Baseline Electronic Case Report Form (eCRF) Packet

Version 4 – August 2023

Document Version History

Version #	Significant Changes	Section	Effective Date
1.0	Initial Launch of Electronic Case Report Forms (eCRFs)		AUGUST 2022
2.0	Protocol Amendment (March 27, 2023) Updated inclusion criteria New Forms: Patient Personal Information; Reporting period and patient status; Therapy Form-Lecanemab Updated Forms: Additional Measures	Patient registration, page 6 Patient personal info, page 7 and 8 Reporting period, page 9 Therapy Form – Lecanemab, page 25 Additional Measures, page 18	APRIL 2023
3.0	New Forms: Therapy Form-Brexpiprazole; Baseline Adverse Events Assessment Form Updated Forms: Baseline Reporting Period and Patient Status; Medical History; Baseline Lifestyle Data; Baseline Novel Therapy; Baseline Therapy Form-Aducanumab; Baseline Therapy Form - Lecanemab	Baseline Reporting Period, page 9 Baseline Adverse Events Assessment Form, page 10 Medical History, page 11 Baseline Lifestyle Data, page 16 Baseline Novel Therapy, page 25 Baseline Therapy Form – Aducanumab, page 26 Baseline Therapy Form – Lecanemab, page 27 Baseline Therapy Form- Brexpiprazole, page 28	JULY 2023

4.0	Updated Forms: Baseline Reporting Period and Patient Status; Baseline Novel Therapy	Baseline Reporting Period and Patient Status Form, page 10 Baseline Novel Therapy Form, page 25	

Patient Registration

Instructions: This form is to be completed for each new patient enrolling into the registry. All the assessments needed to determine eligibility are considered standard of care. In order to be enrolled to the study, case registration must occur via the ACR Clinical Trial Web Application (also referred to as Clinical Trial Management System; CTMS) - https://clinicalweb.acr.org/ClinicalAcrin/faces/jsp/index.jsp

---

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*]
6. Informed consent provided by:
   - Patient
   - Legally Authorized Representative (LAR)

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

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

9. If other language, please specify: _____

10. Has consent been provided for the patient to be contacted about other research studies investigating Alzheimer's disease for which he or she may be a candidate?
    - No
    - Yes

11. Patient's country of residence:
    - USA
    - CA (Canada)
    - Other

12. Patient's Year of Birth_____ *[YYYY]*

Patient Registration, continued.

13. Patient's sex assigned at birth:
    - Male
    - Female
    - Unknown

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

15. Other gender identity, specify: _____

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

Patient Registration, continued.

Enter the patient's information as it appears on their Insurance ID card

Primary Insurance Status:

- Uninsured
- Insured, Medicare Fee for Service
- Insured, Medicare Advantage
- Insured, Medicaid
- Insured Commercial Plan (including TRICARE)
- Other primary insurance status

  Specify Other Insurance Status: _____

☐ If Medicare Advantage, specify provider (*insert code into box)*:

1. Anthem, Inc.
2. Blue Cross Blue Shield
3. CIGNA Health Plans, Inc.
4. CVS Health (Aetna)
5. Humana, Inc.
6. Kaiser Foundation Health Plans, Inc.
7. UnitedHealth Group Inc.
8. WellCare Corporation
9. Other Medicare Advantage provider

   Specify other Medicare Advantage provider: _____

☐ If Commercial Plan (including TRICARE), specify provider (*insert code into box)*:

1. Anthem, Inc.
2. Blue Cross Blue Shield
3. CIGNA Health Plans, Inc.
4. CVS Health (Aetna)
5. Department of Defense – TRICARE
6. Health Care Service Corporation
7. Humana, Inc.
8. Kaiser Foundation Health Plans, Inc.
9. UnitedHealth Group Inc.
10. Other commercial plan

    Specify other primary insurance provider: _____

☐ Does the patient have secondary insurance? (*insert code into box)*

1. No
2. Yes

Patient Registration, continued.

Inclusion / Exclusion Criteria

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
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

ALZ-NET Patient Personal 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.

---

1. ALZ-NET Case ID#: _____
2. First name: _____
3. Middle name *(optional)*: _____
4. Last name: _____
5. Patient's date of birth: ____/_____/_____ [*MM/DD/YYYY*]
6. Primary address: _____
7. Address (line 2): _____
8. City: _____
9. State: _____
10. Zip Code: _____
11. Primary phone number: (_____)-_____-_____
12. Primary email address: _____
13. Social Security Number (SSN): _____-_____-_____
14. Specify Insurance Status
    - Uninsured
    - Insured, Medicare Fee for Service
    - Insured, Medicare Advantage
        i. If Medicare Advantage:
            - 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, specify: _____

- Insured, Medicaid
- Insured, Commercial Plan
    i. If Commercial Plan:
        - 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, Specify

15. Primary Insurance ID Number: _____

16. Primary Insurance Group ID Number: _____

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

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. For each condition, please indicate whether they are part of the patient's past or current medical history.

