ALZHEIMER'S ASSOCIATION
AAIC 22
ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE®
JULY 31–AUG. 4 > SAN DIEGO, USA, AND ONLINE

ALZ-NET:
Using Real World Evidence to Inform the Future of Alzheimer's Treatment and Care

POLICIES

The information included in this presentation may be shared on other platforms.

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DISCLOSURES

Maria Carrillo is a full -time employee of the Alzheimer's Association. She has a daughter that is a full-time graduate student in the USC Neuroscience program.

Gil Rabinovici receives research support from Avid Radiopharmaceuticals, GE Healthcare, Genentech, and Life Molecular Imaging; served on SAB for Eli Lilly, Genentech, and Roche; serves on DSMB for Johnson & Johnson; is an Associate Editor for JAMA Neurology.

Michael Rafii receives research support from Eli Lilly and Eisai Inc.; chairs DSMBs for Alzheon and Biohaven; serves on the SAB for Embic; provides consultation to AC Immune SA and Keystone Bio.

Heather Snyder is a full-time employee of the Alzheimer's Association.

Alzheimer's Association

The Alzheimer's Association forges partnerships with all those with the shared commitment to end Alzheimer's and other dementia, including Alzheimer's organizations around the globe, the National Institutes of Health, National Institute on Aging, universities, corporations and the pharmaceutical, biotech and device industries. With our broad partnerships, we are committed to transparency.

The Alzheimer's Association received 0.7 percent of its total 2021 contributed revenue from the biotechnology, pharmaceutical, diagnostics, and clinical research industries.

This and additional information can be found at www.alz.org/about/transparency.

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ALZHEIMER'S NETWORK FOR TREATMENT & DIAGNOSTICS (ALZ-NET)

ALZHEIMER'S NETWORK

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BROWN School of Public Health

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GOALS AND OBJECTIVES

Develop a multi-site network for enrollment and data collection.

Build and implement resources for clinical readiness in new phase in treatment (i.e., education and training).

Collect patient data at the start and over time, including measures of cognition, function and safety.

Collect and archive brain scans, as well as genetic and biomarker data and blood samples.

Track health outcomes and resource utilization of participants.

Share de-identified data, brain scans and blood samples with the research community.

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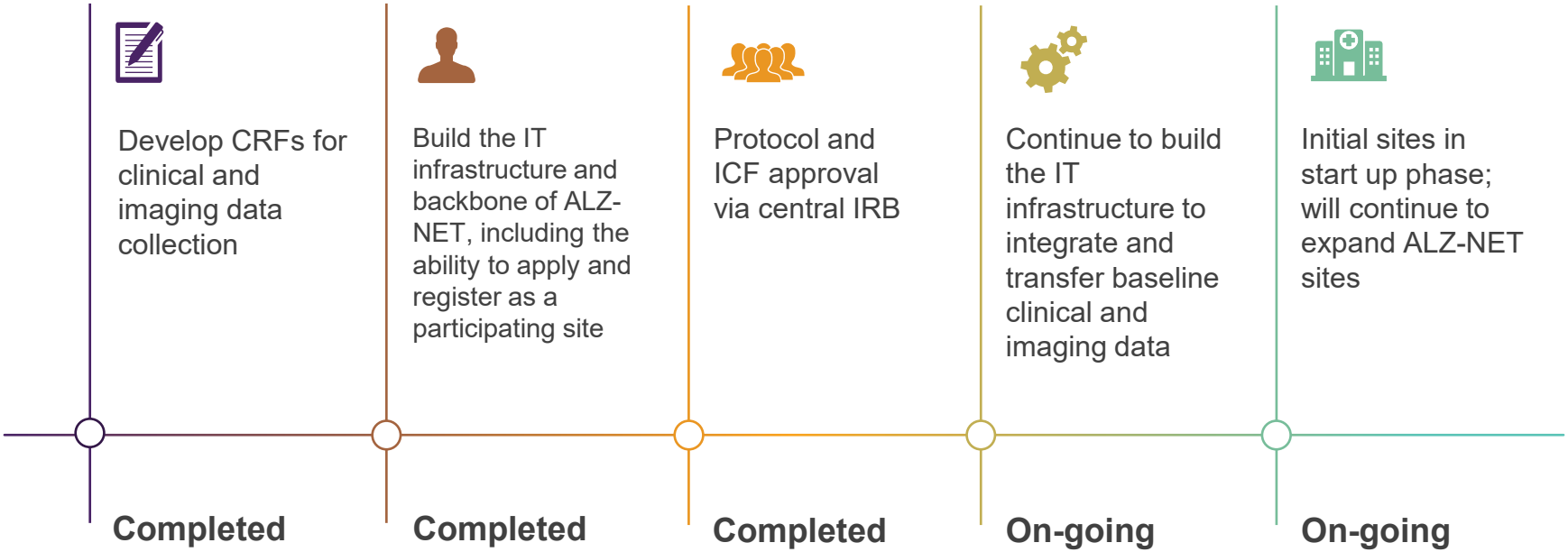
PROGRESS TO DATE



