Baseline Electronic Case Report Form (eCRF) Packet

Version 10 – March 2025

For a comprehensive list of updates made from the previous version, please contact alz-net@acr.org.

Patient Registration – Demography Form

Instructions: This form is to be completed for each new patient enrolling into the registry. All of the assessments needed to determine eligibility are considered standard of care. In order to be enrolled into ALZ-NET, case registration must occur via the ACR's Clinical Trial Web Application (also referred to as Research Management System; RMS) - https://acr-patientregistration.acr.org/

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1. Name of person registering case: _____
2. Name of treating clinician: _____
3. Date informed consent signed by patient or Legally Authorized Representative (LAR):
   _____[*MM/DD/YYYY*]
4. Date of protocol version for which informed consent was obtained: _____[*MM/DD/YYYY*]
5. Informed consent provided by:
   - Patient
   - Legally Authorized Representative (LAR)

   a. If provided by LAR, what is their relationship to the patient? _____

6. In what language was the consent form completed?
   - English
   - Spanish
   - Other language, specify

   a. If other language, please specify: _____

7. Has consent been provided for the patient to be contacted about other research studies investigating Alzheimer's disease for which they may be a candidate?
   - No
   - Yes
8. Patient's country of residence:
   - USA
   - CA (Canada)
   - Other
9. Patient's Year of Birth_____ *[YYYY*]
10. Patient's sex assigned at birth:
    - Male
    - Female
    - Unknown

11. Patient's self-reported identification of their gender:
    - Female
    - Male
    - Other Gender Identity, Specify
    - Prefer not to answer
    - Transgender Female
    - Transgender Male

    a. If other gender identity, specify: _____

12. Patient's self-reported identification of their race (select all that apply from the list below):
    - ☐ American Indian or Alaska Native (For example: Aztec, Blackfeet Tribe, Mayan, Navajo Nation, Nome Eskimo Community)
    - ☐ Asian or Asian American (For example: Asian Indian, Chinese, Filipino, Japanese, Korean, Pakistani, Vietnamese)
    - ☐ Black, African American, or African (For example: African American, Ethiopian, Haitian, Jamaican, Nigerian, Somali)
    - ☐ Hispanic, Latino, or Spanish (For example: Colombian, Cuban, Dominican, Mexican or Mexican American, Puerto Rican, Salvadoran)
    - ☐ Middle Eastern or North African (For example: Algerian, Egyptian, Iranian, Lebanese, Moroccan, Syrian)
    - ☐ Native Hawaiian or other Pacific Islander (For example: Chamorro, Fijian, Marshallese, Native Hawaiian, Tongan)
    - ☐ White or European (For example: English, European, French, German, Irish, Italian, Polish)
    - ☐ None of these fully describe me, specify: _____
    - ☐ Prefer not to answer
    - ☐ Unknown Race

13. Patient's primary insurance/beneficiary status:
    - Uninsured
    - Insured, Medicare Fee for Service
    - Insured, Medicare Advantage
    - Insured, Medicaid
    - Insured Commercial Plan (including TRICARE)
    - Veterans Administration (VA) Healthcare Benefits recipient
    - Other primary insurance status
        - Specify Other Insurance Status: _____

a. If Medicare Advantage, specify provider:
    - Anthem, Inc.
    - Blue Cross Blue Shield
    - CIGNA Health Plans, Inc.
    - CVS Health (Aetna)
    - Humana, Inc.
    - Kaiser Foundation Health Plans, Inc.
    - UnitedHealth Group Inc.
    - WellCare Corporation
    - Other Medicare Advantage provider
        - Specify other Medicare Advantage provider: _____

b. If Commercial Plan (including TRICARE), specify provider:
    - Anthem, Inc.
    - Blue Cross Blue Shield
    - CIGNA Health Plans, Inc.
    - CVS Health (Aetna)
    - Department of Defense – TRICARE
    - Health Care Service Corporation
    - Humana, Inc.
    - Kaiser Foundation Health Plans, Inc.
    - UnitedHealth Group Inc.
    - Other commercial plan
        - Specify other commercial insurance provider: _____

