



Medidata Rave Training

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

Medidata Rave Overview

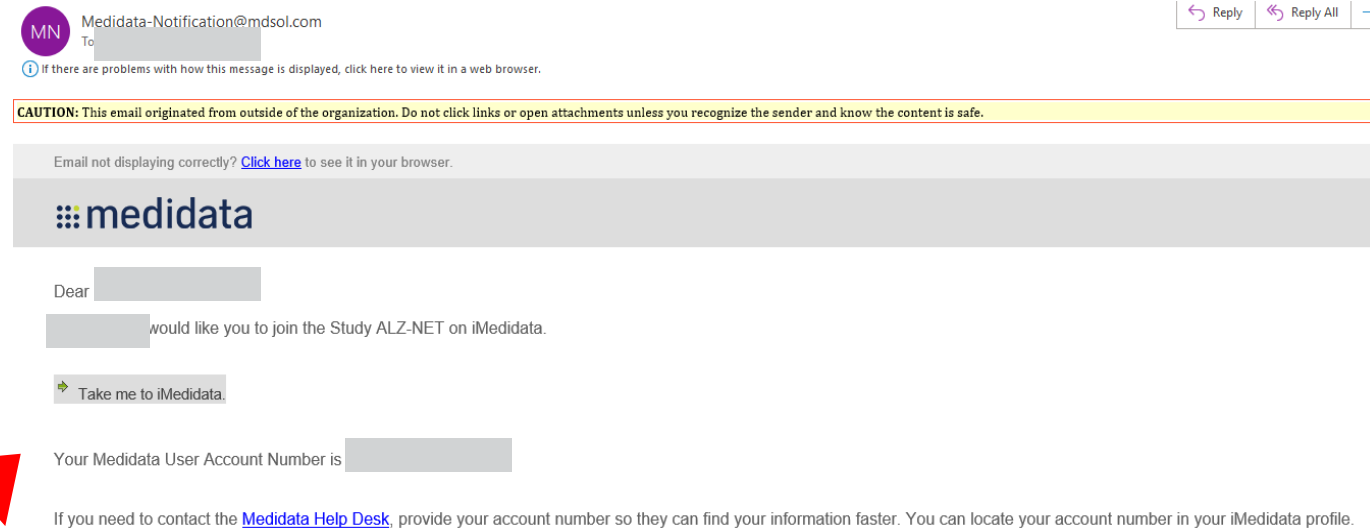
- Medidata Rave serves as the electronic data capture (EDC) for ALZ-NET.
- Each site staff member that will be entering in participant clinical data **must** have a Medidata Rave account to do so.
 - Your Medidata Rave account will be **unique** in that the login **cannot** be used for other applications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

Logging into Medidata – First Time User

Each user will receive an activation email from Medidata-Notification@mdsol.com 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

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.

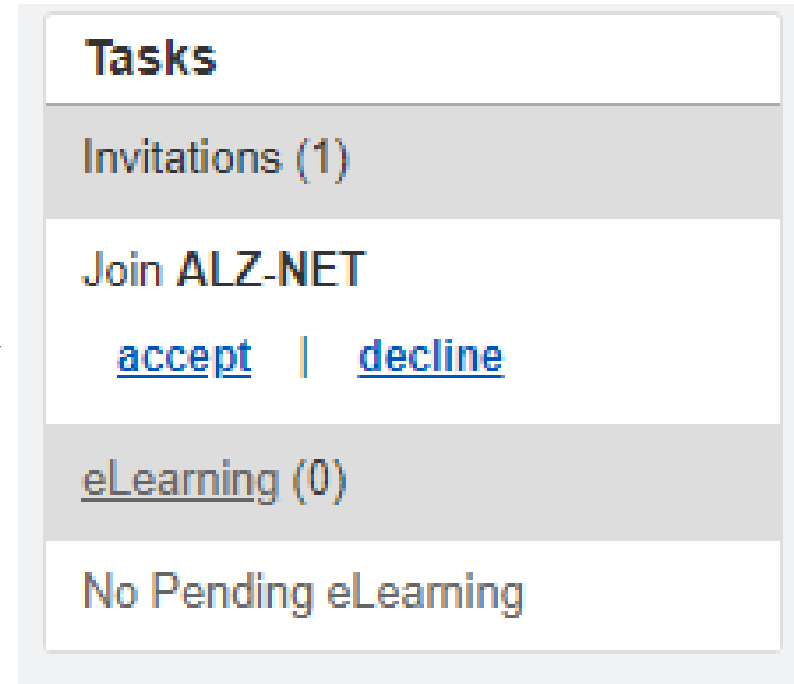
A screenshot of the Medidata login page. The page features the Medidata logo at the top left. Below the logo, the word "Welcome" is centered. The login form consists of a "Username" field with a placeholder "Enter username", a "Password" field with a placeholder "Enter password" and a toggle icon, and 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: English" dropdown menu. Below the form, there is a "Help Documentation" link. At the very bottom, there is 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)