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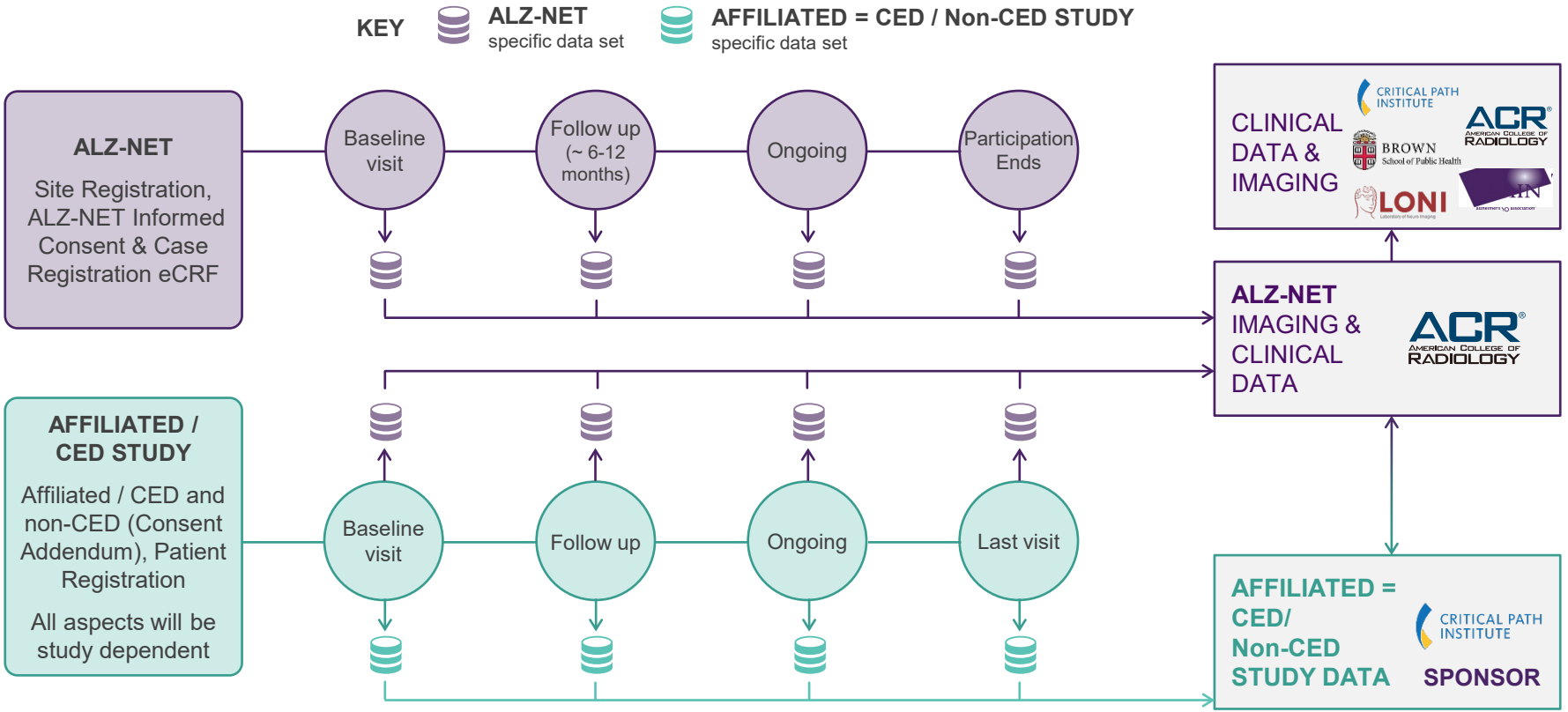
STRUCTURE OVERVIEW