Assessment Date: _____ [*DD/MMM/YYYY]*

Instructions: For any Medical History event which later meets Adverse Event reporting requirements, report it on both this form and on the Adverse Event form.

Please enter Assessment Date and Save the page. Then complete the questions that appear below. NOTE: Additional loglines can be added to report more than one type of the following conditions: autoimmune, chronic infection, cancer, or other central nervous system disease. Use the dropdown to select from one of the four conditions; do not enter any other condition into the Term field.

This is a targeted list of conditions. Only report on those conditions which are listed and/or present in the dropdown menu when adding a login.

#	Medical History Term	Did this medical condition occur? Is this medical condition occurring? ○ Yes ○ No ○ Unknown	Start Date *DDMMMYYYY*	Ongoing ○ Yes ○ No ○ Unknown	End Date *DDMMMYYYY*
1	Atrial fibrillation				
2	Cardiac Arrythmia				
3	Congestive heart failure				
4	Ischemic heart disease				
5	Down syndrome				
6	Chronic liver disease				
7	Autoimmune disorders, specify _____				
8	Multiple sclerosis				
9	Chronic infection, specify_____				

Medical History, continued.

#	Medical History Term	Did this medical condition occur? Is this medical condition occurring? ○ *Yes* ○ *No* ○ *Unknown*	Start Date *DDMMMYYYY*	Ongoing ○ *Yes* ○ *No* ○ *Unknown*	End Date *DDMMMYYYY*
10	Diabetes				
11	Dyslipidemia				
12	Cancer, specify_____				
13	Cerebrovascular disease (without stroke)				
14	Chronic headaches				
15	Epilepsy				
16	Other CNS disease, specify_____				
17	Parkinson's disease				
18	Seizure disorder				
19	Stroke				
20	Transient ischemic attack				
21	Traumatic brain injury				
22	Anxiety				
23	Bipolar affective disorder				
24	Delirium				
25	Depression				
26	Sleep disorder				
27	Chronic kidney disease				
28	Chronic Obstructive Pulmonary Disease (COPD)				

29	Hypertension				

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.

Assessment Date: _____ [*DDMMMYYYY]*

1. Was height performed?	○ Yes ○ No ○ Unknown	_____ ○ centimeters ○ inches
2. Was weight performed?	○ Yes ○ No ○ Unknown	_____ ○ kg ○ lb
3. BMI	*Automatically calculated by EDC system*	
4. Was blood pressure performed?	○ Yes ○ No ○ Unknown	Systolic: _____ mmHg Diastolic: _____mmHg What was the position of the patient when BP was performed? ○ Supine ○ Standing ○ Sitting ○ Semi-Recumbent ○ Unknown
5. Was pulse performed?	○ Yes ○ No ○ Unknown	_____ beats/min
6. Was temperature performed?	○ Yes ○ No ○ Unknown	_____ ○ Celsius ○ Fahrenheit
7. Was respiratory rate performed?	○ Yes ○ No ○ Unknown	_____ breaths/min
8. Was oxygenation saturation performed?	○ Yes ○ No ○ Unknown	_____ %

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.

---

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

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

#	Type of concurrent study ○ Enrolled to an ALZ-NET affiliated study ○ Enrolled in a dementia-related clinical trial not affiliated with ALZ-NET ○ Discontinued from an ALZ-NET affiliated study ○ Other, specify	Name of study	Case ID	Enrollment Date *DDMMMYYYY*	Ongoing? ○ Yes ○ No	Discontinuation Date *DDMMMYYYY*
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.

---

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

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.

---

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
        a. If yes, what is the informant or care partner's relationship to the patient?
        - ○ Spouse/Partner
        - ○ Child(ren)
        - ○ Other relative
        - ○ Caregiver/Household worker/Assisted living
        - ○ Friend/Roommate
        - ○ Someone else, specify relationship: _____

2. What is the patient's marital status:
    - ○ Married
    - ○ Living with partner
    - ○ Widowed
        a. If widowed, for how long? _____ (years)
    - ○ Divorced
        a. If divorced, for how long? _____ (years)
    - ○ Separated
    - ○ Never married
    - ○ Prefer not to answer

3. <u>What are the patient's living arrangements:</u>
    - ○ Patient lives alone

    a. <u>If the patient lives with at least one other person, indicate the person(s) with whom the patient lives (check all that apply):</u>

        - ☐ Spouse/Partner
        - ☐ Child(ren)
        - ☐ Other relative
        - ☐ Caregiver/Household worker/Assisted living
        - ☐ Friend/Roommate
        - ☐ Someone else, specify relationship to patient: _____

Baseline Patient Characteristics, continued.

