CLARiTI

ADRC Consortium for Clarity in ADRD Research Through Imaging

Study Start up and Inclusion Core Processes

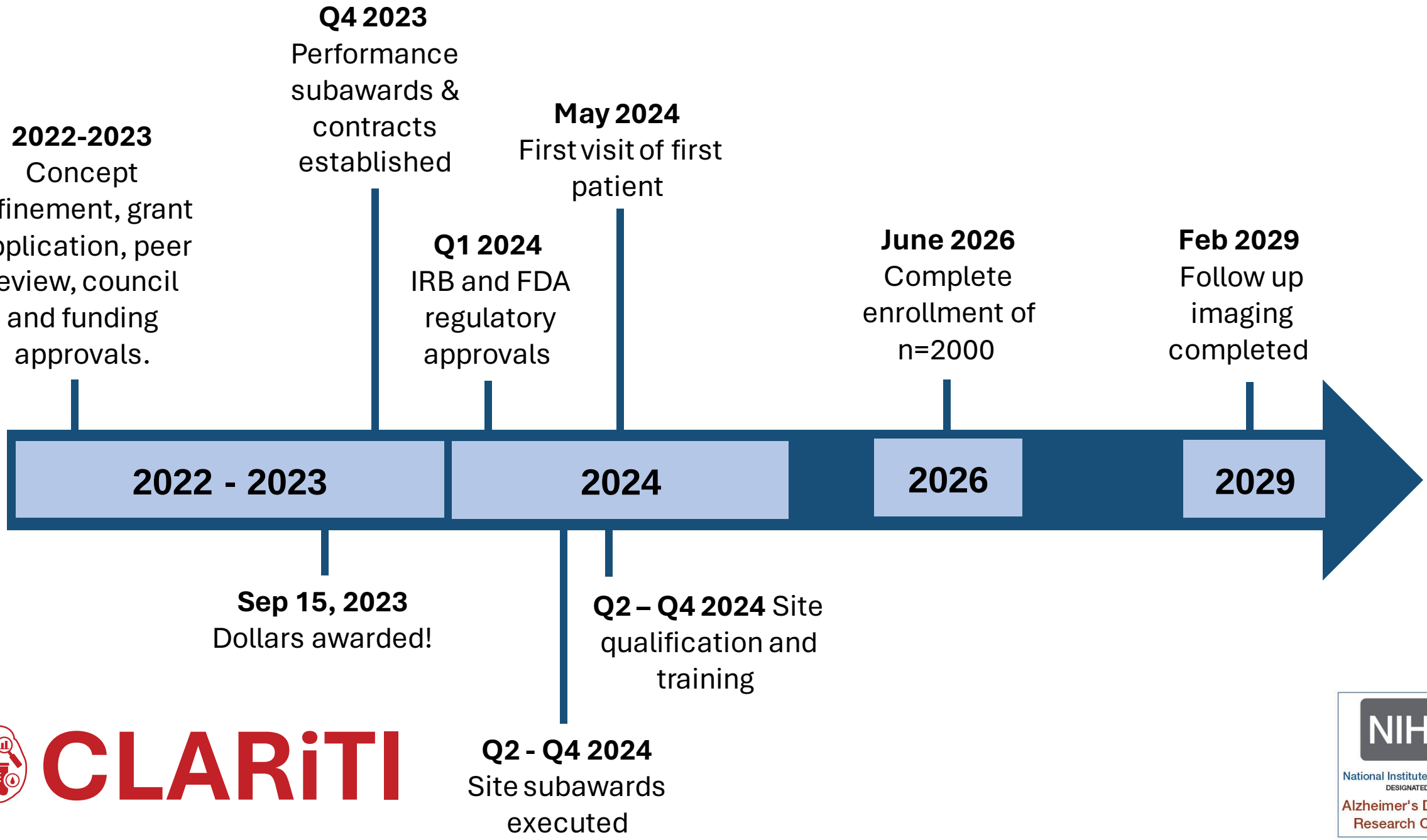
Wednesday, March 27, 2024

Agenda

- CLARiTI updates
  - IND #170860
  - Site readiness checklist
  - Subaward updates
- Inclusion Core Processes
- Q&A
- Announcements