PATIENT ENROLLMENT, DATA COLLECTION AND PATIENT FOLLOW-UP

ALZ-NET will use Medidata Rave, an online electronic data capture system (EDC) and data management system.

Data will be collected in a data dictionary aligned with C-DISC.

Users enter data into electronic case report forms (eCRFs).

Mechanisms are available to minimize manual data entry by site into the EDC.

Other data transfer and collection mechanisms can be facilitated by a variety of applications if the participating site chooses.

Only authenticated users will be permitted to access the applications and ALZ-NET platform.

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WHAT IS AN AFFILIATED STUDY?

Conducted by academia, industry, federal or ALZ-NET study team

Questions could be specific to a given treatment or broad

Could be CED or not CED

ALZ-NET will be flexible to work with each affiliated study specific to the study needs

Data flow will also be flexible through ALZ-NET (ACR), CPAD or affiliated study sponsor

ALZ-NET minimal data set is study sponsor and treatment agnostic; affiliated studies will be able to leverage the ALZ-NET minimal data set for their analyses

PATIENT ENROLLMENT, DATA COLLECTION AND PATIENT FOLLOW-UP

As part of activated sites, providers will enroll patients into ALZ-NET.

ALZ-NET DATA COLLECTION	SITE START-UP[1]	CASE REGISTRATION[2]	BASELINE[3]	FOLLOW-UP[3]
Participating Site Characteristics	x			
Site Investigator (*Prescribing Clinician*) Characteristics	x			
Informed Consent		x		
Eligibility Assessment		x		
Patient Demographics		x		

Primary Inclusion Criteria:

Point of entry to ALZ-NET is at the time the decision has made to treat the patient with a novel FDA-approved therapy or when the site has full documentation that treatment has previously been initiated.

PATIENT ENROLLMENT, DATA COLLECTION AND PATIENT FOLLOW-UP

Providers enter patient data in ALZ-NET in perpetuity until one of the participation endpoints is met (i.e., death, lost to follow up, consent withdrawn).

As long as consent is active and patient continues to receive care, data will be collected through ALZ-NET at applicable time points: **6, 12, 18, 24 months and annually thereafter until a participation endpoint is met.**

ALZ-NET DATA COLLECTION	SITE START-UP[1]	CASE REGISTRATION[2]	BASELINE[3]	FOLLOW-UP[3]
Participating Site Characteristics	x			
Site Investigator (*Prescribing Clinician*) Characteristics	x			
Informed Consent		x		
Eligibility Assessment		x		
Patient Demographics		x		
Concurrent Study Enrollment			x	x
Patient Characteristics			x	o
Medical History			x	x
Lifestyle Data			x	o
Vital Signs			x	x
Clinical Features of Co-pathology			x	x
Additional Measures (*Cognitive, Functional, and Behavioral*)			x	x
AD Diagnosis, Characteristics, and Biomarkers			x	x
Brain Imaging Clinical Data[4]			x	x
Brain Image(s) Transmission[5]			x	x
Concomitant Medications			x	x
AD Treatment and Dosing Log			x	x
MRI Assessment			x	x
Healthcare Encounters (*Hospitalizations and ER Visits*)			x	x
Adverse Events (AEs)			x	x
End of Participation (Death, Lost to Follow up, Consent Withdrawn) – *only if applicable*				x