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

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

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

Clinical Features of Co-pathology

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. Early changes in personality and behavior o Yes o No o Unknown	8. Aphasia o Yes o No o Unknown
9. Vascular lesions on MRI o Yes o No o Unknown	9a. If vascular lesions are present on MRI, check all that apply: ☐ Lacunar infarcts ☐ White matter hyperintensities ☐ Microhemorrhages ☐ 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.

#	Assessment type*	Was assessment performed? ○ Yes ○ No	Assessment Date *DDMMMYYYY*	MMSE Version*	MoCA Version*	Validation concerns (MMSE and/or MoCA only)	Language*	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)

MMSE Version:
MMSE-1
MMSE-2:BV
MMSE-2:SV
MMSE-2:EV
SMMSE
Other, specify

MoCA Version:
MoCA 8.1
MoCA 8.2
MoCA 8.3
Other, specify

Validation Concerns:
Examinee factor
Environmental factor
Administration factor

Language
English
Spanish
Mandarin
Cantonese
Tagalog
Vietnamese
French
Arabic
Korean
Russian
German
Other, specify

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.*

---

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.

---

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

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

   - Typical Presentation of Alzheimer's Disease
   - 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)

Baseline Alzheimer's Disease Diagnosis, continued.

4. Indicate symptoms of impairment that the patient is describing at their most recent clinical evaluation

a. Memory impairment ○ Yes ○ No ○ Unknown	**b. Language impairment** ○ Yes ○ No Unknown	**e. Change in personality** ○ Yes ○ No ○ Unknown
c. Salient visuospatial impairment ○ Yes ○ No Unknown	**d. Salient executive dysfunction** ○ Yes ○ No ○ Unknown	

Diagnostic Testing

***APOE* Genotype**

1. Has *APOE* genotyping been conducted?

- Yes
- No
- Unknown

a. If yes, what was the *APOE* genotyping result?

- E2,E2
- E2,E3
- E2,E4
- E3,E3
- E3,E4
- E4,E4
- Unknown

Cerebrospinal Fluid (CSF)

1. Has CSF been collected for diagnostic purposes?

- Yes
- No
- Unknown

a. If yes, what was the result?

- Results consistent with Alzheimer's Disease
- Results not consistent with Alzheimer's Disease
- Indeterminant

Baseline Alzheimer's Disease Diagnosis, continued.

Blood

1. Has blood been collected for diagnostic purposes?

- o Yes
- o No
- o Unknown

a. If yes, what was the result?

- o Results consistent with Alzheimer's Disease
- o Results not consistent with Alzheimer's Disease
- o Indeterminant

b. If yes, specify the category of protein measured (check all that apply).

- ☐ Plasma Amyloid, Beta
- ☐ Plasma phosphorylated Tau protein

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.

---

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™)

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 and the decision was made to not initiate treatment, please select the reason for not initiating therapy. (check all that apply)

- ☐ Therapy deemed appropriate for patient but not yet initated
- ☐ 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.

When reporting a Missed Dose, please add a log line and report the initial missed dose, the expected dose, 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.

---

1. Date of **first** dose of aducanumab: _____ *DDMMMYYYY*

2. Date of **last** dose of aducanumab *up to and including day of* entry to the registry: _____ *DDMMMYYYY*

#	Dose Type • Titration • Maintenance • Missed Dose	Start Date *DDMMMYYYY*	Expected Date DDMMMYYYY	Start Time (24 hour clock) HH mm	Start Time Unknown	Stop Date *DDMMMYYYY*	Stop Time (24 hour clock) HH mm	Stop Time Unknown	Dose Level • 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	Reason • 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_____
1											
2											
3											

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.

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.

---

1. Date of **first** dose of lecanemab: _____ *DDMMMYYYY*

2. Date of **last** dose of lecanemab *up to and including day of* entry to the registry: _____ *DDMMMYYYY*

#	Was this a Missed Dose? • Yes • No	Start Date *DDMMMYYYY*	Expected Date DDMMMYYYY	Start Time (24 hour clock) HH mm	Start Time Unknown	Stop Date *DDMMMYYYY*	Stop Time (24 hour clock) HH mm	Stop Time Unknown	Dose Level • 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_____
1											
2											
3											

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.

