Form A4a: ADRD–Specific Treatments

ADRC name: _____ Participant ID: _____ Form date: ___ ___ / ___ ___ / ___ ___ ___ ___

Visit #: _____ Examiner's initials: _____

***INSTRUCTIONS**: This form should be used to record treatments known to significantly impact Alzheimer disease and related dementias (ADRD) biomarkers, whether received as part of clinical care or a clinical trial. 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 aducanumab 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 may be completed based on participant interview and/or co-participant report. For additional clarification and examples, see* **UDS Coding Guidebook** *for* **Initial Visit Packet, Form A4a**. *Check only <u>one</u> box per question, unless otherwise stated.*

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

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

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 extended table on Page 2):

Primary Drug Target *(check all that apply)*	Specific treatment and/or trial	Start date *(month/year)*	End date *(month/year)*	How was the treatment provided?	If clinical trial, in which group was the participant?
2a1a. ☐ 1 Amyloid beta **2a1b.** ☐ 1 Tau **2a1c.** ☐ 1 Inflammation **2a1d.** ☐ 1 Synaptic plasticity/ neuroprotection **2a1e.** ☐ 1 Other target(s) _____	_____ _____	__ __ / __ __ __ __	__ __ / __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown
2b1a. ☐ 1 Amyloid beta **2b1b.** ☐ 1 Tau **2b1c.** ☐ 1 Inflammation **2b1d.** ☐ 1 Synaptic plasticity/ neuroprotection **2b1e.** ☐ 1 Other target(s) _____	_____ _____	__ __ / __ __ __ __	__ __ / __ __ __ __	☐ 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

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 _____

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

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)*	End date *(month/year)*	How was the treatment provided?	If clinical trial, in which group was the participant?
2c1a. ☐ 1 Amyloid beta **2c1b.** ☐ 1 Tau **2c1c.** ☐ 1 Inflammation **2c1d.** ☐ 1 Synaptic plasticity/ neuroprotection **2c1e.** ☐ 1 Other target(s) _____	_____ _____	__ __ / __ __ __ __	__ __ / __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown
2d1a. ☐ 1 Amyloid beta **2d1b.** ☐ 1 Tau **2d1c.** ☐ 1 Inflammation **2d1d.** ☐ 1 Synaptic plasticity/ neuroprotection **2d1e.** ☐ 1 Other target(s) _____	_____ _____	__ __ / __ __ __ __	__ __ / __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown
2e1a. ☐ 1 Amyloid beta **2e1b.** ☐ 1 Tau **2e1c.** ☐ 1 Inflammation **2e1d.** ☐ 1 Synaptic plasticity/ neuroprotection **2e1e.** ☐ 1 Other target(s) _____	_____ _____	__ __ / __ __ __ __	__ __ / __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown
2f1a. ☐ 1 Amyloid beta **2f1b.** ☐ 1 Tau **2f1c.** ☐ 1 Inflammation **2f1d.** ☐ 1 Synaptic plasticity/ neuroprotection **2f1e.** ☐ 1 Other target(s) _____	_____ _____	__ __ / __ __ __ __	__ __ / __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown
2g1a. ☐ 1 Amyloid beta **2g1b.** ☐ 1 Tau **2g1c.** ☐ 1 Inflammation **2g1d.** ☐ 1 Synaptic plasticity/ neuroprotection **2g1e.** ☐ 1 Other target(s) _____	_____ _____	__ __ / __ __ __ __	__ __ / __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown
2h1a. ☐ 1 Amyloid beta **2h1b.** ☐ 1 Tau **2h1c.** ☐ 1 Inflammation **2h1d.** ☐ 1 Synaptic plasticity/ neuroprotection **2h1e.** ☐ 1 Other target(s) _____	_____ _____	__ __ / __ __ __ __	__ __ / __ __ __ __	☐ 1 Clinical care ☐ 2 Clinical trial ☐ 3 Clinical care and clinical trial	☐ 1 Active treatment ☐ 2 Placebo ☐ 9 Unknown