



ALZ-NET Summary Table of Data Elements

This resource provides a detailed overview of the data elements that are collected by the Alzheimer’s Network for Treatment and Diagnostics (ALZ-NET). The tables below categorize and outline the required and optional data elements that participating sites should capture within their patients’ medical records. For an exact set of ALZ-NET data elements and structure, refer to the ALZ-NET Case Report Form Packet found on the ALZ-NET website.

Key:

x	The electronic case report form (eCRF) and all associated data are <u>required</u> to be submitted.
o	The eCRF and all associated data are <u>optional</u> to be submitted.

Table 1: ALZ-NET SITE AND INVESTIGATOR DATA ELEMENTS

ALZ-NET SITE AND INVESTIGATOR DATA ELEMENTS	Site/Staff Registration Process
Site Data – Protocol Section 7.1	
Primary contact information	x
Site address (physical and mailing)	x
Nature of site	x
Characteristics of multi-disciplinary dementia care team	x
Race and ethnicity percentages of patient population	x
Enrollment feasibility	x
Utilization of physician extenders	x
Licensing and access to cognitive, function, and behavioral assessments	x
Access to infusion services	x
Access to accredited imaging services	x
Site Investigator Data – Protocol Section 8.1	
Name (<i>operations purpose only</i>)	x
Contact information (<i>operations purpose only</i>)	x
Type of provider	x
NPI Number	x
Board Certifications and Sub-specialties	x
Experience in dementia care	x
Experience with novel AD therapies	x

Table 2: ALZ-NET PARTICIPANT DATA ELEMENTS

ALZ-NET PARTICIPANT DATA ELEMENTS	Case Registration	Baseline	Follow up
<i>Case Registration Form – Protocol Section 12.1</i>			
<i>Informed Consent</i>			
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		
Eligibility criteria verification	X		
<i>Patient Demographics and Information</i>			
Date of Birth	X		
Country of residence	X		
Sex assigned at birth	X		
Gender	X		
Race/Ethnicity	X		
ALZ-NET Case ID number	X		
Name (first, middle, last)	X		
Address of Residence (street, city, state, zip)	X		
Telephone (home and cell)	X		
Email	X		
Social Security Number (claims purposes)	X		
Primary Insurance Status	X		
Insurance ID number	X		
Insurance Group ID Number	X		
<i>Concurrent Study Enrollment Form – Protocol Section 12.2</i>			
ALZ-NET Affiliated Study		X	X
Dementia related clinical trial not affiliated with ALZ-NET		X	X
<i>Participant Characteristics – Protocol Section 12.3</i>			
Informant or care partner		X	
Informant or care partner’s relationship to patient		X	
Marital status		X	
If widowed, how long		X	
If divorced, how long		X	
Living arrangements (alone or w. others)		X	
If patient lives with others, with whom		X	
Educational attainment		X	

Preferred language		X	
Family history of AD		X	
Medical History (Pre-populated Log Format) – Protocol Section 12.4/ Clinical Events Form – Protocol Section 12.11			
Cardiac disorders			
Atrial fibrillation, Cardiac arrhythmia, Congestive heart failure, and Ischemic heart disease		X	X
Congenital, familial, and genetic disorders			
Down’s syndrome		X	X
Hepatobiliary disorders			
Chronic liver disease		X	X
Immune system disorders			
Autoimmune disorders (specify) and Multiple sclerosis		X	X
Infections and infestations			
Chronic Infection		X	X
Metabolism and nutrition disorders			
Diabetes and Dyslipidemia		X	X
Neoplasms benign, malignant, and unspecified (including cysts and polyps)			
Cancer (specify)		X	X
Nervous system disorders			
Cerebrovascular disease without stroke, Chronic headaches, Other CNS disease, Parkinson's disease, Schizophrenia, Seizure disorder, Stroke, TIA, and TBI		X	X
Nervous system disorders			
Anxiety, Bipolar affective disorder, Delirium, Depression, and Sleep disorder		X	X
Renal and urinary disorders			
Chronic Kidney disease		X	X
Respiratory, thoracic and mediastinal disorders			
Chronic Obtrusive pulmonary disease		X	X
Vascular disorders			
Hypertension		X	X
Lifestyle Data – Protocol Section 12.5			
Tobacco use		X	O
Alcohol use		X	O
If consuming alcohol, consumption amount		X	O
Cannabis use or Cannabis derived products		X	O
Other recreational drug use		X	O
Physical exercise		X	O
If currently exercising, how often		X	O
Vital Signs – Protocol Section 12.6			
Height / weight		X	X

