Directors Session Panel

Sarah Biber, PhD, NACC Program Director

Monday, May 1, 2023

ADRC Spring Meeting

ADRD-Disease Modifying Drugs

Form A4a: ADRD-Specific Treatments

INITIAL VISIT PACKET UNIFORM DATA SET (UDS) VERSION 4.0

Form A4a: ADRD–Specific Treatments

In-person ☐ Remote ☐ Not completed ☐ ___ ___ *(Reason not completed: 95=Physical problem, 96=Cognitive/behavioral problem, 97=Other, 98=Verbal refusal)*

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

Visit #: _____ Examiner's initials: _____ Language: English ☐ Spanish ☐ Chinese ☐

***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 should 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 one box per question, unless otherwise stated.*

1. Has the participant ever been prescribed or been enrolled in a clinical trial of a 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, use 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?

Advancing the ADRD Field

- A4a – Captures information on any ADRD drugs that have been administered in the person's life (in clinical care or in a clinical trial)
- Observational "phase 4 trial" – UDS infrastructure is in place for longitudinal tracking
- N.B. Dosage information is not captured

ADRD-Disease Modifying Drugs

Form A4a: ADRD-Specific Treatments

INITIAL VISIT PACKET UNIFORM DATA SET (UDS) VERSION 4.0

NACC

Form A4a: ADRD–Specific Treatments

In-person ☐ Remote ☐ Not completed ☐ ___ ___ *(Reason not completed: 95=Physical problem, 96=Cognitive/behavioral problem, 97=Other, 98=Verbal refusal)*

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

Visit #: _____ Examiner's initials: _____ Language: English ☐ Spanish ☐ Chinese ☐

***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 should 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 one box per question, unless otherwise stated.*

1.	Has the participant ever been prescribed or been enrolled in a clinical trial of a 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, use 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?