14. Does the patient have secondary insurance?
    - No
    - Yes

Patient Registration – Eligibility Checklist

Instructions: All eligibility criteria must be confirmed by a site investigator and/or the patient's medical records, prior to registration. Note, there are only inclusion criteria for ALZ-NET. The person submitting this form certifies that all of the following are correct:

1. Patient or patient's legally authorized representative (LAR) (e.g., spouse or legal guardian) has the ability to understand the purpose and risks of ALZ-NET and provide signed and dated informed consent and authorization to use protected health information (PHI) in accordance with national and local patient privacy regulations.	○ No ○ Yes
2. Patient is at least 18 years of age at the time of informed consent.	○ No ○ Yes
3. Patient has a diagnosis of MCI or dementia with clinical suspicion of Alzheimer's disease (AD) as contributing pathology and 1) is being evaluated for treatment or 2) will be initiating treatment or 3) has already initiated treatment with novel FDA-approved AD therapies in real world clinical practice.	○ No ○ Yes
4. If treatment is initiated at time of consent, patient meets appropriate label requirements and treatment follows appropriate use recommendations for novel FDA-approved AD therapy/therapies.	○ No ○ Yes ○ Not Applicable
5. Patient's treating clinician has made the decision to provide clinical care or treatment prior to patient consent and independently of the purpose of ALZ-NET.	○ No ○ Yes

Patient Registration - Patient Information

Instructions: ALZ-NET participants provide authorization via the informed consent process to have the below personal information provided to ALZ-NET. This data is entered by authorized site staff via a secure data transfer portal, ACR DART (Data Analysis and Research Toolkit). This data is kept secure and separate from the patient's clinical data and only accessed and used to collect health insurance claims data and/or contact for future research if the patient provided additional consent to that optional component of ALZ-NET. Sites must enter the patient's name exactly as it appears on their primary insurance ID card or medical record.

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1. First name: _____
2. Middle name *(optional)*: _____
3. Last name: _____
4. Patient's date of birth: ____/_____/_____ [*MM/DD/YYYY*]
5. Patient's country of residence: _____
6. Primary address: _____
7. Address (line 2): _____
8. City: _____
9. State: _____
10. Zip Code *(9 digits preferred)*: _____
11. Primary phone number: (_____)-_____-_____
12. Primary email address: _____
13. Social Security Number (SSN): _____-_____-_____ *(optional)*
14. Primary Insurance ID Number: _____ *(optional)*
15. Primary Insurance Group ID Number: _____ *(optional)*

Baseline Reporting Period and Patient Status

1. Reporting period **end** date: (Derived from date of registration)

If yes, Most Recent Type of contact with the Patient? (Select all that apply; at least 1 option must be checked)

- ☐ In-person clinic visit
- ☐ Telemedicine visit

Baseline Adverse Events Assessment

Did the patient experience any Adverse Events after the initiation of novel therapy up to the time of enrollment to the registry?

- Yes
- No

If yes, please record details on the Adverse Events form located at the Subject Level.

Did the patient experience any ARIA Adverse Events after the initiation of novel therapy up to the time of enrollment to the registry?

- Yes
- No

If yes, please record details on the ARIA Adverse Events form located at the Subject Level.

Medical History

Please enter Assessment Date and Save the page. Then complete the questions that appear below.
Assessment Date: _____ [*DD/MMM/YYYY]*

Instructions: Do not report MCI/dementia/Alzheimer's Disease on this form. These conditions are captured on the Baseline Alzheimer's Disease Diagnosis form. For any Medical History condition which meets Adverse Event reporting requirements, whether at Baseline or if determined at a later date, the condition must be reported on both the Medical History form and on the Adverse Event form. If treatment has been initiated prior to registration, adverse event reporting starts on the treatment start date, not registration date. *Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record. For each condition, please indicate whether they are part of the patient's past or current medical history.*

#	Medical History Term	Has this medical condition previously occurred and/or is it currently occurring? o Yes o No o Unknown	Start Date *YYYY* *(Enter UNK if unknown)*	Ongoing o Yes o No o Unknown	End Date *YYYY* *(Enter UNK if unknown)*
1	Atrial fibrillation				
2	Cardiac arrythmia				
3	Congestive heart failure				
4	Ischemic heart disease (e.g., CAD, angina, MI)				
5	Down syndrome				
6	Diabetes				
7	Dyslipidemia (e.g., elevated total cholesterol, LDL and triglycerides, decreased HDL cholesterol)				
8	Cerebrovascular disease (without stroke) (e.g., white matter hyperintensities, intracranial atherosclerosis)				
9	Chronic headaches				
10	Seizure disorder				

Medical History, continued.