CLARiTI

NIH National Institute on Aging DESIGNATED Alzheimer's Disease Research Center



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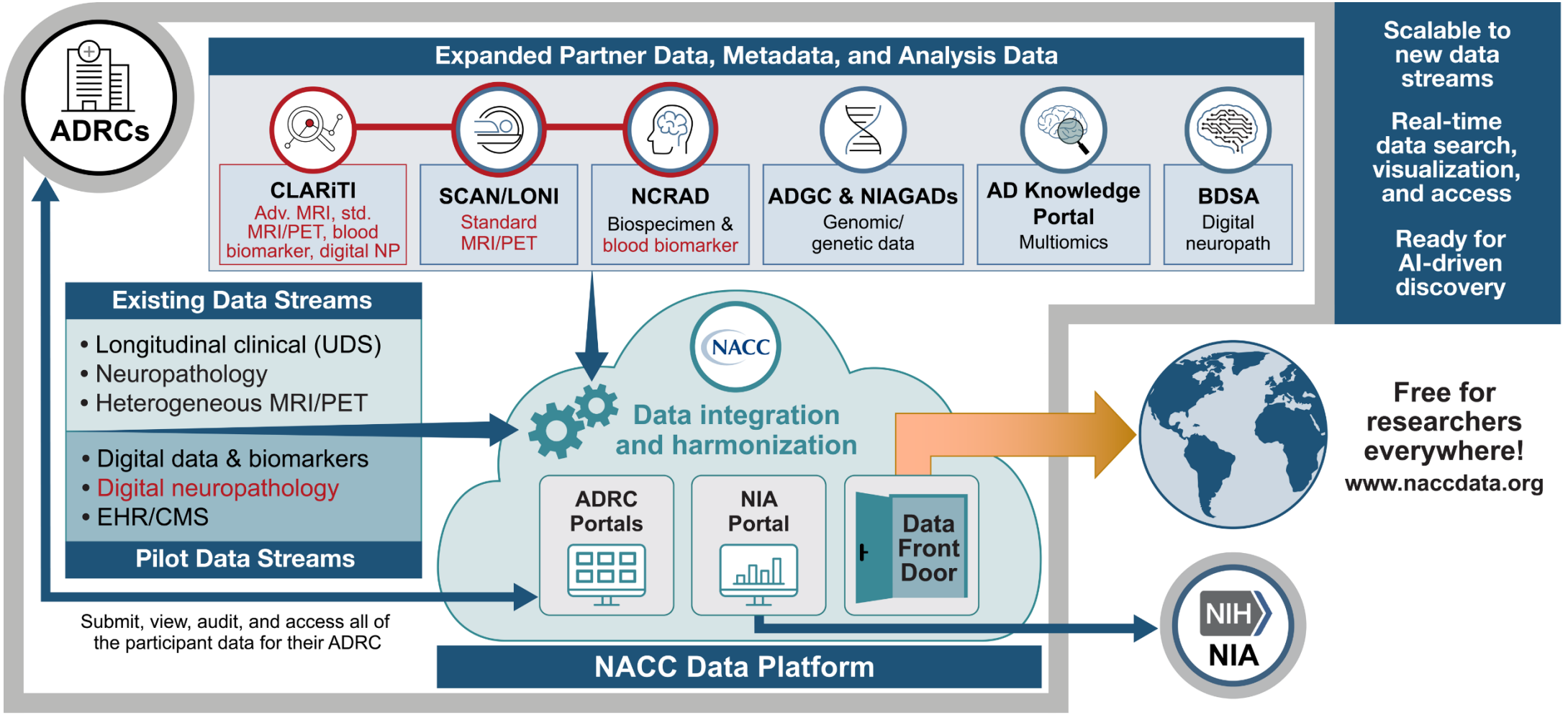
National Institute on Aging DESIGNATED Alzheimer's Disease Research Center

NACC Data Platform: A Modern Cloud-based Multimodal Data Integration and Harmonization Platform



IND Approval

- IND #170860 was approved by the FDA on March 6th
- The *Study May Proceed* letter available via a link on our website.
- This IND covers the following tracers that will be *delivered* to sites: MK-6240, NAV4694, and PI-2620. It also covers local MK-6240 manufacturing if under Lantheus purview.
- CLARiTI project coordinator will confirm radioligand choices and delivery address of tracers.
- If necessary, your site will be added to the relevant work orders with the radioligand companies, and your coordinator will collect a 1572 form from your site investigator.
- For sites that are producing tracers (PiB, NAV4694, FTP, PI-2620) you will need to reference your local site IND.