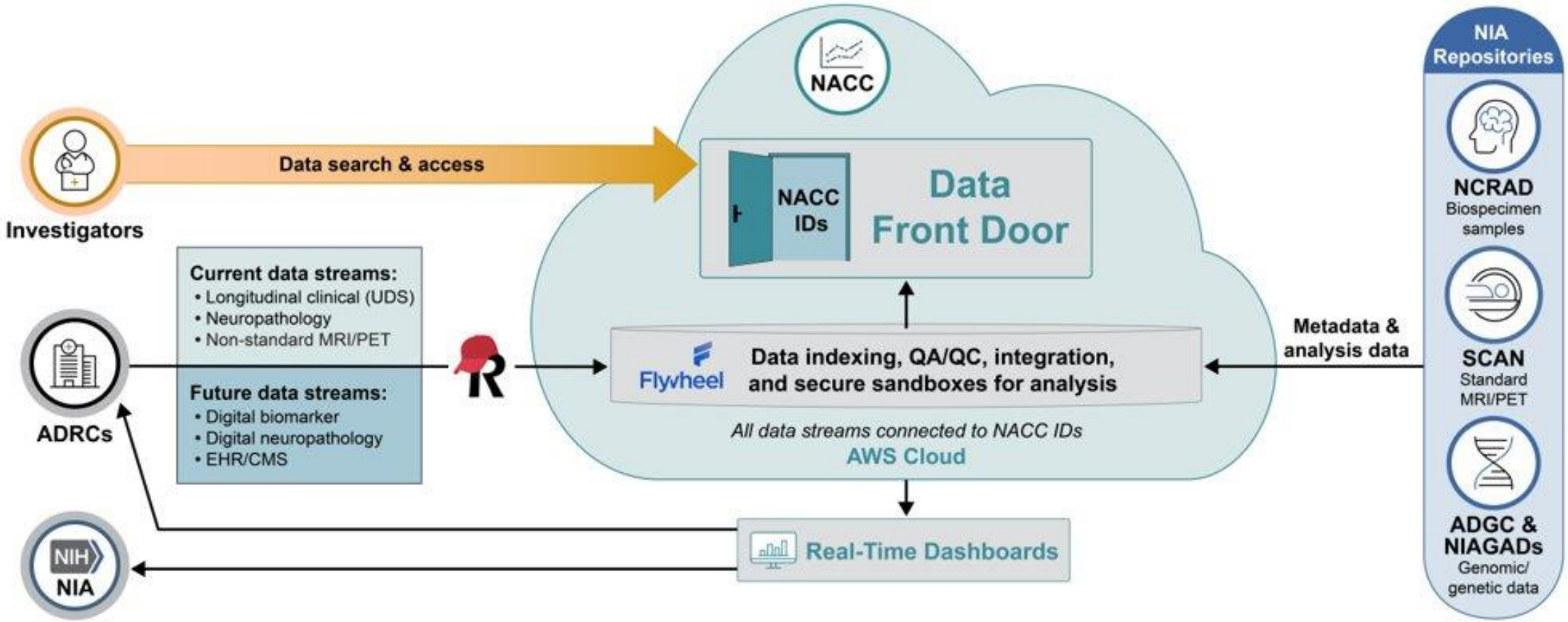
Advancing the ADRD Field

- Opportunities to build interoperability with other ADRD studies
  - Via co-enrollment with UDS
  - Via building interoperability

ALZHEIMER'S NETWORK

ALZHEIMER'S ASSOCIATION

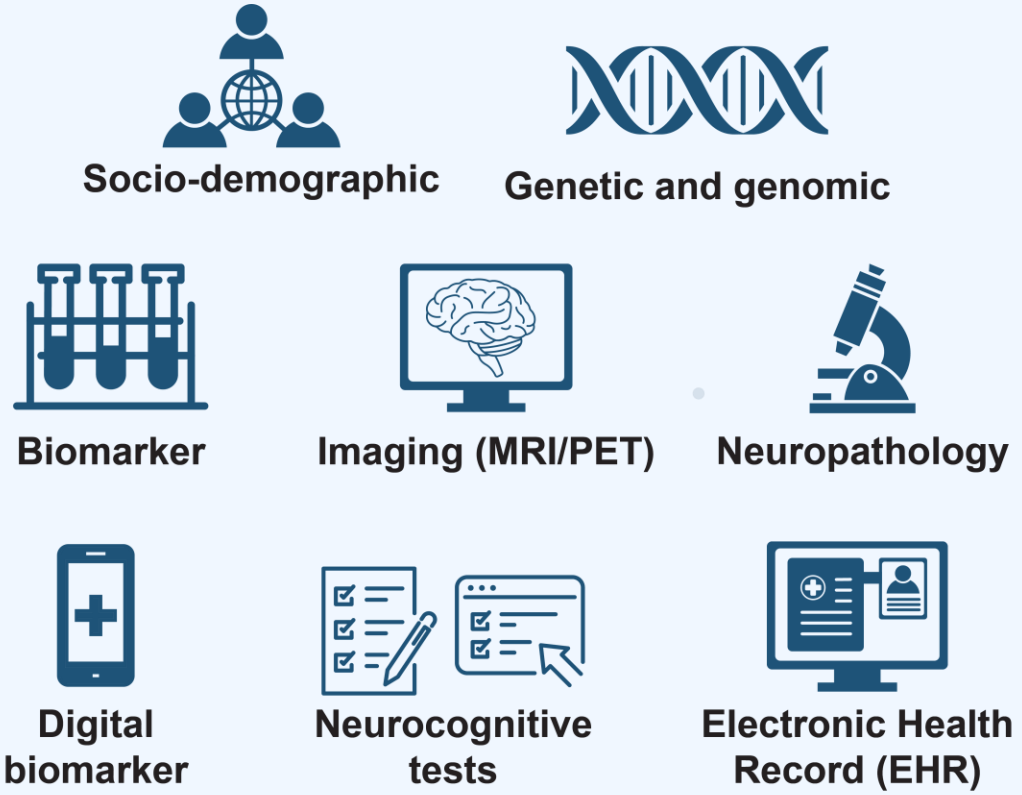
NACC's New Multimodal, Cloud-based, Data Platform Makes it Easier to Build Interoperability with Other Studies



NACC Infrastructure to Track Individual Data

Access to Rich Multimodal Data for Treated and Untreated Participants

This is an opportunity to study the impact of disease modifying drugs on data and biomarkers found within the NACC Data Platform



Thank you!