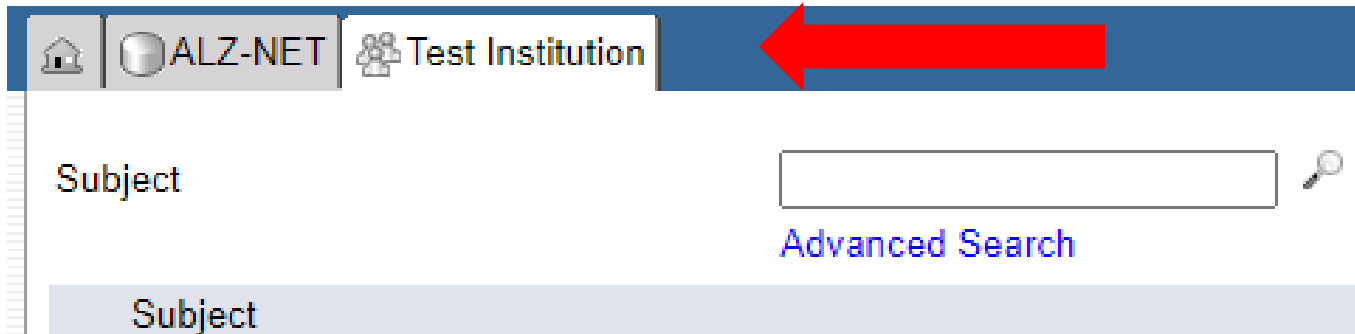
No Pending eLearning

Medidata Rave Home Page

The screenshot displays the Medidata Rave Home Page interface. On the left, there is a sidebar with sections: 'Apps' (containing RAVE EDC, ACR, RAVE Modules, and 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 visible. 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

The screenshot displays a web application interface. At the top, there is a breadcrumb trail: Home > ALZ-NET > Test Institution > 1242-001-SD. On the left side, a navigation menu is highlighted with a red box, listing the following sections: 1242-001-SD, Enrollment Forms, Baseline, Medical History, Concomitant Medications, Adverse Events, ARIA Adverse Events, and TRIAD Submission Log. The main content area shows 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". 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)".

Subject: 1242-001-SD
Page: Demography - Enrollment Forms

Subject Initials (LFM)