x = Required form o = Optional form

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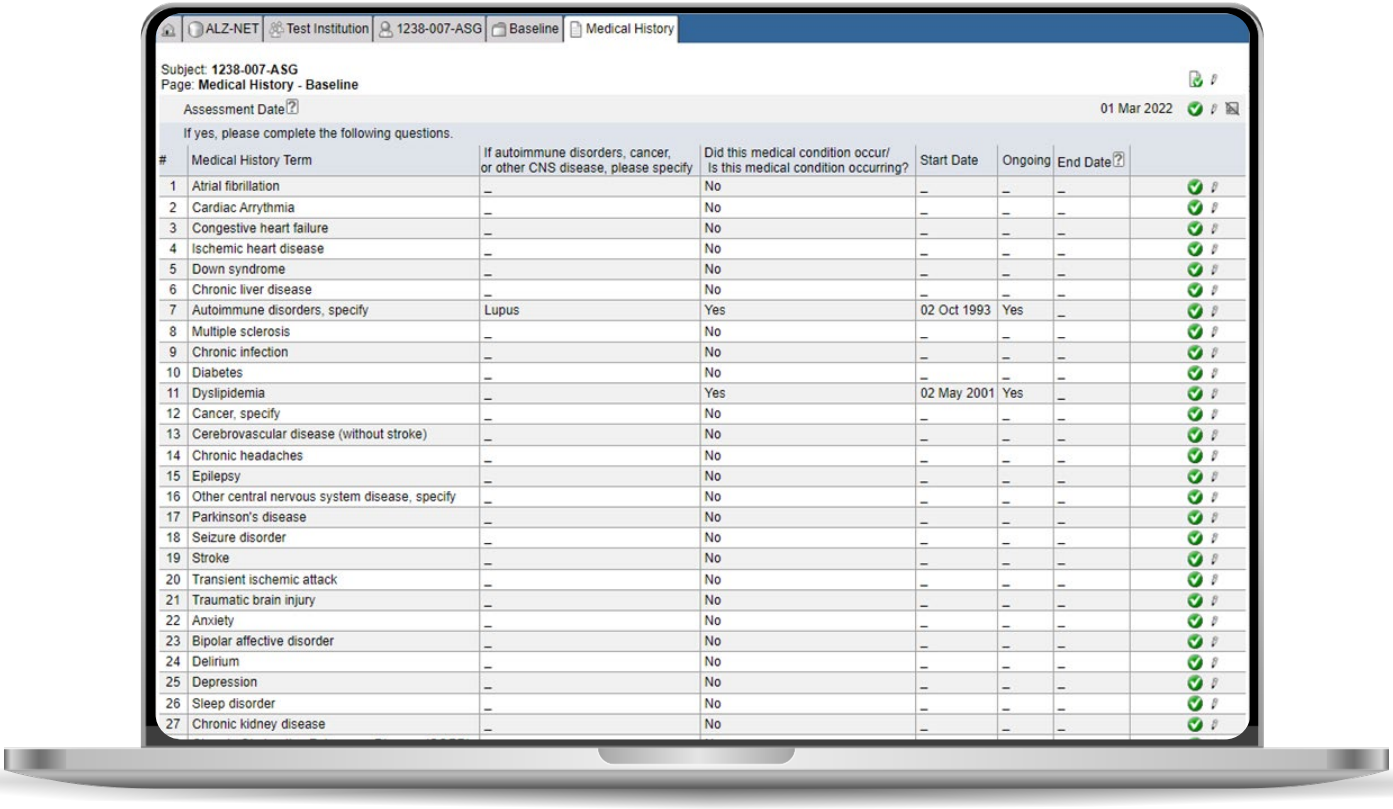
CRF: BASELINE MEDICAL HISTORY



ALZ-NET | Test Institution | 1238-007-ASG | Baseline | Medical History

Subject: **1238-007-ASG**
Page: **Medical History - Baseline**

Assessment Date: 01 Mar 2022

If yes, please complete the following questions.