#	**Medical History Term**	**Did this medical condition occur? Is this medical condition occurring?** ○ *Yes* ○ *No* ○ *Unknown*	**Start Date** *YYYY* *(Enter UNK if unknown)*	**Ongoing** ○ *Yes* ○ *No* ○ *Unknown*	**End Date** *YYYY* *(Enter UNK if unknown)*
11	Stroke				
12	Transient ischemic attack				
13	Traumatic brain injury				
14	Anxiety				
15	Delirium				
16	Depression				
17	Sleep disorder (e.g. apnea, insomnia)				
18	Hypertension				
19	Other, Specify: _____				

Vital Signs

Instructions: The data elements below must be collected by authorized site staff during a standard of care clinical visit and documented in the patient's medical record.

At Baseline: Report the most recent vital signs obtained up to an including the day of enrollment to the registry.

During Follow-Up: Report the most recent vital signs obtained within this data collection reporting period.

Were vital signs obtained during this reporting period?

- o Yes
- o No

1. Was height measured?	o Yes o No o Unknown	_____ o centimeters o inches
2. Was weight measured?	o Yes o No o Unknown	_____ o kg o lb
3. BMI	*Automatically calculated by EDC system*	
4. Was blood pressure performed?	o Yes o No o Unknown	Systolic: _____ mmHg Diastolic: _____mmHg o

Baseline Concurrent Study Enrollment

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.

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1. Is the patient currently enrolled in any ALZ-NET affiliated studies or any dementia-related clinical trial not affiliated with ALZ-NET?
   - o Yes
   - o No

2. Has the patient discontinued enrollment from any ALZ-NET affiliated studies?
   - o Yes
   - o No
   - o Not Applicable

#	Type of concurrent study o Enrolled to an ALZ-NET affiliated study o Enrolled in a dementia-related clinical trial not affiliated with ALZ-NET o Discontinued from an ALZ-NET affiliated study o Other, specify	Name of study	Case ID	Enrollment Date *DDMMMYYYY* *(Enter UNK if unknown)*	Ongoing? o Yes o No	Discontinuation Date *DDMMMYYYY* *(Enter UNK if unknown)*
1						
2						
3						
4						
5						

Baseline Lifestyle Data

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.

Does the site have information (from medical record or patient/caregiver reporting) about any of the following: tobacco usage, alcohol use, cannabis use, cannabis-derived use, recreational drug use, or amount of exercise?

- Yes *(if yes, then answer the form in entirety)*
- No *(if no, do not complete the rest of the form)*

1. Has the patient ever used tobacco?
   - Never
   - Previously
   - Currently
   - Unknown
2. Has the patient ever consumed alcohol?
   - Never
   - Previously
   - Currently
   - Unknown

   a. If **currently** consuming alcohol, how many drinks does the patient consume **per week** on average:
      - Less than or equal to 1 drink
      - Approximately 2 drinks
      - Greater than or equal to 3 drinks
      - Unknown
3. Has the patient ever used cannabis or cannabis-derived products?
   - Never
   - Previously
   - Currently
   - Unknown
4. Has the patient ever used other recreational drugs?
   - Never
   - Previously
   - Currently
   - Unknown
5. Is the patient currently engaging in physical exercise?
   - Yes
   - No
   - Unknown

   a. If the patient is currently exercising, how many hours per week do they exercise: *(Note: Please report to the nearest quarter hour.)* _____ hours/week

      ☐ Number of hours per week they exercise is unknown *(check if applicable)*

Baseline Patient Characteristics

Instructions: Data elements below must be collected by authorized site staff during interview with patient and recorded within the medical record. All responses must be self-reported by the patient.