BMI (Automatically calculated)		X	X
Vitals (blood pressure, pulse, temp, resp. rate, and O2%)		X	X
Clinical Features of Co-Pathology – Protocol Section 12.7			
Motor weakness		X	O
Gait disorder (e.g. frequent falls)		X	O
Parkinsonism		X	O
Visual hallucinations		X	O
REM Sleep Behavior Disorder (RBD)		X	O
Fluctuating cognition with variations in attention and alertness		X	O
Early changes in personality and behavior		X	O
Aphasia		X	O
Vascular lesions on MRI		X	O
If vascular lesions are present, which type		X	O
Additional Assessments – Protocol Section 12.8			
Cognitive Measures			
MoCA and/or MMSE		X	X
Was the assessment performed?		X	X
Assessment Date		X	X
MMSE Version or MoCA Version (MMSE-1, MMSE-2:BV, MMSE-2:SV, MMSE-2:EV, SMMSE, MoCA 8.1, MoCA 8.2, MoCA 8.3, other_)		X	X
MMSE/MoCA Validation concerns (Examinee factor, environmental factor, or administration factor)		X	X
Language (English, Spanish, Mandarin, Cantonese, Tagalog, Vietnamese, French, Arabic, Korean, Russian, German, Other)		X	X
Total Score		X	X
AD8			
AD8 Assessment date		O	O
AD8 Language (English, Spanish, Mandarin, Cantonese, Tagalog, Vietnamese, French, Arabic, Korean, Russian, German, Other)		O	O
AD8 Total Score		O	O
Functional Measures			
FAQ		X	X
FAQ Assessment Date		X	X
FAQ Language (English, Spanish, Mandarin, Cantonese, Tagalog, Vietnamese, French, Arabic, Korean, Russian, German, Other)		X	X
FAQ Total Score		X	X
Behavioral Measures			
NPI-Q		O	O
NPI-Q Assessment Date		O	O

NPI-Q Language (English, Spanish, Mandarin, Cantonese, Tagalog, Vietnamese, French, Arabic, Korean, Russian, German, Other)		o	o
NPI Total Score		o	o
Concomitant Medications (log format) – Protocol Section 12.9			
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
AD Diagnosis Form – Protocol Section 12.10			
AD Clinical Characteristics			
Clinical Disease Stage		x	x
Age of cognitive symptom Onset - date if known (year)		x	
Year of cognitive symptom onset		x	
Age at diagnosis - date if known		x	
Year of diagnosis		x	
Presentation of Cognitive Impairment (Typical vs Atypical)		x	x
Symptoms of impairment (Memory impairment, language impairment, salient visuospatial impairment, salient executive dysfunction, change in personality)		x	x
Diagnostic Testing			
APOE Genotyping, result if available (E2,E2; E2,E3; E2,E4; E3,E3; E3,E4; E4,E4; Unknown)		x	o
APOE genotyping conducted		x	o
Cerebrospinal Fluid collected		x	o
Cerebrospinal Fluid Results		x	o
Blood Assay collected		x	o
Blood Assay result		x	o
Protein Measured (Plasma amyloid, Beta; plasma phosphorylated Tau protein)		x	o
Clinical Imaging Submission – Protocol Section 12.12			
Imaging to report for the time period		x	x
Imaging Modality		o	o
Amyloid Positron emission tomography (PET)		o	o
Tau Positron emission tomography (PET)		o	o

