Follow-up Electronic Case Report Form (eCRF) Packet

Version 9 – March 2025

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

Follow-Up Reporting Period and Patient Status

1. Reporting period **start** date *(Derived from end date of previous reporting period plus 1 day)*

2. Reporting period **end** date: (Derived from date of registration plus follow-up visit time period e.g. 6-monhts, 12-months, etc.)

3. Is *Treating Investigator* (Derived) still the treating investigator?

   - Yes
   - No

   If no, please enter the name of the new treating investigator: _____

4. Has the site had any contact, excluding infusion-only visits, with the patient since the last reporting period?
   - Yes
   - No

If no, reason?

- Unable to contact patient/LAR via any method (phone call, text, in-person, etc.)
- LAR indicates that patient too ill for visit/contact
- Informed of patient's death/obituary notice
- Other

  If Other, specify _____

If yes, please add a new log line for each encounter with a dementia care clinician?
Please document all clinic visits the patient had with a Dementia Care Clinician that occurred since the last reporting period. Please do not include infusion only or imaging only visits on this form. Infusions are captured on the Novel Therapy forms. Imaging is captured on the Image submission log.

Encounter Date *(DDMMMYYYY)*	Encounter Type: • In-person clinic visit • Telemedicine visit	Purpose of Encounter: • Routine/ Follow-Up • Unscheduled • Other	If Other, Specify

Follow-Up Conditions and Medications Assessment

1. Did any previously reported ongoing Medical History conditions end since the last data entry timepoint?
   - Yes
   - No

   If yes, please update the Medical History form located within the Baseline folder.

2. Did any previously reported ongoing Clinical Event conditions end since the last data entry timepoint?
   - Yes
   - No

   If yes, please update the Clinical Events form located at the subject level.

3. Did any new Clinical Event conditions begin since the last data entry timepoint?
   - Yes
   - No

   If yes, please complete the Clinical Events form located at the subject level.

4. Did any previously reported ongoing Concomitant Medications end or did any new Concomitant Medications begin since the last data entry timepoint?
   - Yes
   - No

   If yes, please update the Concomitant Medications form located at the Subject Level.

5. Did any previously reported Adverse Events recover/resolve or did the patient experience any new Adverse Events since the last data entry time point?
   - Yes
   - No

   If yes, please update the Adverse Events form located at the Subject Level.

6. Did any previously reported ARIA Adverse Events recover/resolve or did the patient experience any new ARIA Adverse Events since the last data entry time point?
   - Yes
   - No

   If yes, please update the ARIA Adverse Events form located at the Subject Level.

Clinical Events

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.

Instructions:

- *This form is used to report Clinical Events.*
- *Please report all NEW clinical events and UPDATES to previously reported clinical events.*
- *Please report ANY condition for which the patient is currently prescribed medication and/or is of clinical significance in the opinion of the treating clinician.*
- *If a second incidence of a clinical event occurs, add a new log line to report the second incidence; do NOT overwrite the original event.*
- *For any condition which also meets Adverse Event reporting requirements report it on both this form and on the Adverse Events form.*

NOTE: A change in grade does NOT constitute a new event.

#	**Clinical Event Term (***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 logline.***)**	**Did this clinical event start during this reporting period?** ○ *Yes* ○ *No* ○ *Unknown*	**Start Date** *MMMYYYY* *(Enter UNK if unknown)*	**Ongoing** ○ *Yes* ○ *No* ○ *Unknown*	**End Date** *MMMYYYY* *(Enter UNK if unknown)*
1	Atrial fibrillation				
2	Cardiac arrythmia				
3	Congestive heart failure				
4	Ischemic heart disease (e.g., CAD, angina, MI)				
5	Diabetes				
6	Dyslipidemia (e.g., elevated total cholesterol, LDL and triglycerides, decreased HDL cholesterol)				
7	Cerebrovascular disease (without stroke) (without stroke) (e.g., white matter hyperintensities, intracranial atherosclerosis)				
8	Chronic headaches				
9	Seizure disorder				
10	Stroke				
11	Transient ischemic attack				

Clinical Events, continued.

#	Clinical Event Term	Did this clinical event start during this reporting period? ○ *Yes* ○ *No* ○ *Unknown*	Start Date *MMMYYYY* *(Enter UNK if unknown)*	Ongoing ○ *Yes* ○ *No* ○ *Unknown*	End Date *MMMYYYY* *(Enter UNK if unknown)*
12	Traumatic brain injury				
13	Anxiety				
14	Delirium				
15	Depression				
16	Sleep disorder (e.g. apnea, insomnia)				
17	Hypertension				
18	Other, Specify: _____				

Vital Signs

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

Were vital signs obtained during this reporting period?

- o Yes
- o No

Assessment Date: _____ *DDMMMYYYY*

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

Follow-Up 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.

Instructions: Concurrent studies previously reported as ongoing will be pulled into the log automatically. For each, please indicate if it is still ongoing or provide a discontinuation date. For each newly enrolled to study, please add a log line.

Since the last reporting period, did the patient newly enroll to any ALZ-NET affiliated or dementia-related clinical trials not affiliated with ALZ-NET?