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1. Does the patient have an informant or care partner who, in the Investigator's opinion, has frequent and sufficient contact with the patient as to be able to provide accurate information about the patient's cognitive and functional abilities?
    - ○ Yes
    - ○ No

2. What is the patient's highest level of education completed:
    - o No formal education
    - o Grade school
    - o Middle school
    - o Attended high school but did not graduate
    - o High school graduate
    - o High school equivalence
    - o Some college or associate degree
    - o Bachelor's degree
    - o Master's degree
    - o Doctoral or professional degree
    - o Unknown

3. What is the patient's preferred language?
    - o English
    - o Spanish
    - o Other, specify: _____

4. Does the patient have a family history of Alzheimer's Disease?
    - o Yes
    - o No
    - o Unknown

Clinical Features Form

Instructions: The data elements below must be collected by authorized site staff during a standard of care clinical visit.

Based on the clinician's most recent clinical assessment, indicate whether any of these co-pathologies exist for the patient:

1. Motor weakness o Yes o No o Unknown	2. Gait disorder (e.g., frequent falls) o Yes o No o Unknown
3. Parkinsonism o Yes o No o Unknown	4. Visual hallucinations o Yes o No o Unknown
5. REM Sleep Behavior disorder (RBD) o Yes o No o Unknown	6. Fluctuating cognition with variations in attention and alertness o Yes o No o Unknown
7. Changes in personality and behavior o Yes o No o Unknown	8. Language impairment (e.g. aphasia) o Yes o No o Unknown
9. Memory Impairment o Yes o No o Unknown	10. Salient visuospatial impairment o Yes o No o Unknown
11. Salient executive dysfunction o Yes o No o Unknown	12. Agitation o Yes o No o Unknown
13. Psychosis o Yes o No o Unknown	14. Vascular lesions on MRI o Yes o No o Unknown
14a. If vascular lesions are present on MRI, check all that apply: ☐ Lacunar infarcts ☐ White matter hyperintensities ☐ Intracerebral hemorrhages (ICH) >1cm ☐ Microhemorrhages (microH) Number of microhemorrhages: _____ ☐ Number unknown ☐ Superficial siderosis ☐ Cortical strokes ☐ Other, specify Specify other vascular lesion_____	

Additional Measures

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record. ***At Baseline-report on the most recent assessments performed. *During Follow-Up-report on all assessments performed during the reporting period.**

#	Assessment type*	Was assessment performed? o Yes o No	Assessment Date *MMMYYYY*	Total Score
1				
2				
3				
4				
5				
6				
7				

Assessment type:
Mini-Mental State Examination (MMSE)
Montreal Cognitive Assessment (MoCA)
Functional Activities Questionnaire (FAQ)
AD8 Screening Interview
Neuropsychiatric Inventory Questionnaire (NPI-Q)

Baseline Healthcare Utilization

Instructions: This form should only be completed if the patient is currently on treatment. If the patient is not on treatment, ***DO NOT*** *complete this form. Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.*

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1. **Since beginning treatment** with a novel FDA-approved therapy, has the patient been to the ER?
    - Yes
    - No
    - Unknown

        a) If yes, how many ER visits? _____

2. **Since beginning treatment** with a novel FDA-approved therapy, has the patient been hospitalized?
    - Yes
    - No
    - Unknown

        a) If yes, how many days in total? _____

Baseline Alzheimer's Disease Diagnosis

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.

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1. What was the patient's clinical disease stage at their most recent clinical evaluation?

- o Mild Cognitive Impairment (MCI) due to Alzheimer's Disease
- o Mild Alzheimer's Disease
- o Moderate Alzheimer's Disease
- o Severe Alzheimer's Disease

Alzheimer's Disease Clinical Characteristics:

1. Patient's age at onset of cognitive symptoms: _____ ☐ Age unknown
   Year of cognitive symptom onset, if known: _____ ☐ Year unknown

2. Patient's age at diagnosis of cognitive impairment: _____ ☐ Age unknown
   Year of diagnosis, if known: _____ ☐ Year unknown

3. Describe the patient's presentation of cognitive impairment at their most recent clinical evaluation:

- o Typical Presentation of Alzheimer's Disease
- o Atypical Presentation of Alzheimer's Disease

If atypical, check all that apply:

- ☐ The primary symptoms are not related to memory (e.g., primary deficits in executive functions, language, visuospatial, psychiatric, or motor functions)
- ☐ Presence of significant co-morbidities that can contribute to cognitive decline (e.g., medical conditions, pre-existing neurological or psychiatric conditions, substance abuse or other drug effects)
- ☐ The course of clinical progression is atypical (i.e., not slowly and gradually progressive)
- ☐ The clinical course has mixed features of AD and non-AD dementing illnesses (e.g., Parkinson's disease, Lewy body disease, frontotemporal dementia)

4. Was diagnostic testing (APOE genotype, cerebrospinal fluid (CSF) AD biomarker assay, blood-base AD biomarker assay, imaging) performed up to and including the time of enrollment to the registry?

