SD  
Page: Adverse Events - Adverse Events

Currently viewing line 1 of 1.  
Click here to return to "Complete View".

Apply to Record

Adverse Event Term

Was this an SAE?  Yes  No

Did this AE result in death?  Yes  No

Was this AE life threatening?  Yes  No

Did this AE require prolonged hospitalization?  Yes  No

Did this AE cause persistent or significant disability/incapacity?  Yes  No

Did this AE cause a congenital anomaly/birth defect?  Yes  No

Was this an other medically important serious event?  Yes  No

AE Reference ID

Start date: (dd-mon-yyyy)  ...

Ongoing?  Yes  No

Stop date: (dd-mon-yyyy)  ...

Outcome:  Fatal  
 Not Recovered/Not Resolved  
 Resolved/Recovered with Sequelae  
 Recovered/Resolved  
 Recovering/Resolving  
 Unknown

# Entering Patient Information – Reporting an ARIA Adverse Event

ALZ-NET Test Institution 1242-001-SD ARIA Adverse Events ARIA Adverse Events

Subject: 1242-001-SD  
Page: ARIA Adverse Events - ARIA Adverse Events

Currently viewing line 1 of 1.  
Click here to return to "Complete View".

Apply to Record

Adverse Event:

Was the ARIA event serious?  Yes  No

Did this AE result in Death?  Yes  No

Was this AE life threatening?  Yes  No

Did this AE Require prolonged hospitalization?  Yes  No

Did this AE cause Persistent or significant disability/incapacity?  Yes  No

Did this AE cause a Congenital anomaly/birth defect?  Yes  No

Was this AE an other medically important serious event?  Yes  No

AE/SAE tracking number:

Start date: (dd-Mon-yyyy)

Ongoing?  Yes  No

Stop date: (dd-Mon-yyyy)

Outcome:  Fatal  
 Not Recovered/Not Resolved  
 Resolved/Recovered with Sequelae  
 Recovered/Resolved  
 Recovering/Resolving  
 Unknown

The AE/SAE tracking number will be generated within Rave



# Entering Patient Information – Reporting an ARIA Adverse Event

Radiological severity:

Action taken with Alzheimer's therapy:

Relationship to Alzheimer's therapy:  Not Related  Related

Concomitant treatment given:  
*If yes, record on the appropriate concomitant therapy form.*  Yes  No

Resulted in withdrawal from [study]?  Yes  No

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Click 'Save' after all information has been entered



If patient is withdrawing from ALZ-NET, please indicate 'Yes' or 'No'



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