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: 9 – February 2025

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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ALZ-NET DATA COLLECTION	SITE START-UP[1]	PATIENT REGISTRATION (ENROLLMENT)[2]	PATIENT PARTICIPATION[3]
Participating Site Characteristics	x		
Site Investigator (Prescribing Clinician) Characteristics	x		
Patient Demography		x	
Informed Consent		x	
Eligibility Checklist		x	
Patient Information		x	
Adverse Events (AEs) / ARIA Adverse Events			x
Medical History			x
Vital Signs			x
Concurrent Study Enrollment			x
Lifestyle Data			x
Patient Characteristics			x
Clinical Features			x
Additional Measures (***Cognitive, Functional, and Behavioral***)			x
Healthcare Utilization (***Hospitalizations and ER Visits***)			x
AD Diagnosis			x
Diagnostic Testing			x
AD Treatment and Dosing Log			x
Clinical Imaging Submission[4]			x
Concomitant Medications			x
End of Participation (Death, Lost to Follow-up, Withdrawal of Consent) – ***only if applicable***			x
Imaging Assessment[5]			x

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.*
5. *Image assessment data are captured from submitted radiology reports.*

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

Adverse Events 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
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
Patient Characteristics	Informant or care partner		X	
	Highest educational attainment		X	
	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
	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
Novel therapy *(specific form for each therapy)*	Therapy type		X	X
	Start date		X	X
	Stop date		X	X
	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
	Modality		X	X
	Type of PET performed (PET only)		X	X

	Date of Imaging		X	X
	Use of IV contrast (MRI only)		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 Events	ARIA 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 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
	Retification 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

Table 3. IMAGING ASSESSMENT. Imaging data derived from radiology report uploaded by participating ALZ-NET dementia practice.

Form	Data Element	By Report
PET Imaging Assessment Form	Ligand administered and dose	o
	Scan date	o
	Scan result	o
	Image quantification	o
MRI Imaging Assessment Form	Scan date	o
	Clinical indication	o
	Magnet strength	o
	Presence of ARIA (y/n)	o
	If yes, type of ARIA:	o
	ARIA-E - Number of areas of abnormality - Size of largest area of abnormality - Radiographical severity	o
	ARIA-H (Microhemorrhages and ICH >1cm) - Radiographical severity - Number of microhemorrhages - Number of ICH >1cm	o
	ARIA-H (Superficial siderosis) - Radiographical severity - Number of superficial siderosis areas	o