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

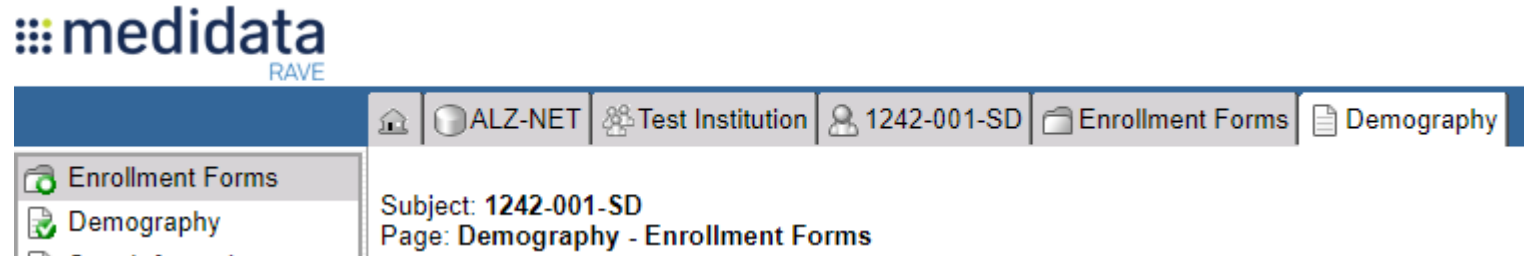
The screenshot shows the Medidata Rave interface. At the top left is the Medidata RAVE logo. Below it is a navigation bar with icons for Home, ALZ-NET, Test Institution, and Patient ID (1242-003-SD). A dropdown menu is open, listing various data entry forms: 1242-003-SD, Enrollment Forms, Baseline, Medical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

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

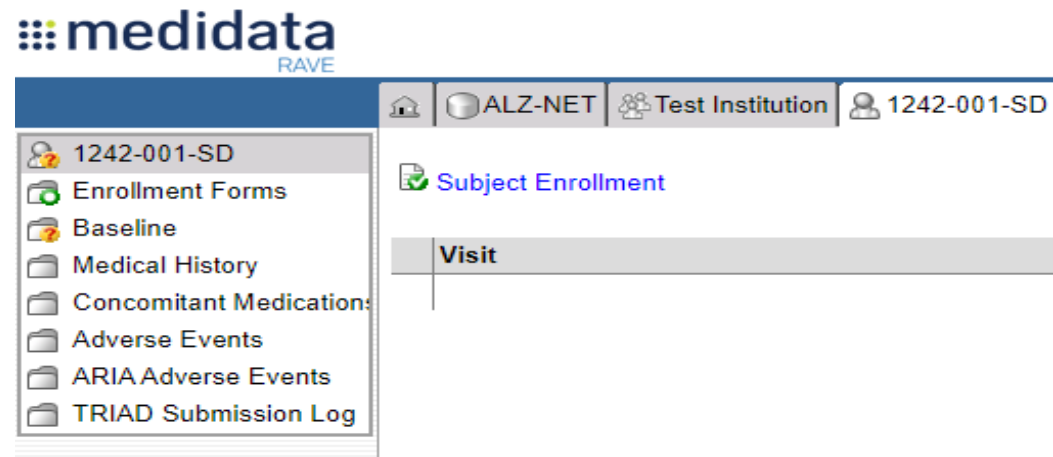
The screenshot shows the Medidata RAVE interface for the 'Vital Signs - Baseline' form. The top navigation bar includes Home, ALZ-NET, Test Institution, Patient ID (1242-003-SD), Baseline, and Vital Signs. The left sidebar lists various forms, with 'Baseline' selected. The main content area displays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