Magnetic Resonance (MRI)		o	o
Type of PET Performed (PET only, PET/CT, PET/MRI, N/A for MRI)		o	o
Date of Imaging		o	o
IV contrast usage (with contrast, without contrast, with and without contrast, unknown)		o	o
Amyloid PET Assessment – Protocol Section 12.13			
Scan date, time, and duration		o	o
Ligand administered, including dosage		o	o
Scan result		o	o
Scan quality assessment		o	o
Image quantification (SUVR, Centiloid, Z-score)		o	o
Tau PET Assessment – Protocol Section 12.14			
Scan date, time, and duration		o	o
Ligand administered, including dosage		o	o
Scan result		o	o
MRI Assessment (initial and repeated monitoring) – Protocol Section 12.15			
Scan date and clinical indication		x	x
MRI Method (sequences collected and magnet strength)		x	x
ARIA-E		x	x
ARIA-H Microhemorrhages (\leq 1cm in diameter)		x	x
ARIA-H Superficial siderosis		x	x
Hemorrhages $>$ 1 cm diameter		x	x
White matter T2 hyperintense lesions		o	o
Lacunar infarct (\leq 1.5cm in diameter)		o	o
Ischemic infarct ($>$ 1.5cm in diameter; irrespective of anatomic location)		o	o
AD Treatment and Dosing – Protocol Section 12.16			
Novel FDA-approved AD Therapeutic		x	x
Previous Use		x	x
Date of initiation		x	x
Status of treatment and details on any discontinuation		x	x
Dosing Log		x	x
Healthcare Encounters - Protocol Section 12.17			
Hospitalizations (if yes, how long)		x	x
Emergency Room (ER) Visits (if yes, how many)		x	x
Adverse Events/ ARIA Events - Protocol Section 12.18			
AEs and SAEs		x	x
SAE (yes/no)		o	o
Death (yes/no)		o	o
Life threatening (yes/no)		o	o
Inpatient or prolongation of hospitalization (yes/no)		o	o

Disability/incapacity (yes/no)		0	0
Anomaly/birth defect (yes/no)		0	0
Medically important (yes/no)		0	0
Start Date/Ongoing/Stop Date		0	0
Outcome (fatal, not recovered/resolved, resolved/recovered with sequelae, recovered/resolved, recovering/resolving, unknown)		0	0
Severity (mild, moderate, severe)		0	0
Action Taken		0	0
Relationship		0	0
Expectedness (expected/unexpected)		0	0
Concomitant Treatment (yes/no)		0	0
Withdrawal from registry (yes/no)		0	0
Reported to FDA program/drug manufacturer (yes/no)		0	0
To which entity (FDA/Drug manufacturer)		0	0
Earliest date of reporting		0	0
ARIA Assessment form (if present)			X
SAE (yes/no)		0	0
Death (yes/no)		0	0
Life threatening (yes/no)		0	0
Inpatient or prolongation of hospitalization (yes/no)		0	0
Disability/incapacity (yes/no)		0	0
Anomaly/birth defect (yes/no)		0	0
Medically important (yes/no)		0	0
Start Date/Ongoing/Stop Date		0	0
Outcome (fatal, not recovered/resolved, resolved/recovered with sequelae, recovered/resolved, recovering/resolving, unknown)		0	0
Severity (mild, moderate, severe)		0	0
Action Taken		0	0
Relationship		0	0
Concomitant Treatment (yes/no)		0	0
Withdrawal from registry (yes/no)		0	0
Reported to FDA program/drug manufacturer (yes/no)		0	0
To which entity (FDA/Drug manufacturer)		0	0
Earliest date of reporting		0	0
End of Participation (Death, Lost to Follow up, Consent Withdrawn) - Protocol Section 11.8			
Death			0
Date of death			0
Primary cause of death (Alzheimer's disease, AD treatment, ARIA AE, other)			0
Lost to Follow-Up			0

1 st contact attempt (date/type of contact)			0
2 nd contact attempt (date/type of contact)			0
3 rd contact attempt (date/type of contact)			0
Date lost to follow-up determined			0
Withdrawal of Consent			0
Withdrawn consent date			0
By whom (patient, LAR)			0
Level of withdrawal			0
Which component			0
Reason			0