- o Yes
- o No

If yes, please complete the Diagnostic Testing form located at the Subject level

Diagnostic Testing Log

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.

	Diagnostic Testing Type ○ APOE genotype ○ Cerebrospinal Fluid AD biomarker assay (CSF) ○ Blood-based AD biomarker assay ○ Imaging	Date of test *MMMYYYY*	Blood/CF/Imaging Result ○ Results consistent with Alzheimer's Disease ○ Results **not** consistent with Alzheimer's Disease ○ Indeterminant	If ApoE genotyping, what are the genotype results? ○ E2,E2 ○ E2,E3 ○ E2,E4 ○ E3,E3 ○ E3,E4 ○ E4,E4 ○ APOE4 carrier (specific alleles unknown) ○ APOE4 non-carrier (specific alleles unknown)	If imaging, what type of imaging? ○ Amyloid PET ○ Tau PET ○ FDG-PET ○ MRI
1					
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Baseline Novel Therapy Administration YN

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.

As AD therapies receive approval from the FDA, options below will be updated. The selection made on this form will trigger the roll-out of the appropriate therapy-specific eCRF for data entry.

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1. Has the patient received any doses of a novel FDA-approved AD therapy prior to their enrollment in the registry?

- Yes
- No
- Unknown

a) If yes, please indicate which therapy the patient has received (check all that apply):
   - Aducanumab (Aduhelm)
   - Lecanemab (Leqembi)
   - Brexpiprazole (Rexulti)
   - Donanemab (Kisunla)

b) If no, please indicate if the patient has completed initial evaluation for treatment?
   - Yes
   - No
   - Unknown

c) If the patient has completed initial evaluation, please select the reason for not initiating therapy. (check all that apply)

- ☐ Therapy deemed appropriate for patient but not yet initiated
- ☐ Treating clinician decided that treatment is contraindicated due to prior health conditions (i.e. MRI shows pre-existing vascular insult risk for ARIA high)
- ☐ Disease stage not conducive to treatment currently
- ☐ Genetic testing for APOE status not performed
- ☐ Lack of healthcare coverage for diagnostics
- ☐ Lack of healthcare coverage for treatment
- ☐ Biomarker confirmation not completed
  i. Please select the Reason why biomarker confirmation not completed?
     - No access to imaging
     - Patient does not want CSF LP
     - Other, please specify
- ☐ Other, specify

Baseline Novel Therapy – Aducanumab

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.

Report ALL doses administered prior to enrollment to the registry - up to and including the day of entry. When reporting a Missed Dose, please add a log line and report the initial missed dose, the expected date, and the reason.
- If the patient has had multiple missed doses in a row and the reason for missing the dose remains the same, only report the initial missed dose.
- If the patient has had multiple missed doses in a row and the reason for missing the dose has changed, please add a log line for each missed dose so that the change in reason can be captured.

#	**Dose Type** • Titration • Maintenance • Missed Dose	**Date of Infusion** *DDMMM YYYY*	**Expected Date** *DDMMM YYYY*	**Dose Level (mg/kg)** • 1 mg/kg • 3 mg/kg • 6 mg/kg • 10 mg/kg • Other, specify____	**Since the previous dose, has there been any changes to the dose/treatment?** (Select "Not Applicable" when reporting the very first dose of drug taken.) • Yes • No • Not Applicable	**If yes, reason for treatment change** • Dose increased • Dose reduced due to AE/SAE (other than ARIA) • Dose reduced due to ARIA • Held/missed due to AE/SAE (other than ARIA) • Held/missed due to ARIA • Treatment changed to another FDA-approved novel therapy • Treatment discontinued; patient will not continue with another FDA-approved novel therapy • Held/missed by patient/caregiver decision, specify_____
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Baseline Novel Therapy – Lecanemab

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.

