# ALZ-NET Summary Table of Data Elements

**Overview:** This resource provides the detailed data elements that are collected by the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET).

Required and optional data elements are designated by the key. All data should be captured within the patients' medical records. *Note: For an exact set of ALZ-NET data elements and structure, reference the ALZ-NET Case Report Form Packets.*

**Protocol Version:** January 10, 2025
**eCRF Version: 15 –** April 2026
**Last updated:** 5/7/2026

**Key:**

| | |
|---|---|
| x | The electronic case report form (eCRF) and all associated data are **required** to be submitted. |
| o | The eCRF and all associated data are **required** to be submitted ***if available.*** |
| Forms available at subject level in Medidata RAVE independent of data collection timepoint | |

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1. *Information submitted via the site registration questionnaire and staff registration questionnaire on the ALZ-NET website.*
2. *Data submitted during the patient registration process via the ACR's research management system. The date of patient registration becomes the date of the baseline timepoint for data entry.*
3. *Data submitted via one of the ACR approved clinical data transfer mechanisms at applicable data collection time points (i.e. baseline and/or follow up).*
4. *Transmission of brain images occurs via ACR's CONNECT and TRIAD applications.*

**Table 1.** ALZ-NET SITE AND INVESTIGATOR DATA ELEMENTS. *All data elements completed as part of the site/staff registration process.*

| Form | Data Element |
|---|---|
| Site Data | Primary Contact Information |
| | Site address (physical and mailing) |
| | Nature of site |
| | Characteristics of multi-disciplinary dementia care team |
| | Race and ethnicity percentages of patient population |
| | Enrollment feasibility |
| | Utilization of physician extenders |
| | Licensing and access to cognitive, function, and behavioral assessments |
| | Access to infusion services |
| | Access to accredited imaging services |
| Site Investigator Data | Name (operations purpose only) |
| | Contact information (operations purpose only) |
| | Type of provider |
| | NPI Number |
| | Board Certifications and Sub-specialties |
| | Experience in dementia care |
| | Experience with novel AD therapies |

**Table 2**. ALZ-NET PARTICIPANT DATA ELEMENTS. *Data collected at R = Registration, B = Baseline, F = Follow-up.*

| Form | Data Element | Collection Timepoint | | |
|---|---|---|---|---|
| | | R | B | F |
| Patient Registration – Demography Form | Name of Person registering case | X | | |
| | Name of treating clinician | X | | |
| | Date ICF signed | X | | |
| | Date of protocol version for which ICF was obtained | X | | |
| | Informed consent provided by | X | | |
| | If provided by LAR, what is their relationship to the patient | X | | |
| | ICF language | X | | |
| | Optional study component verification | X | | |
| | Country of residence | X | | |
| | Year of birth | X | | |
| | Sex assigned at birth | X | | |
| | Self-reported gender | X | | |
| | Self-reported race/ethnicity | X | | |
| | Primary insurance/beneficiary status | X | | |
| | Secondary insurance status | X | | |
| Patient Registration – Eligibility Checklist | Patient/LAR understanding of ALZ-NET | X | | |
| | Patient is 18 years of age at time of consent | X | | |
| | Diagnosis of MCI/dementia | X | | |
| | Patient meets label requirements for FDA-approved AD therapies | X | | |
| | Patient/Provider decision for treatment | X | | |
| Patient Information | First Name | X | | |
| | Middle Name | X | | |
| | Last Name | X | | |
| | Date of birth | X | | |
| | Country of residence | X | | |
| | Primary address | X | | |
| | Address line 2 | X | | |
| | City | X | | |
| | State | X | | |
| | Zip Code | X | | |
| | Primary Phone | X | | |
| | Primary Email | X | | |
| | Social Security Number | X | | |
| | Primary Insurance ID Number | X | | |
| | Primary Insurance Group ID Number | X | | |
| Reporting Period and Patient Status | Reporting period end date | | X | X |
| | Visit type (if applicable) | | X | X |
| | Review of electronic medical record (y/n) | | | X |