Instruction:

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
		DDMMMYYYY
			Dose Level
			• 0.5 mg
			• 1 mg
			• 2 mg
			• 3 mg
			• Other, specify____
				Ongoing?
				• Yes
				• No
					Stop Date
					DDMMMYYYY
						Reason Stopped
						• Dose increased
						• Dose reduced due to AE/SAE (other than ARIA)
						• Held/missed due to AE/SAE (other than ARIA)
						• Treatment changed to another FDA-approved novel therapy
						• Treatment discontinued; patient will not continue with another FDA-approved therapy
						  • Dose increased
						  • Dose reduced due to AE/SAE
						  • Treatment changed to another FDA-approved therapy
						  • Treatment discontinued; patient will not continue with another FDA-approved therapy

1						
2						
3						
4						
5						
6						

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 submit images via TRIAD. Refer to the ALZ-NET protocol for additional details.

PLEASE NOTE if incorrect data is entered in the Date of Imaging or the Imaging Modality fields, users will not be able to change the data once the form is saved. If an error is made, the log line containing the error must be inactivated and a new log line must be added to enter the correct data.

---

1. Did the patient have any imaging to report for this time period?

#	**Imaging Modality** • Amyloid Positron emission tomography (PET) • Tau Positron emission tomography (PET)	**Type of PET Performed** • PET only • PET/CT • PET/MRI • Not Applicable (select for MRI)	**Date of Imaging** *DDMMMYYYY*	**Indicate the use of IV contrast (MRI)** • With Contrast • Without Contrast • With and Without Contrast • Unknown
1				
2				
3				
4				
5				
6				
7				
8				
9				

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.

Instructions: 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 *DDMMMYYYY*	Ongoing • Yes • No • Unknown	End Date *DDMMMYYYY*	Indication • Medical History • Clinical Event • Adverse Event • ARIA Adverse Event • Other_____
1									
2									
3									
4									
5									
6									

** See key on next page*

Concomitant Medications, continued.

#	Concomitant Medication Name	Dose	Units*	Frequency*	Route*	Start Date *DDMMMYYYY*	Ongoing • Yes • No • Unknown	End Date *DDMMMYYYY*	Indication • Medical History • Clinical Event • Adverse Event • ARIA Adverse Event • Other_____
8									
9									
10									
11									

Units:
app, apl
cap
drop, gtt
g
inh
mg
ug
L
mL
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: Record only **1** AE per line in Rave EDC. Refer to protocol for reporting criteria. Data elements below must be collected by authorized clinical staff during standard of care clinical visit and documented in the patient's medical record.*

Instructions: This form is used to report Adverse Events.

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

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…**
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											

Adverse Events, continued.

#	Outcome • Fatal • Not Recovered/Not Resolved • Resolved/Recovered with Sequelae • Recovered/Resolved • Recovering/Resolving • Unknown	Severity • Mild • Moderate • Severe	Action Taken • Dose Not Changed • Drug Withdrawn • Drug Interrupted • Dose Reduced • Dose Increased • Not Applicable • Unknown	Relationship • Definite • Probable • Possible • Unlikely • 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	To which entity? • FDA • Drug manufacturer	Earliest date of reporting *DDMMMYYYY* **OR** Date unknown
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

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) • Symptomatic ARIA-H (Microhemorrhage) • 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…**
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											

ARIA Adverse Events, continued.

#	Outcome • Fatal • Not Recovered/Not Resolved • Resolved/Recovered with Sequelae • Recovered/Resolved • Recovering/Resolving • Unknown	Severity • Mild • Moderate • Severe	Action Taken • Dose Not Changed • Drug Withdrawn • Drug Interrupted • Dose Reduced • Dose Increased • Not Applicable • Unknown	Relationship • Definite • Probable • Possible • Unlikely • 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	To which entity? • FDA • Drug manufacturer	Earliest date of reporting *DDMMMYYYY* **OR** Date unknown
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

Protocol Deviation

#	Select the protocol event being reported	Protocol Deviation Occurrence Date	Date Protocol Deviation was Discovered	Describe the Protocol deviation	What Was Done to Rectify the Situation and/or Prevent Future Occurrence?	At what reporting period did this Study Deviation Occur
	• 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 • Other, specify_____	*DDMMMYYYY*	*DDMMMYYYY*	*Free text box*	*Free text box*	Enrollment/Registration Baseline 6-month 12-month 18-month 24-month Year 3 Year 4 Year 5 Other, Specify _____
1						
2						
3						
4						
5						
6						
7						
8						