Report ALL doses administered prior to enrollment to the registry - up to and including the day of entry. When reporting a Missed Dose, please add a log line and report the initial missed dose, the expected date, and the reason.
- If the patient has had multiple missed doses in a row and the reason for missing the dose remains the same, only report the initial missed dose.
- If the patient has had multiple missed doses in a row and the reason for missing the dose has changed, please add a log line for each missed dose so that the change in reason can be captured.

#	**Was this a Missed Dose?** • Yes • No	**Date of Infusion** *DDMMM YYYY*	**Expected Date** *DDMMM YYYY*	**Dose Level (mg/kg)** • 10mg/kg • Other, specify__	**Since the previous dose, has there been any changes to the dose/treatment?** (Select "Not Applicable" when reporting the very first dose of drug taken.) • Yes • No • Not Applicable	**If yes, reason for treatment change** • Dose increased • Dose reduced due to AE/SAE (other than ARIA) • Dose reduced due to ARIA • Held/missed due to AE/SAE (other than ARIA) • Held/missed due to ARIA • Treatment changed to another FDA-approved novel therapy • Treatment discontinued; patient will not continue with another FDA-approved novel therapy • Held/missed by patient/caregiver decision, specify_____
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Baseline Novel Therapy – Donanemab

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.

Report ALL doses administered prior to enrollment to the registry - up to and including the day of entry. When reporting a Missed Dose, please add a log line and report the initial missed dose, the expected date, and the reason.
- If the patient has had multiple missed doses in a row and the reason for missing the dose remains the same, only report the initial missed dose.
- If the patient has had multiple missed doses in a row and the reason for missing the dose has changed, please add a log line for each missed dose so that the change in reason can be captured.

#	**Dose Type** • Titration • Maintenance • Missed Dose	**Date of Infusion** *DDMMM YYYY*	**Expected Date** *DDMMM YYYY*	**Dose Level** • 350mg • 700mg • 1050mg • 1400mg • Other, specify__	**Since the previous dose, has there been any changes to the dose/treatment?** (Select "Not Applicable" when reporting the very first dose of drug taken.) • Yes • No • Not Applicable	**If yes, reason for treatment change** • Dose increased • Dose reduced due to AE/SAE (other than ARIA) • Dose reduced due to ARIA • Held/missed due to AE/SAE (other than ARIA) • Held/missed due to ARIA • Treatment changed to another FDA-approved novel therapy • Treatment discontinued; patient will not continue with another FDA-approved novel therapy • Held/missed by patient/caregiver decision, specify_____
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Baseline Novel Therapy – Brexpiprazole

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.

When reporting a change in Dose Level, enter a Stop Date and the Reason Stopped for the previous dose level and add a new log line for the new dose level.

When reporting a discontinuation of treatment, enter a Stop Date and the Reason Stopped.

#	**Dose Type** • Titration • Maintenance	**Start Date** *MMMYYYY*	**Dose Level** • 0.5 mg • 1 mg • 2 mg • 3 mg • Other, specify____	**Ongoing?** • Yes • No	**Stop Date** *MMMYYYY*	**Reason Stopped** • Dose increased • Dose reduced due to AE/SAE • Treatment changed to another FDA-approved novel therapy • Treatment discontinued; patient will not continue with another FDA-approved therapy
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Clinical Imaging Submission

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.

If imaging modality is MRI, please **select Not Applicable** for the type of PET Performed field.

PLEASE NOTE This form is now located within the ALZ-NET web portal. Data must be entered there and will be pushed for view-only access in RAVE. DICOM image data is submitted via TRIAD. Refer to the ALZ-NET protocol for additional details.

#	**Timepoint** • Baseline • 6-Months • 12-Months • 18-Months • 24-Months • 3 years • 4 years • 5 years	**Date of Imaging** *DDMMMYYYY*	**Imaging Modality** • Amyloid Positron emission tomography (PET) • Tau Positron emission tomography (PET) • Magnetic Resonance Imaging (MRI) • Fluorodeoxyglucose-positron emission tomography (FDG-PET)	**Type of PET Performed** • PET only • PET/CT • PET/MRI • Not Applicable (select for MRI)	**Who will submit radiological imaging?** *This is a drop down of activated ALZ-NET imaging facilities. Select 'self-upload' if your site will upload DICOM. Select 'Unknown' if the imaging facility you work with is not listed.*	**Image Accession #** *Free text. If # is unknown, enter 'UNK'*	**Radiology Report Upload** *Pdf upload functionality for associated imaging*
1							
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7							

Concomitant Medications

Instructions: Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record. Record only 1 medication per line in Rave EDC. Provide the full trade or propriety name of the medication; otherwise, the generic name may be recorded. Report all medications that a patient is currently prescribed. Previously entered medications can be updated (e.g., changed from Ongoing to having an End Date). Each NEW instance of a medication is to be reported on a NEW log line.