- o Yes
- o No

#	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)*
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Follow-Up 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.

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1. **Since the last reporting period**, have there been any changes to any of the following: tobacco usage, alcohol use, cannabis use, cannabis-derived use, recreational drug use, or amount of exercise?
    - Yes *(If yes, answer the form in its entirety.)*
    - No *(If no, do not complete the rest of the form.)*
2. Has the patient ever used tobacco?
    - Never
    - Previously
    - Currently
    - Unknown
3. 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
4. Has the patient ever used cannabis or cannabis derived products?
    - Never
    - Previously
    - Currently
    - Unknown
5. Has the patient ever used other recreational drugs?
    - Never
    - Previously
    - Currently
    - Unknown
6. 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: _____ hours/week (Note: Please report to the nearest quarter hour.)

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

Clinical Features Form

Instructions: The data elements below must be collected by authorized 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:

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

Follow-up Healthcare Utilization

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. **Since the last reporting period**, has the patient been to the ER?
    - Yes
    - No
    - Unknown

        a) If yes, how many ER visits? _____

2. **Since the last reporting period**, has the patient been hospitalized?
    - Yes
    - No
    - Unknown

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

Follow-up 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 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. 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)

2. Was diagnostic testing (APOE genotype, cerebrospinal fluid (CSF) AD biomarker assay, blood-base AD biomarker assay, imaging) performed up during this reporting period?

- o Yes
- o No

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

Follow-up 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. Were novel therapy(ies) initiated prior to this data collection timepoint?
    - o Yes
    - o No
    - o Unknown
2. Has the patient received any doses of a novel FDA-approved AD therapy since the last data entry timepoint?
    - o Yes
    - o No
    - o Unknown

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

b) If novel therapy was not previously initiated and was not received since the last data entry timepoint, please indicate if the patient has completed initial evaluation for treatment?
- o Yes
- o No
- o Unknown

c) 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 (check all that apply)?
        - o No access to imaging
        - o Patient does not want CSF LP
        - o Other, please specify
- ☐ Other, specify

Follow-up 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 during this reporting period. *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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Follow-up 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 during this reporting period.

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.

#	**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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Follow-up 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*
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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
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** *DDMMM YYYY*	**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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5												
6												
7												
8												

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 • Uknown	**To which entity** • FDA • Drug manufacturer	**Earliest date of reporting** *DDMMMYYYY* **OR** Date unknown
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6									
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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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Death Details

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

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1. Date of death: _____ *DDMMMYYYY*

2. What was the patient's primary cause of death?
   - Alzheimer's Disease
   - Alzheimer's Disease treatment
   - ARIA AE
   - Other cause, specify _____

Lost to Follow-up

1st contact attempt _____*DDMMMYYYY*

Type of contact

- ☐ Phone
- ☐ Letter
- ☐ Email
- ☐ Text
- ☐ Certified mail

2nd contact attempt _____*DDMMMYYYY*

Type of contact

- ☐ Phone
- ☐ Letter
- ☐ Email
- ☐ Text
- ☐ Certified mail

3rd contact attempt _____*DDMMMYYYY*

Type of contact

- ☐ Phone
- ☐ Letter
- ☐ Email
- ☐ Text
- ☐ Certified mail

Name and title of person responsible for data on this form _____

Date of lost to follow-up determination _____*DDMMMYYYY*

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 • 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 _____
1						
2						
3						
4						
5						
6						
7						

Withdrawal of Consent

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

Instructions: *Per protocol, patients are allowed to reconsent at any time to one or more optional components of registry-related activities. In these situations, use the Add Event feature to select the Reconsent form.*

Note: *For those patients who previously withdrew consent from ALL registry-related activities, they must re-enroll if they wish to continue participation.*

#	**Withdrawn Consent Date** *DDMMMYYYY*	**By whom?** • Patient • Legally Authorized Representative (LAR)	**Level of withdrawal?** • Withdraws from one or more components of registry-related activities AND remains on the registry • Withdraws from ALL registry-related activities	**Which Component?** • To be contacted for other research opportunities	**Reason?** • Patient no longer receiving dementia care at this site • Patient/LAR feel that participation is burdensome to patient • Concern over privacy and use of data collected • Concern over financial cost of dementia care • No reason provided • Other, specify
1					
2					
3					
4					

Optional Components Reconsent Log

Instructions: *This form is only to be completed for those patients who had previously withdrawn consent from one or more of the optional components of registry-related activities AND remained on the registry and who are now reconsenting to one or more of these components.*

Note: *For those patients who previously withdrew consent from ALL registry-related activities, they must re-enroll if they wish to continue participation in the registry. This form is NOT to be completed for those patients.*

#	**Date of reconsent** *DDMMMYYYY*	**By whom?** • Patient • LAR	**Which component?** • To be contacted for other research opportunities	**Reason?** • Patient again receiving dementia care at this site • Patient/LAR no longer feel that participation is burdensome to patient • Patient started new or resumed previous novel FDA-approved therapy • No longer concerned over privacy/use of data collected • No longer concerned over financial cost of dementia care • No reason provided • Other	**Other, specify_____**