#	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
1	Atrial fibrillation	_	No	_	_	_
2	Cardiac Arrythmia	_	No	_	_	_
3	Congestive heart failure	_	No	_	_	_
4	Ischemic heart disease	_	No	_	_	_
5	Down syndrome	_	No	_	_	_
6	Chronic liver disease	_	No	_	_	_
7	Autoimmune disorders, specify	Lupus	Yes	02 Oct 1993	Yes	_
8	Multiple sclerosis	_	No	_	_	_
9	Chronic infection	_	No	_	_	_
10	Diabetes	_	No	_	_	_
11	Dyslipidemia	_	Yes	02 May 2001	Yes	_
12	Cancer, specify	_	No	_	_	_
13	Cerebrovascular disease (without stroke)	_	No	_	_	_
14	Chronic headaches	_	No	_	_	_
15	Epilepsy	_	No	_	_	_
16	Other central nervous system disease, specify	_	No	_	_	_
17	Parkinson's disease	_	No	_	_	_
18	Seizure disorder	_	No	_	_	_
19	Stroke	_	No	_	_	_
20	Transient ischemic attack	_	No	_	_	_
21	Traumatic brain injury	_	No	_	_	_
22	Anxiety	_	No	_	_	_
23	Bipolar affective disorder	_	No	_	_	_
24	Delirium	_	No	_	_	_
25	Depression	_	No	_	_	_
26	Sleep disorder	_	No	_	_	_
27	Chronic kidney disease	_	No	_	_	_

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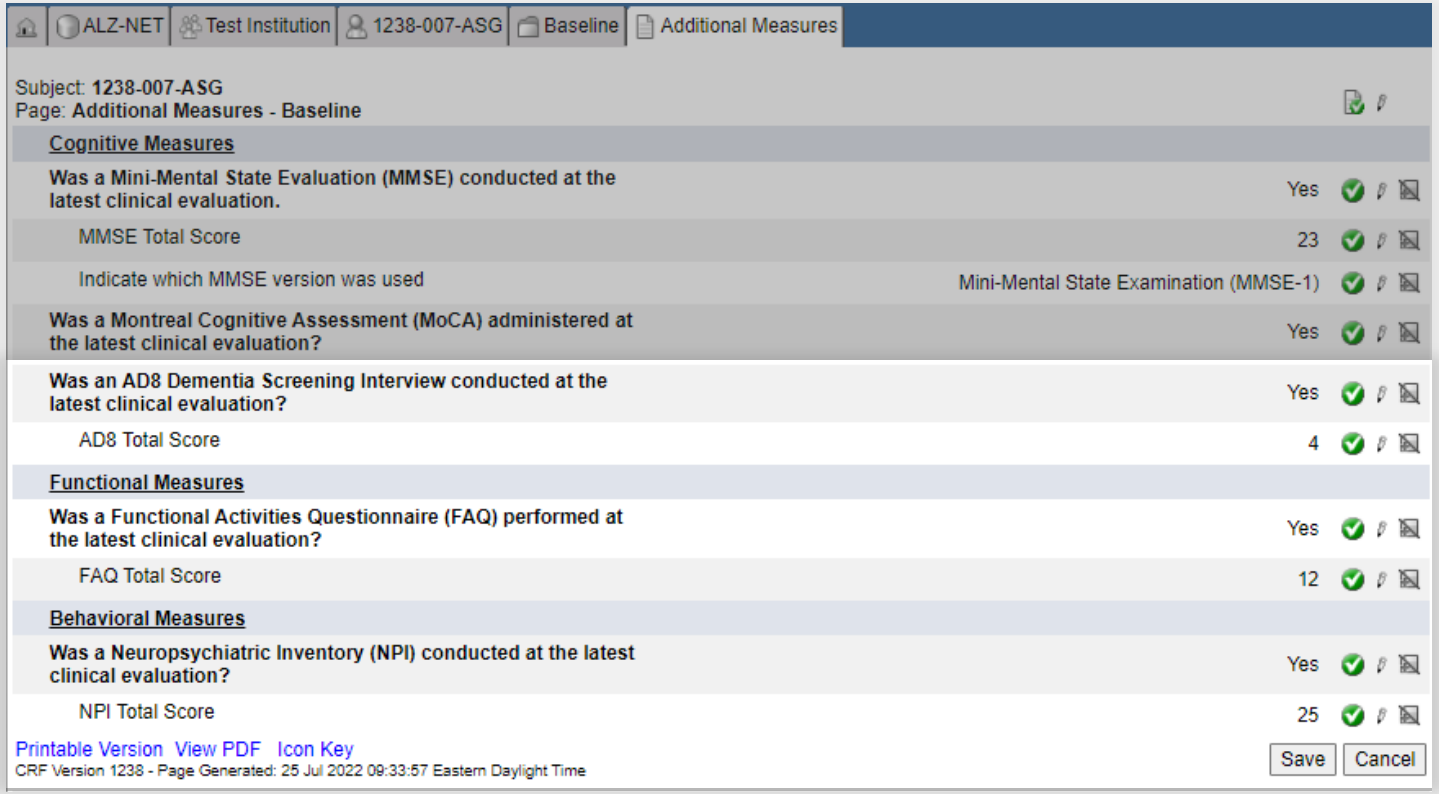
CRF: COGNITION & FUNCTION

