FOLLOW-UP VISIT PACKET UNIFORM DATA SET (UDS) VERSION 4.0



Examiner's

Form A4a: ADRD–Specific Treatments

1a. Since the last UDS visit, is new information available concerning any of the participant's prescribed treatments or clinical trial(s) of a treatment expected to modify ADRD biomarkers? 2. Please provide information about the clinical treatment(s) and/or trial(s). INCLUDE ALL HISTORICAL CLINICAL TREATMENT(S) AND/OR TRIAL(S) even if there is no new information on those treatments/trials. If there is a new treatment and/or trial to report, please add it after all of the historical information. (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 trials (99/9999	ADRC: _			PTID:		Form date:/	./ `	Visit #:	initials:				
dementics (ADRD) biomarkers, whether a disease-modifying treatment that is FDA-approved for ADRD and received as part of cilinical care or an investigational treatment received as part of a cilinical trial. For treatments received as part of cilinical care or an investigational treatment received as part of cilinical care or an investigational treatment received as part of the cilinical care at the time of cilinical branch in 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 infisions), the treatment should be included an both this form and the AM Medication form. Participation in any ADRD and trail over an individual's lifetime should be included and both this form and the AM Medication form. Participation in any ADRD and trail over an individual's lifetime should be included in the type of treatment can be found via ClinicalTrials.gov and is summarized in "latheimer's disease drug development pipeline." 1 This form should be completed based on participant interview and/or co-participant report. For additional clarification and examples, see UDS Coding Guidebook, Form A4a. Check only one box per question, unless otherwise stated. 1. Has the participant ever been prescribed a treatment or been enrolled in a clinical trial of a lab. Since the last UDS visit, is new information available concerning any of the participant's prescribed treatments or clinical trial (s) of a treatment expected to modify ADRD biomarkers? 2. Please provide information about the clinical treatment(s) and/or trial(s). INCLUDE ALL HISTORICAL CLINICAL TREATMENT(S) AND/OR TRIAL(S) even if there is no new information on those treatments/trials. If there is a new treatment and/or trial to report, please add it after all of the historical information. (If participant is exposed to more than two treatments and/or trial(s). In Clinical care lab (month) year) lab (Participant ever experienced amyloid related imaging abnormalities—dema (ARIA	□1 Eng	lish	□1 In-persor	(reason):	Key (remote r	2=Too physically ir 3=Homebound or 4=Refused in-perso	npaired nursing home						
treatment expected to modify ADRD biomarkers? 1 Yes 9 Unknown (END FORM HERE)	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 based on participant interview and/or co-participant report. For additional												
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Primary Drug Target (check all that apply) Amyloid beta Inflammation Infla	2.	TREATMENT(S) AND/OR TRIAL(S) even if there is no new information on those treatments/trials. If there is a new treatment and/or trial to report, please add it after all of the historical information.											
1 Tau 1 Inflammation 1 Synaptic plasticity/ neuroprotection 1 Other target(s) 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? 3a. Since the last UDS visit, is new information available concerning the participant's experience of 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? 3b. What major adverse events associated with treatments expected to modify ADRD biomarkers did they 3b2. 1 Amyloid related imaging 3b1. 1 Amyloid related imaging abnormalities-edema (ARIA-E) abnormalities-edema (ARIA-E) 3b3. 1 Other issues				treatment and/	(99/9999	(month/year) (99/9999=Unknown;	treatm	ent	which group was				
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1 Cummings et al., "Alzheimer's disease drug development pipeline: 2024," Alzheimer's and Dementia. 2024 April 24; 10(2):e12465.

Participant ID:		Form date:	_ / /	Visit #:						
2. Please provide information about the clinical treatment(s) and/or trial(s). INCLUDE ALL HISTORICAL CLINICAL TREATMENT(S) AND/OR TRIAL(S) even if there is no new information on those treatments/trials. If there is a new treatment and/or trial to report, please add it after all of the historical information. (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					
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