Note: Complete the Medical History, Clinical Events, Adverse Events, and/or ARIA Adverse Events forms PRIOR to completing this form.
Note: Do NOT report the novel FDA-approved AD therapies on this form. Each novel FDA-approved AD therapy has its own specific form.

#	**Concomitant Medication Name**	**Dose**	**Units***	**Frequency***	**Route***	**Start Date** *MMMYYYY* *(Enter UNK if unknown)*	**Ongoing** • Yes • No • Unknown	**End Date** *MMMYYYY* *(Enter UNK if unknown)*	**Indication** • Medical History • Clinical Event • Adverse Event • ARIA Adverse Event • Other_____
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** See key on next page*

Concomitant Medications, continued.

#	**Concomitant Medication Name**	**Dose**	**Units***	**Frequency***	**Route***	**Start Date** *MMMYYYY* *(Enter UNK if unknown)*	**Ongoing** • Yes • No • Unknown	**End Date** *MMMYYYY* *(Enter UNK if unknown)*	**Indication** • Medical History • Clinical Event • Adverse Event • ARIA Adverse Event • Other_____

Units:

app, apl
cap
drop, gtt
g
inh
mg
ug
L
mL
mcg
mEq
%
puff
supp
tab
Tbsp
tsp
patch
IU
spray
units
Other
Unknown

Frequency:

Daily
Twice Per Day
Three times Per Day
Four Times Per Day
Every Other Day
Once Per Week
Every Two weeks
Once Per Month
Immediately
As Needed
Once
Other
Unknown

Route:

Intramuscular
Intraocular
Nasal
Oral
Rectal
Inhalation
Subcutaneous
Topical
Transdermal
Vaginal
Other
Unknown

Adverse Events

Instructions: This form is used to report Adverse Events if at least one of the following criteria is met.

- Expected AEs per FDA label of the prescribed novel AD therapeutic
- Unexpected AEs that are considered to be possibly, probably, or definitely related to a novel FDA-approved AD therapeutic.
- AEs that cause a 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)

Note: Do not use this form to report ARIA AEs. All ARIA AEs (diagnoses and signs/symptoms) are to be reported on the ARIA Adverse Events and ARIA Adverse Events Signs and Symptoms forms.

Note: If the Adverse Event reported is one of the terms listed on the Medical History or Clinical Events form, please be sure it is also reported on one of those forms at the corresponding reporting period.

Note: If a diagnosis has been made which meets the AE reporting requirements, report only the diagnosis and not the associated signs/symptoms. If a diagnosis has not been made and there are signs/symptoms which meet AE reporting requirements, report the signs/symptoms.

#	**Adverse Event**	**SAE** • Yes • No	**Death** • Yes • No	**Life threatening** • Yes • No	**Inpatient or prolongation of hospitalization** • Yes • No	**Disability/ incapacity** • Yes • No	**Anomaly/ birth defect** • Yes • No	**Medically Important** • Yes • No	**Start Date** *DDMMMYYYY*	**Ongoing** • Yes • No	**Stop Date** *DDMMMYYYY* **Continue on next page…**
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Adverse Events, continued.

#	**Outcome** • Fatal • Not Recovered/Not Resolved • Resolved/Recovered with Sequelae • Recovered/Resolved • Recovering/Resolving • Unknown	**Severity** • Mild • Moderate • Severe	**Action Taken with Alzheimer's therapy** • Dose Not Changed • Drug Withdrawn • Drug Interrupted • Dose Reduced • Dose Increased • Not Applicable • Unknown	**Relationship to Alzheimer's therapy** • Definite • Probable • Possible • Unrelated	**Expectedness** • Expected • Unexpected	**Concomitant Treatment** • Yes • No If yes, record treatment on the Concomitant Medications form	**Withdrawal from registry** • Yes • No	**Reported to FDA program and/or drug manufacturer** • Yes • No • Unknown	**To which entity** • FDA • Drug manufacturer	**Earliest date of reporting** *DDMMMYYYY* **OR** Date unknown
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ARIA Adverse Events

Instructions: This form is used to report ARIA Adverse Events.

