Follow-up Electronic Case Report Form (eCRF) Packet

Version 5 – January 2024

Document Version History

Version #	Significant Changes	Section	Effective Date
1.0	Initial Launch of Follow-up Electronic Case Report Forms (eCRFs)		April 2023
2.0	New Forms: Follow-up Novel Therapy - Brexpiprazole; Follow-up Adverse Event Assessment Updated Forms: Clinical Events; Follow-Up Lifestyle Data; Follow-up Novel Therapy Administration; Follow-Up Novel Therapy-Aducanumab; Follow-Up Novel Therapy-Lecanemab;	Follow-Up Adverse Event Assessment Form, page 4 Clinical Events Form, page 5 Follow-Up Lifestyle Data, page 9 Follow-Up Novel Therapy Form, page 17 Follow-Up Novel Therapy-Aducanumab, page 18 Follow-Up Novel Therapy-Lecanemab, page 19 Follow-Up Novel Therapy-Brexpiprazole, page 20	July 2023
3.0	Updated Forms: Reporting Period and Patient Status; Follow-Up Novel Therapy	Reporting Period and Patient Status, page 3 Follow-Up Novel Therapy, page 17	August 2023
4.0	Updated Forms: Follow-Up Reporting Period and Patient Status; Clinical Events; Vital Signs; Clinical Features of Co-pathology; Additional Measures; Follow-Up Alzheimer's Disease Diagnosis; Follow-Up Novel Therapy	Follow-Up Reporting Period and Patient Status, page 4 Clinical Events, page 6-7 Vital Signs, page 8 Clinical Features of Co-Pathology, page 13	October 2023

		Additional Measures, page 14 Follow-Up Alzheimer's Disease Diagnosis, page 16-17 Follow-Up Novel Therapy Administration, page 18	
5.0	New Forms: ARIA AE Signs and Symptoms Updated Forms: AE Form; ARIA AE Form	ARIA Adverse Events Signs and Symptoms, page 30 Adverse Events Form, page 26-27 ARIA AE Form, page 28-29	January 2024

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 visits on this form. Infusions are captured on the Novel Therapy forms.)

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

Follow-Up Adverse Events Assessment

Did the patient experience any Adverse Events since the last data entry time point?

- 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 since the last data entry time point?

- Yes
- No

If yes, please record details on 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.

Assessment Date: _____ *DDMMMYYYY*

Please enter Assessment Date and Save the page. Then complete the questions that appear below.

Instructions:

- Please assess EACH Clinical Event Term listed and respond Yes/No for each. A Yes response is only to be used for NEW clinical events which began during this reporting period. Please note: a change in grade does not constitute a new event.

- If a previously reported event has resolved, please go to the form on which it was first reported (Medical History or Clinical Events form) and update to include the End Date.

- For any Clinical Event which also meets Adverse Event reporting requirements, report it on both this form and on the Adverse Event form.

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.

#	**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** *DDMMMYYYY*	**Ongoing** ○ *Yes* ○ *No* ○ *Unknown*	**End Date** *DDMMMYYYY*
1	Atrial fibrillation				
2	Cardiac arrythmia				
3	Congestive heart failure				
4	Ischemic heart disease				
5	Liver disease				
6	Autoimmune disorders, specify _____				
7	Multiple sclerosis				
8	Chronic infection, specify_____				
9	Diabetes				

Clinical Events, continued.

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

Vital Signs

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

Assessment Date: _____ *DDMMMYYYY*

Were vital signs obtained during this reporting period?

- Yes
- No
- Unknown

1. Was height measured?	○ Yes ○ No ○ Unknown	_____ ○ centimeters ○ inches
2. Was weight measured?	○ 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	_____ %

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?

- Yes
- No

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

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.)

Follow-Up 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. **Since the last reporting period**, have there been any changes to any of the following: caregiver partnership, marital status, living arrangements, education, language, family history of Alzheimer's disease?
    - Yes (**If yes,** answer the form in its entirety.)
    - No (**If no**, do not complete the rest of the form.).

2. 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: _____

3. 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

Follow-Up Patient Characteristics, continued.