| | | | | |
|---|---|---|---|---|
| Adverse Events, Conditions, and Medication Assessment | Adverse event after initiation of therapy (y/n), if yes see Adverse Events | | X | X |
| | ARIA Adverse Events (y/n) – if yes, see ARIA Adverse Events | | X | X |
| | New Imaging conducted (y/n) - If yes, see Clinical Imaging Submission | | | X |
| | New or updated medical history / clinical events (y/n) - if yes, see Medical History/Clinical Events | | | X |
| | New or updated concomitant medications (y/n) - if yes, see Concomitant Medications | | | X |
| Medical History / Clinical Events | Assessment Date | | X | |
| | Atrial fibrillation | | X | |
| | Cardiac arrythmia | | X | |
| | Congestive heart failure | | X | |
| | Ischemic heart disease/coronary artery disease | | X | |
| | Down syndrome | | X | |
| | Diabetes | | X | |
| | Dyslipidemia | | X | |
| | Cerebrovascular disease (without stroke) | | X | |
| | Chronic headaches | | X | |
| | Seizure disorder | | X | |
| | Stroke | | X | |
| | Ischemic heart attack | | X | |
| | Traumatic brain injury | | X | |
| | Anxiety | | X | |
| | Delirium | | X | |
| | Depression | | X | |
| | Sleep disorder (e.g. apnea, insomnia) | | X | |
| | Hypertension | | X | |
| Vital Signs | Vital signs obtained (y/n) | | X | X |
| | Height | | X | o |
| | Weight | | X | o |
| | BMI | | X | o |
| | Blood pressure | | X | o |
| Concurrent Study Enrollment | ALZ-NET affiliated study | | X | X |
| | Dementia related clinical trial not affiliated with ALZ-NET | | X | X |
| Lifestyle Data | Medical record lifestyle data availability (y/n) | | X | X |
| | Tobacco use | | o | o |
| | Alcohol use, if yes drinks per week | | o | o |
| | Cannabis use | | o | o |
| | Recreational drug use | | o | o |
| | Physical exercise, if yes hours per week | | o | o |
| | Informant or care partner | | X | |
| | Highest educational attainment | | X | |

| | | | | |
|---|---|---|---|---|
| Patient Characteristics | Preferred language | | X | |
| | Family history of Alzheimer's disease | | X | |
| Clinical Features Co-pathology | Motor weakness | | X | X |
| | Gait disorder (e.g. frequent falls) | | X | X |
| | Parkinsonism | | X | X |
| | Visual hallucinations | | X | X |
| | REM Sleep Behavior Disorder (RBD) | | X | X |
| | Fluctuating cognition with variations in attention and alertness | | X | X |
| | Early changes in personality and behavior | | X | X |
| | Language impairment (e.g. aphasia) | | X | X |
| | Memory Impairment | | X | X |
| | Salient visuospatial impairment | | X | X |
| | Salient executive dysfunction | | X | X |
| | Agitation | | X | X |
| | Psychosis | | X | X |
| | Vascular lesions on MRI | | X | X |
| Additional Measures | Assessment Type (MMSE, MoCA, FAQ, AD8, NPI-Q) | | X | X |
| | Assessment Performed | | X | X |
| | Assessment Date | | X | X |
| | Total Score | | X | X |
| Healthcare Utilization | Emergency room visits | | X | X |
| | Hospitalizations | | X | X |
| Alzheimer's Disease Diagnosis | Clinical disease stage | | X | X |
| | Age at onset of cognitive symptoms | | X | X |
| | Age at diagnosis of cognitive symptoms | | X | X |
| | Suspected etiology contributing to impairment | | | |
| | Presentation of impairment | | X | X |
| Diagnostic Testing Log | Diagnostic Testing Type (ApoE, Blood-based AD biomarker assay, cerebrospinal fluid AD biomarker assay, imaging) | | X | X |
| | Date of test | | X | X |
| | Results of test | | X | X |
| | If ApoE genotyping, result | | X | X |
| | If imaging, type of imaging | | X | X |
| Novel Therapy Administration | Received dose of novel FDA-approved therapy prior to data collection timepoint | | X | X |
| | If yes, doses completed and therapy type | | X | X |
| | If no, initial evaluation for treatment status | | X | X |
| | If yes to completed initial evaluation, decision for not initiating therapy | | X | X |
| | Therapy type | | X | X |
| | Start date | | X | X |
| | Stop date | | X | X |