Note: Do not use this form to report non-ARIA AEs. Non-ARIA AEs are to be reported on the Adverse Events form.

#	**Adverse Event** • Asymptomatic ARIA-E • Symptomatic ARIA-E • Asymptomatic ARIA-H (Microhemorrhage (microH)) • Symptomatic ARIA-H (Microhemorrhage (microH)) • Asymptomatic ARIA-H Intracerebral hemorrhage (ICH) >1cm)) • Symptomatic ARIA-H Intracerebral hemorrhage (ICH) >1cm)) • Asymptomatic ARIA-H (Superficial Siderosis) • Symptomatic ARIA-H (Superficial Siderosis)	**SAE** • Yes • No	**Death** • Yes • No	**Life threatening** • Yes • No	**Inpatient or prolongation of hospitalization** • Yes • No	**Disability/ incapacity** • Yes • No	**Anomaly/ birth defect** • Yes • No	**Medically Important** • Yes • No	**Start Date** *DDMMMYYYY*	**Ongoing** • Yes • No	**Stop Date** *DDMMMYYYY* **Continue on next page…**
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ARIA Adverse Events, continued.

#	**Outcome** • Fatal • Not Recovered/Not Resolved • Resolved/Recovered with Sequelae • Recovered/Resolved • Recovering/Resolving • Unknown	**Clinical Severity** • Mild • Moderate • Severe	**Action Taken** • Dose Not Changed • Drug Withdrawn • Drug Interrupted • Dose Reduced • Dose Increased • Not Applicable • Unknown	**Relationship** • Definite • Probable • Possible • Unrelated	**Concomitant Treatment** • Yes • No If yes, record treatment on the Concomitant Medications form	**Withdrawal from registry** • Yes • No	**Reported to FDA program and/or drug manufacturer** • Yes • No • Unknown	**To which entity** • FDA • Drug manufacturer	**Earliest date of reporting** *DDMMMYYYY* **OR** Date unknown
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ARIA Adverse Events Signs and Symptoms

Instructions: This form is used to report ARIA Adverse Events.

Note: Do not use this form to report non-ARIA AEs. Non-ARIA AEs are to be reported on the Adverse Events form.

#	**ARIA AE Logline** (Derived in Rave)	**AE:** (Derived in Rave)	**Start Date** (Derived in Rave)	**Signs/Symptom** • Confusion • Gate disturbance • Headache • Nausea • Seizure • Tremor • Visual change • Other, specify	**Did this sign/symptom occur** • Yes • No • Unknown	**Start Date** DDMMMYYYY	**Ongoing** • Yes • No	**End Date** DDMMMYYYY	**Severity** • Mild • Moderate • Severe	**Relationship to ARIA event** • Definite • Probable • Possible • Unrelated
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Protocol Deviation

Instructions: This form is used to report applicable deviations from standard administrative procedures and the ALZ-NET protocol.

Note: Do not use this form to report deviations from site or treatment specific protocols.

#	**Select the protocol event being reported** • Patient consented with ICF which had been changed without IRB approval • Patient consented with non-current ICF • Patient enrolled without consent • Patient enrolled to a protocol version which had been changed without IRB approval • Patient enrolled under expired IRB approval • Inclusion/exclusion criteria not met at time of enrollment to registry • There was a breach in patient confidentiality • Duplicate enrollment • Other, specify_____	**Protocol Deviation Occurrence Date** *DDMMMYYYY*	**Date Protocol Deviation was Discovered** *DDMMMYYYY*	**Describe the Protocol deviation** *Free text box*	**What Was Done to Rectify the Situation and/or Prevent Future Occurrence?** *Free text box*	**At what reporting period did this Study Deviation Occur** Enrollment/Registration Baseline 6-month 12-month 18-month 24-month Year 3 Year 4 Year 5 Other, Specify _____
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