4. What are the patient's living arrangements:
    - Patient lives alone

    If the patient lives with at least one other person, indicate the person(s) with whom the patient lives (check all that apply):

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

5. 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 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 ○ Yes ○ No ○ Unknown	2. Gait disorder (e.g., frequent falls) ○ Yes ○ No ○ Unknown
3. Parkinsonism ○ Yes ○ No ○ Unknown	4. Visual hallucinations ○ Yes ○ No ○ Unknown
5. REM Sleep Behavior disorder (RBD) ○ Yes ○ No ○ Unknown	6. Fluctuating cognition with variations in attention and alertness ○ Yes ○ No ○ Unknown
7. Early changes in personality and behavior ○ Yes ○ No ○ Unknown	8. Aphasia ○ Yes ○ No ○ Unknown
9.Agitation ○ Yes ○ No ○ Unknown	10.Psychosis ○ Yes ○ No ○ Unknown
11. Vascular lesions on MRI ○ Yes ○ No ○ Unknown	11a. 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. ***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? ○ Yes ○ No	Assessment Date *DDMMMYYYY*	MMSE Version*	MoCA Version*	Validation concerns (MMSE and/or MoCA only)	Language*	Total Score

Assessment type:

Mini-Montreal 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

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?

- Mild Cognitive Impairment due to Alzheimer's Disease
- Mild Alzheimer's Disease
- Moderate Alzheimer's Disease
- Severe Alzheimer's Disease

Alzheimer's Disease Clinical Characteristics:

1. 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)

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

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

Follow-up Alzheimer's Disease Diagnosis, continued.

Diagnostic Testing

APOE Genotype

1. Has *APOE* genotyping been conducted since the last study visit?
   - Yes
   - No
   - Unknown

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

- E2,E2
- E2,E3
- E2,E4
- E3,E3
- E3,E4
- E4,E4
- APOE4 carrier (specific alleles unknown)
- APOE4 non-carrier (specific alleles unknown)

Cerebrospinal Fluid (CSF)

1. Has CSF been collected for diagnostic purposes since the last study visit?
   - Yes
   - No
   - Unknown

a. If yes, what was the result?

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

Blood

1. Has blood been collected for diagnostic purposes since the last study visit?
   - Yes
   - No
   - Unknown

a. If yes, what was the result?

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

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

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

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) indicated prior to this data collection timepoint?
    - Yes
    - No
    - Unknown

2. Has the patient received any doses of a novel FDA-approved AD therapy since the last data entry timepoint?
    - 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 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?
        - Yes
        - No
        - 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)?
                - No access to imaging
                - Patient does not want CSF LP
                - 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.

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	Start Date *DDMMMYYYY*	Expected Date DDMMMYYYY	Start Time (24 hour clock) HH nn	Start Time Unknown	Stop Date *DDMMMYYYY*	Stop Time (24 hour clock) HH nn	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											
4											

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.

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	Start Date *DDMMMY YYY*	Expected Date DDMMMY YYY	Start Time (24 hour clock) HH nn	Start Time Unknown	Stop Date *DDMMMY YYY*	Stop Time (24 hour clock) HH nn	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											
4											

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 *DDMMMYYYY*	Stop Date *DDMMMYYYY*	Dose Level • 0.5 mg • 1 mg • 2 mg • 3 mg • Other, specify____	Stop Date *DDMMMYYYY*	Reason Stopped • • 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.

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1. Did the patient have any imaging to report for this time period?
   - No
   - Yes

#	**Imaging Modality** • Amyloid Positron emission tomography (PET) • Tau Positron emission tomography (PET) • Magnetic Resonance (MRI)	**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				
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6				
7				
8				
9				
10				
11				

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									
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6									
7									
8									
9									

** 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_____
10									
11									
12									
13									
14									

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. 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	To which entity? • FDA • Drug manufacturer	Earliest date of reporting DDMMMYYYY **OR** Date unknown
1										
2										
3										
4										
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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											
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6											
7											
8											
9											
10											

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	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 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)	AE: (Derived)	Start Date (Derived)	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
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

Death Details

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

---

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

#	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 via the ACR Clinical Trial Web Application 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 via the ACR Clinical Trial Web Application 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_____**