REQUIRED:

- MMSE or MoCA
- FAQ

OPTIONAL:

- AD8
- NPI-Q



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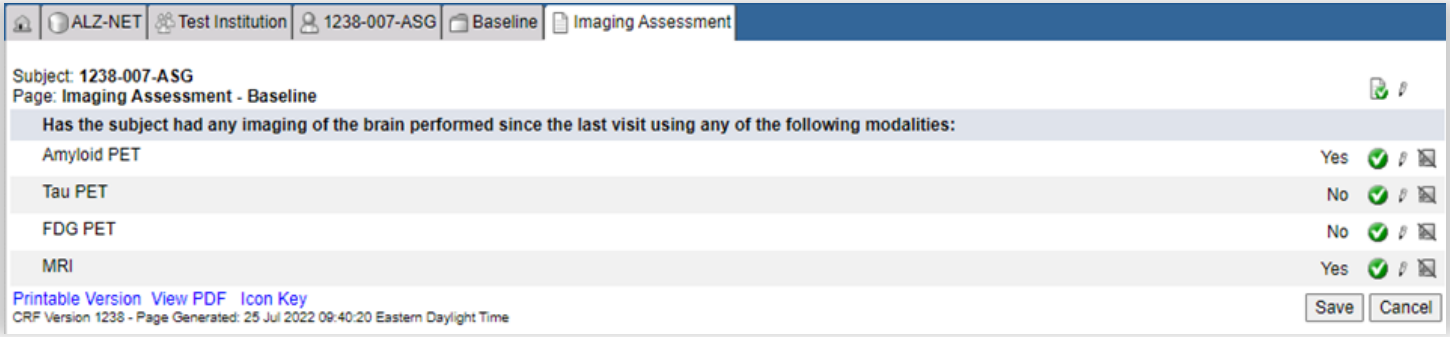
IMAGING: DATA COLLECTION



Imaging sites aligned with participating site; consistent site/scanner encouraged for ARIA screening and monitoring

DICOM and accompanying report will be uploaded to ACR via TRIAD/CONNECT

Imaging and timing of imaging via label and AURs, as applicable.

ACR to extract applicable clinical data and archive images.

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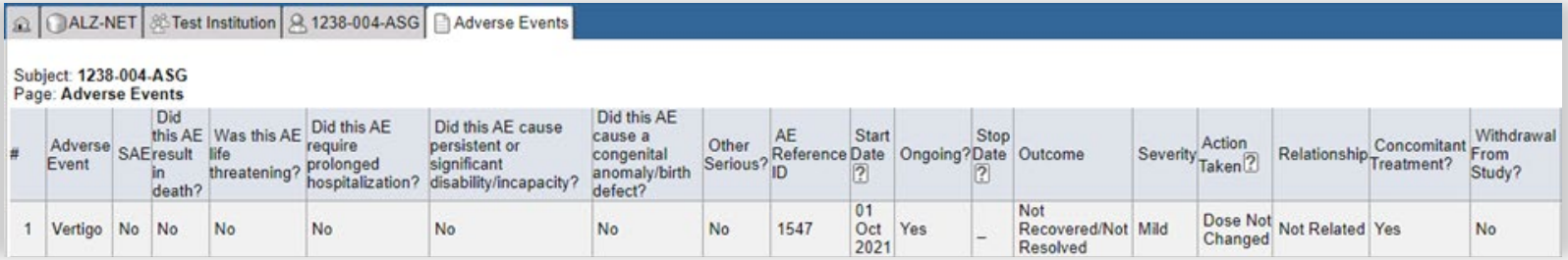
CRF: ADVERSE EVENTS