Entering Patient Information

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

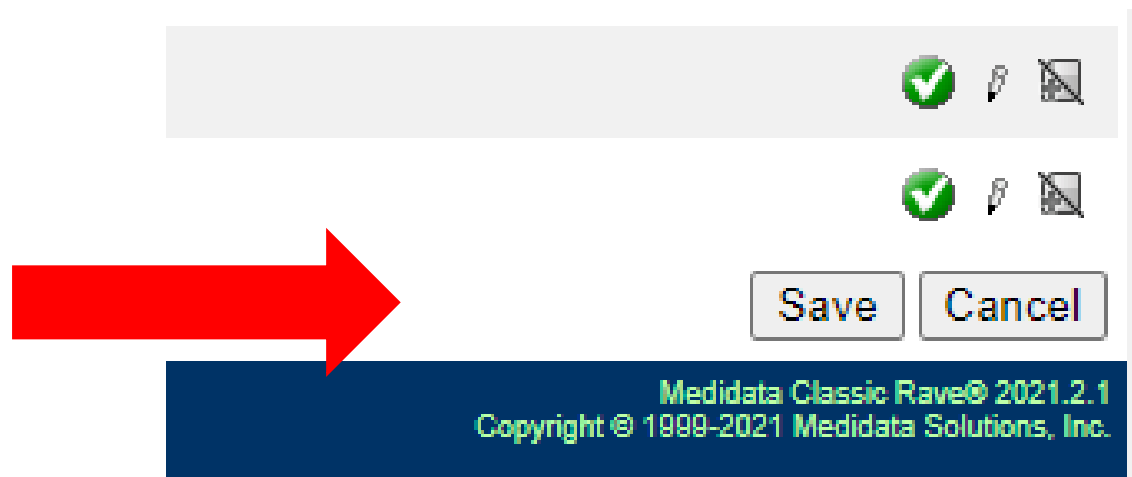


The full list of forms that need to be completed will be listed on the left side of the screen.

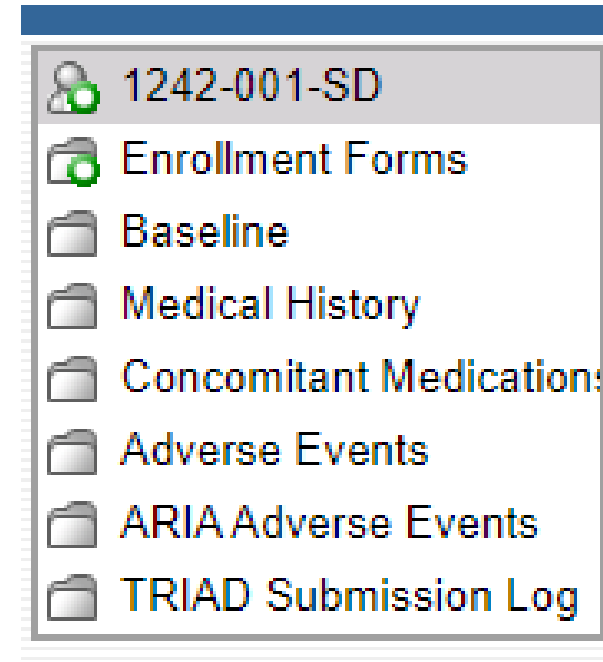
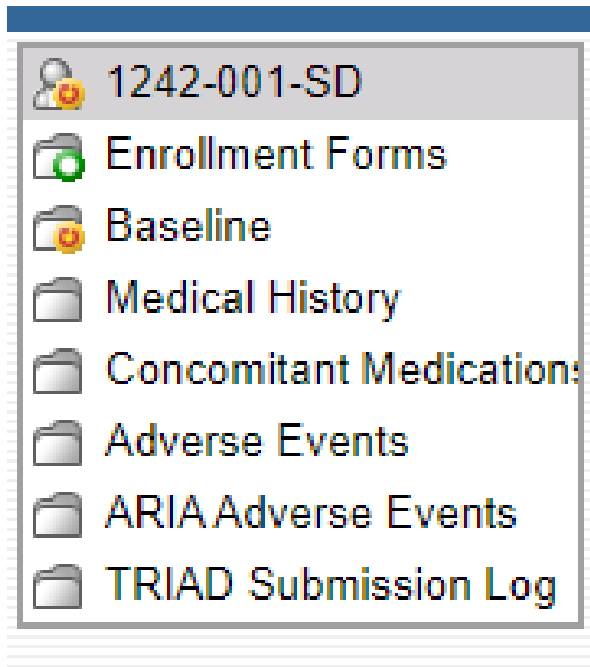


Accessing ALZ-NET in Medidata Rave

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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CRF Version 1242 - Page Generated: 23 Sep 2022 12:02:49 Eastern Daylight Time

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

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 1242 - Page Generated: 23 Sep 2022 12:03:23 Eastern Daylight Time

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





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