Form A4a: ADRD–Specific Treatments

ADRC: _____ PTID: _____ Form date: __ __ / __ __ / __ __ __ __ Visit #: _____ Examiner's initials: _____

Language:
☐1 English
☐2 Spanish

Mode:
☐1 In-person
☐2 Remote *(reason):* ___
☐1 Telephone ☐2 Video

Key (remote reason): *1=Too cognitively impaired*
2=Too physically impaired
3=Homebound or nursing home
4=Refused in-person visit
5=Other

***INSTRUCTIONS**: This form should be used to record treatments expected to significantly impact Alzheimer disease and related dementias (ADRD) biomarkers, whether a disease-modifying treatment that is FDA-approved for ADRD and received as part of clinical care or an investigational treatment received as part of a clinical trial. For treatments received as part of clinical care, only those that are FDA-approved for disease-modification of ADRD should be included on this form. If the participant is receiving one of these treatments as part of their clinical care at the time of clinical assessment (e.g., they are receiving lecanemab infusions), the treatment should be included on both this form and the A4 Medication form. Participation in any ADRD drug trial over an individual's lifetime should be included. If available, the ClinicalTrials.gov identifier should be entered into the "specific treatment and/or trial" cell. Information on the type of treatment can be found via ClinicalTrials.gov and is summarized in* "Alzheimer's disease drug development pipeline." [1] *This form should be completed by the clinician based on participant interview and/or co-participant report. For additional clarification and examples, see* **UDS Coding Guidebook** *for* **Form A4a**. *Check only <u>one</u> box per question, unless otherwise stated.*

1. Has the participant ever been prescribed a treatment or been enrolled in a clinical trial of a treatment expected to modify ADRD biomarkers?

☐0 No **(END FORM HERE)**
☐1 Yes
☐9 Unknown **(END FORM HERE)**

2. Please provide information about the clinical treatment(s) and/or trial(s)
(If participant is exposed to more than two treatments and/or trials, use extended table on Page 2):

Primary Drug Target *(check all that apply)*	**Specific treatment and/ or trial**	**Start date** *(99/9999 =Unknown)*	**End date** *(month/year) (99/9999=Unknown; 88/8888=Ongoing)*	**How was the treatment provided?**	**If clinical trial, in which group was the participant?**
☐1 Amyloid beta ☐1 Tau ☐1 Inflammation ☐1 Synaptic plasticity/ neuroprotection ☐1 Other target(s) _____	_____ *NCT–*_____	__ __ / __ __ __ __	__ __ / __ __ __ __	☐1 Clinical care ☐2 Clinical trial ☐3 Clinical care and clinical trial	☐1 Active treatment ☐2 Placebo ☐9 Unknown
☐1 Amyloid beta ☐1 Tau ☐1 Inflammation ☐1 Synaptic plasticity/ neuroprotection ☐1 Other target(s) _____	_____ *NCT–*_____	__ __ / __ __ __ __	__ __ / __ __ __ __	☐1 Clinical care ☐2 Clinical trial ☐3 Clinical care and clinical trial	☐1 Active treatment ☐2 Placebo ☐9 Unknown

3. Has the participant ever experienced amyloid related imaging abnormalities–edema (ARIA-E), amyloid related imaging abnormalities–hemorrhage (ARIA-H), or other major adverse events associated with treatments expected to modify ADRD biomarkers?

☐0 No **(END FORM HERE)**
☐1 Yes
☐9 Unknown **(END FORM HERE)**

3a. What major adverse events associated with treatments expected to modify ADRD biomarkers did they experience?
(check all that apply)

3a1. ☐1 Amyloid related imaging abnormalities–edema (ARIA-E)
3a2. ☐1 Amyloid related imaging abnormalities–hemorrhage (ARIA-H)
3a3. ☐1 Other issues
_____
_____

2.	Please provide information about the clinical treatment(s) and/or trial(s) *(continued from Page 1):*				
Primary Drug Target *(check all that apply)*	**Specific treatment and/ or trial**	**Start date** *(month/year) (99/9999 =Unknown)*	**End date** *(month/year) (99/9999=Unknown; 88/8888=Ongoing)*	**How was the treatment provided?**	**If clinical trial, in which group was the participant?**
☐ 1 Amyloid beta ☐ 1 Tau ☐ 1 Inflammation ☐ 1 Synaptic plasticity/ neuroprotection ☐ 1 Other target(s) _______________	____________ *NCT–*_________	__ __/ __ __ __ __	__ __/ __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown
☐ 1 Amyloid beta ☐ 1 Tau ☐ 1 Inflammation ☐ 1 Synaptic plasticity/ neuroprotection ☐ 1 Other target(s) _______________	____________ *NCT–*_________	__ __/ __ __ __ __	__ __/ __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown
☐ 1 Amyloid beta ☐ 1 Tau ☐ 1 Inflammation ☐ 1 Synaptic plasticity/ neuroprotection ☐ 1 Other target(s) _______________	____________ *NCT–*_________	__ __/ __ __ __ __	__ __/ __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown
☐ 1 Amyloid beta ☐ 1 Tau ☐ 1 Inflammation ☐ 1 Synaptic plasticity/ neuroprotection ☐ 1 Other target(s) _______________	____________ *NCT–*_________	__ __/ __ __ __ __	__ __/ __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown
☐ 1 Amyloid beta ☐ 1 Tau ☐ 1 Inflammation ☐ 1 Synaptic plasticity/ neuroprotection ☐ 1 Other target(s) _______________	____________ *NCT–*_________	__ __/ __ __ __ __	__ __/ __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown
☐ 1 Amyloid beta ☐ 1 Tau ☐ 1 Inflammation ☐ 1 Synaptic plasticity/ neuroprotection ☐ 1 Other target(s) _______________	____________ *NCT–*_________	__ __/ __ __ __ __	__ __/ __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown

[1] Cummings et al., "Alzheimer's disease drug development pipeline: 2022," Alzheimer's and Dementia. 2022 May 4; 8(1):e12295.