Providers will continue to report AE/SAEs through MedWatch mechanisms


ALZ-NET | Test Institution | 1238-004-ASG | Adverse Events

Subject: **1238-004-ASG**
Page: **Adverse Events**

#	Adverse Event	SAE	Did this AE result in death?	Was this AE life threatening?	Did this AE require prolonged hospitalization?	Did this AE cause persistent or significant disability/incapacity?	Did this AE cause a congenital anomaly/birth defect?	Other Serious?	AE Reference ID	Start Date	Ongoing?	Stop Date	Outcome	Severity	Action Taken	Relationship	Concomitant Treatment?	Withdrawal From Study?
1	Vertigo	No	No	No	No	No	No	No	1547	01 Oct 2021	Yes	–	Not Recovered/Not Resolved	Mild	Dose Not Changed	Not Related	Yes	No

ALZ-NET will collect information on AE/SAEs through Common Terminology Criteria for Adverse Events (CTCAE), including:

- Expected AEs per FDA label of the prescribed novel AD therapeutic.
- Unexpected AEs that are grade 3 or higher, per CTCAE grading scale
- AEs that cause change in management of the prescribed novel FDA-approved AD therapeutic.
- Events associated with the prescribed novel FDA-approved AD therapeutic(s), in the opinion of the site investigator (attribution categories of possible, probable, and definite).
- All serious adverse events (SAEs).

EXAMPLES: QUESTIONS ALZ-NET COULD ADDRESS

Leveraging ALZ-NET to build real-world evidence for approved treatments and to support innovative drug discovery programs.

We will be able to answer questions with this data set such as:

- Longitudinal change across decades
- Identifying responders and non-responders, predictors of response and non-response
- Comparing aggregated data on outcomes across MOA and classes of therapeutics
- Meeting requirements of CED for the new class of treatments available now and those coming on the horizon.

What is learned through ALZ-NET could help create more equitable access to treatments and offers an opportunity to improve clinical care.

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A SHARED VISION: WHY PARTICIPATE?

Partnerships & Network

Align with trusted partnering organizations towards our shared goal of advancing treatment and care

Building Evidence

Leverage ALZ-NET infrastructure, sites, and regulatory grade data collection for innovative treatment evaluation

Education & Training

Be a part of building the future of a clinical readiness program to treat Alzheimer's and all dementia

Reimbursement

Utilize ALZ-NET to meet coverage determination requirements for FDA-approved treatments

ALZ-NET

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IF YOU ARE INTERESTED IN BECOMING A SITE

Participating Sites must demonstrate the use of a multi-disciplinary dementia care team and optimal medical management.

Participating sites must have clinical expertise and infrastructure to provide novel FDA approved AD therapies consistent with the safety monitoring outlined in applicable FDA approved labels.

Aspects of a qualified participating site include but are not limited to:

- Access to accredited and appropriate radiological services for diagnostic and safety brain imaging;
- Access to infusion services;
- Access to emergency services;
- Access to standard cognitive, behavioral, and functional assessments used in dementia care.

To access a **site feasibility questionnaire** and for more information:

Or visit, **alz.org/alznetwork**

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IF YOU ARE INTERESTED IN BECOMING A SITE

The criteria to be considered a site investigator, otherwise known as a prescribing clinician:

- Hold credentials that authorize the prescription of novel FDA-approved therapies for patients with AD. (APPs with prescribing authority to serve as site co-investigators)
- Review all applicable FDA prescribing labels and published Appropriate Use Recommendations for novel FDA-approved therapies for AD
- Review the ALZ-NET operations training modules on the ALZ-NET website.
- Complete training for research with human subjects (e.g., CITI, GCP).
- Obtain access and complete training specific to the ALZ-NET Electronic Data Capture (EDC) System

To access a **site feasibility questionnaire** and for more information:

Or visit, **alz.org/alznetwork**

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A NEW PHASE

Treatment **Care** **Research**

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