| | | | | |
|---|---|---|---|---|
| Novel therapy *(specific form for each therapy)* | Dose level | | X | X |
| | Changes to dose/treatment | | X | X |
| | If yes, reasons for changes | | X | X |
| Clinical Imaging Submission | Imaging reported (y) | | X | X |
| | Timepoint | | X | X |
| | Date of Imaging | | X | X |
| | Imaging Modality | | X | X |
| | Type of PET performed (PET only) | | X | X |
| | Use of IV contrast (MRI only) | | X | X |
| | Submitter of imaging | | X | X |
| | Accession # | | X | X |
| | Radiology report (pdf file upload) | | X | X |
| Concomitant Medications | Medication name | | X | X |
| | Dose | | o | o |
| | Units | | o | o |
| | Frequency | | o | o |
| | Route | | o | o |
| | Start Date | | o | o |
| | Ongoing | | o | o |
| | End Date | | o | o |
| | Indication | | o | o |
| Adverse Events | Adverse event | | X | X |
| | SAE | | o | o |
| | Death | | o | o |
| | Life threatening | | o | o |
| | Inpatient or prolonged hospitalization | | o | o |
| | Disability/incapacity | | o | o |
| | Anomaly/birth defect | | o | o |
| | Medically important | | o | o |
| | Start Date | | o | o |
| | Ongoing | | o | o |
| | Stop Date | | o | o |
| | Outcome | | o | o |
| | Severity | | o | o |
| | Action Taken with Alzheimer's Therapy | | o | o |
| | Expectedness | | o | o |
| | Concomitant Treatment | | o | o |
| | Withdrawal from registry | | o | o |
| | Reported to FDA program and/or drug manufacturer | | o | o |
| | If yes, entity type | | o | o |
| | Earliest date of reporting | | o | o |
| | ARIA adverse event | | X | X |
| | SAE | | o | o |

| | | | | |
|---|---|---|---|---|
| ARIA Adverse Events | Death | | o | o |
| | Life threatening | | o | o |
| | Inpatient or prolonged hospitalization | | o | o |
| | Disability/incapacity | | o | o |
| | Anomaly/birth defect | | o | o |
| | Medically important | | o | o |
| | Start Date | | o | o |
| | Ongoing | | o | o |
| | Stop Date | | o | o |
| | Outcome | | o | o |
| | Clinical Severity | | o | o |
| | Radiographical Severity | | o | o |
| | Action Taken with Alzheimer's Therapy | | o | o |
| | Expectedness | | o | o |
| | Concomitant Treatment | | o | o |
| | Withdrawal from registry | | o | o |
| | Reported to FDA program and/or drug manufacturer | | o | o |
| | If yes, entity type | | o | o |
| | Earliest date of reporting | | o | o |
| ARIA Adverse Events Signs and Symptoms | ARIA AE Logline (derived from Rave) | | o | o |
| | AE (derived from Rave) | | o | o |
| | Start date (derived from Rave) | | o | o |
| | Signs/symptoms | | o | o |
| | Sign/symptom occurrence | | o | o |
| | Start Date | | o | o |
| | Ongoing | | o | o |
| | End Date | | o | o |
| | Severity | | o | o |
| | Relationship to ARIA | | o | o |
| Protocol Deviation | Event reported | | o | o |
| | Occurrence date | | o | o |
| | Deviation discovery date | | o | o |
| | Rectification of situation | | o | o |
| | Deviation reporting period | | o | o |
| Death Details | Cause of Death | | | o |
| | Date of Death | | | o |
| Loss to Follow-up | 1st contact attempt | | | o |
| | Type of contact (1) | | | o |
| | 2nd contact attempt | | | o |
| | Type of contact attempt (2) | | | o |
| | 3rd contact attempt | | | o |
| | Type of contact | | | o |
| | Name and title of person responsible for data | | | o |

| | | | | |
|---|---|---|---|---|
| | Date of Loss to Follow-up determination | | | o |
| Withdrawal of Consent | Withdrawal of Consent Date | | | o |
| | Withdrawal of consent by whom | | | o |
| | Level of withdrawal | | | o |
| | Consent component | | | o |
| | Reason for withdrawal of consent | | | o |
| Optional Components Reconsent Log | Date of reconsent | | | o |
| | Withdrawal of consent by whom | | | o |
| | Consent component | | | o |
| | Reason for withdrawal of consent | | | o |
| | Other, specify | | | o |
| Off Study | Off Study Date | | | o |
| | Primary reason for going off study | | | o |