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 required to be submitted.
o	The eCRF and all associated data are optional 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 (*operations purpose only*)	x
Contact information (*operations purpose only*)	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**
*Case Registration Form – **Protocol Section 12.1***			
Informed Consent			
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		
Patient Demographics and Information			
Year of Birth	x		
Country of residence	x		
Sex assigned at birth	x		
Gender	x		
Race/Ethnicity	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		
Insurance Status	x		
Insurance ID number	x		
Insurance Group ID Number	x		
Concurrent Study Enrollment Form – *Protocol Section 12.2*			
ALZ-NET Affiliated Study		x	x
Dementia related clinical trial not affiliated with ALZ-NET		x	x
Participant Characteristics – *Protocol Section 12.3*			
Informant or care partner (Y/N) – if yes, relationship to patient		x	
Marital status		x	
If widowed, how long		x	
If divorced, how long		x	
Living arrangements (alone or w. others) – if w. others, whom		x	
Educational attainment		x	
Preferred language		x	
Family history of AD		x	

Medical History *(Pre-populated Log Format) – Protocol Section 12.4*			
Cardiac disorders			
Atrial fibrillation, Cardiac arrythmia, 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
Behavioral and Psychological 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 (Y/N)		x	x
Assessment Date		x	x
Version of assessment		x	x
Validation concerns (Examinee factor, environmental factor, or administration factor)		x	x
Language		x	x
Total Score		x	x
AD8		o	o
Assessment date		o	o
Language		o	o
Total Score		o	o
Functional Measures			
FAQ		x	x
Assessment Date		x	x
Language		x	x
Total Score		x	x
Behavioral Measures			
NPI-Q		o	o
Assessment Date		o	o
Language		o	o
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		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 Events Form – *Protocol Section 12.11*			
Atrial fibrillation			x
Cardiac Arrythmia			x
Congestive heart failure			x
Ischemic heart disease			x
Chronic liver disease			x
Autoimmune disorders, specify			x
Multiple sclerosis			x
Chronic infection, specify			x
Diabetes			x
Dyslipidemia			x
Cancer, specify			x
Cerebrovascular disease (without stroke)			x
Chronic headaches			x
Epilepsy			x
Other CNS disease, specify			x
Parkinson’s disease			x
Seizure disorder			x
Stroke			x

Transient ischemic attack			x
Traumatic brain injury			x
Anxiety			x
Bipolar affective disorder			x
Delirium			x
Depression			x
Sleep disorder			x
Chronic kidney disease			x
Chronic Obstructive Pulmonary Disease (COPD)			x
Hypertension			x
Clinical Imaging Submission – Protocol Section 12.12			
Imaging to report for the time period		x	x
Imaging Modality		o	o
If PET, type performed		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 (≤ 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 (≤ 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)		o	o
Anomaly/birth defect (yes/no)		o	o
Medically important (yes/no)		o	o
Start Date/Ongoing/Stop Date		o	o
Outcome (fatal, not recovered/resolved, resolved/recovered with sequelae, recovered/resolved, recovering/resolving, unknown)		o	o
Severity (mild, moderate, severe)		o	o
Action Taken		o	o
Relationship		o	o
Expectedness (expected/unexpected)		o	o
Concomitant Treatment (yes/no)		o	o
Withdrawal from registry (yes/no)		o	o
Reported to FDA program/drug manufacturer (yes/no)		o	o
To which entity (FDA/Drug manufacturer)		o	o
Earliest date of reporting		o	o
ARIA Assessment form (if present)			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)		o	o
Anomaly/birth defect (yes/no)		o	o
Medically important (yes/no)		o	o
Start Date/Ongoing/Stop Date		o	o
Outcome (fatal, not recovered/resolved, resolved/recovered with sequelae, recovered/resolved, recovering/resolving, unknown)		o	o
Severity (mild, moderate, severe)		o	o
Action Taken		o	o
Relationship		o	o

Concomitant Treatment (yes/no)		o	o
Withdrawal from registry (yes/no)		o	o
Reported to FDA program/drug manufacturer (yes/no)		o	o
To which entity (FDA/Drug manufacturer)		o	o
Earliest date of reporting		o	o
End of Participation *(Death, Lost to Follow up, Consent Withdrawn) - Protocol Section 11.8*			
Death			o
Date of death			o
Primary cause of death (Alzheimer's disease, AD treatment, ARIA AE, other)			o
Lost to Follow-Up			o
1st contact attempt (date/type of contact)			o
2nd contact attempt (date/type of contact)			o
3rd contact attempt (date/type of contact)			o
Date lost to follow-up determined			o
Withdrawal of Consent			o
Withdrawn consent date			o
By whom (patient, LAR)			o
Level of withdrawal			o
Which component and reason why			o