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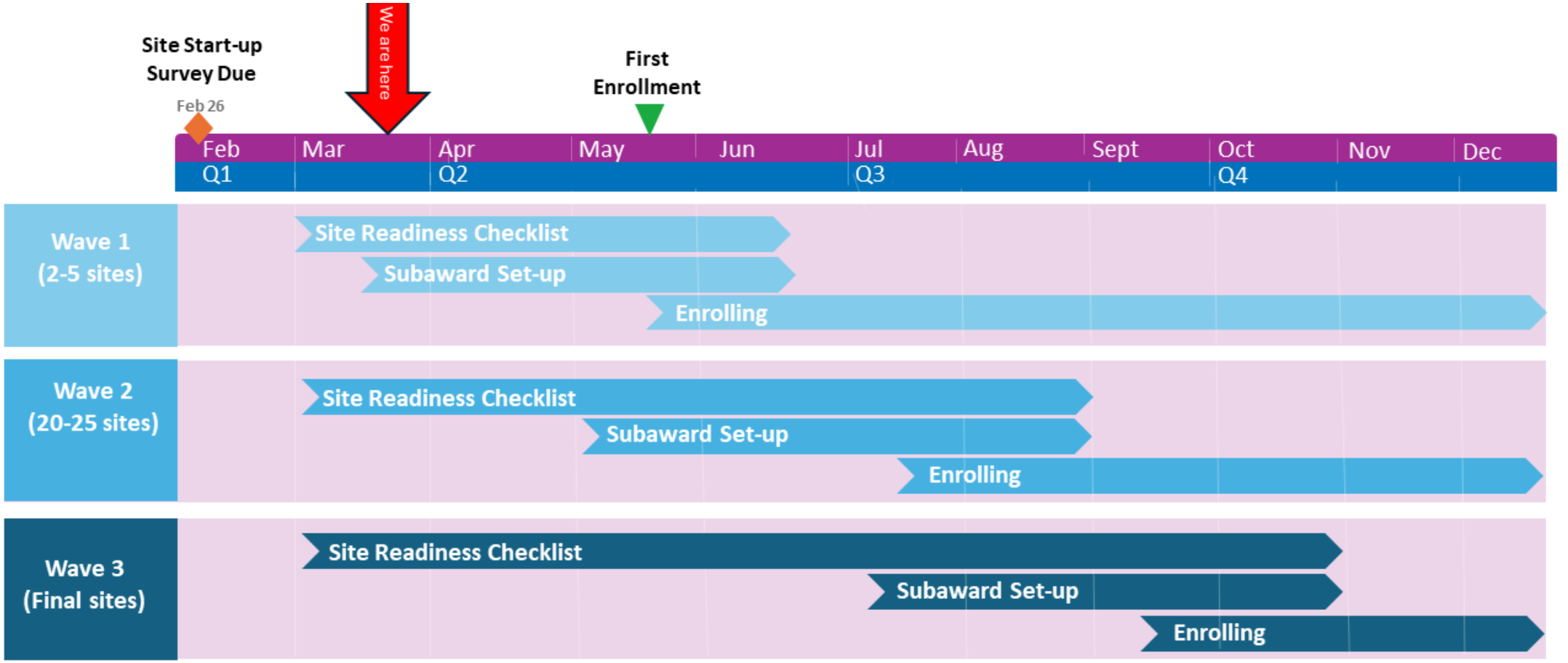
Site readiness checklist

Record ID	CLARiTI Site Start-up survey	Inclusion Core Site Survey March 2024	Primary Admin Project Coordinator	NACC Site Coordinator	Site Initiation Meeting Completed	Site Clariti Study Coordinator Designated	Site Clariti Outreach Specialist Designated	Site Biomarker Disclosure Survey Completed	NACC Subaward Executed	NCRAD MTA Modified	IRB Review Ceded To WCG	WCG Approval	SCAN Qualified Site	Radiotracers Selected	Manufacturer Sow Filed	FDA 1572 Filed	UWisc Central Monitoring Training	Flywheel Account Status	LONI Training	ADCFB Protocol Training With NCRAD	Blood Collection Kits Ordered	Site Recruitment Strategy Finalized	CLARiTI Disclosure Process	EDC CRF Account Status	Site Activation Notice Sent	First Visit Complete
2 Boston University ADRC	✓	✓	●																							
4 Columbia University ADRC	✓		●																							
6 Emory University, Goizueta ADRC	✓		●																							
7 Massachusetts ADRC	✓		●																							
8 Indiana University ADRC	✓	✓	●																							
9 Johns Hopkins ADRC	✓		●																							
10 Mayo Clinic ADRC	✓		●																							
11 Mount Sinai School of Medicine ADRC	✓	✓	●																							
12 NYU ADRC	✓		●																							
13 Northwestern ADRC	✓		●																							
14 Oregon Health and Science University, ADRC	✓		●																							
15 Rush University Alzheimer's Disease Center	✓		●																							
16 UC Davis ADRC	✓	✓	●																							
18 UCSD Shiley-Marcos ADRC	✓	✓	●																							
19 University of Kentucky ADRC	✓	✓	●																							
21 Penn ADRC / Penn Memory Center	✓		●																							
22 University of Pittsburgh ADRC	✓		●																							
26 University of Washington ADRC	✓		●																							
27 Washington University Knight ADRC	✓		●																							
30 USC ADRC	✓	✓	●																							
31 UC Irvine, ADRC	✓		●																							
33 Arizona ADRC	✓		●																							
35 UCSF ADRC	✓	✓	●																							
37 Wisconsin ADRC	✓		●																							
38 University of Kansas ADRC	✓		●																							
39 Stanford ADRC	✓		●																							
40 Yale University ADRC			●																							
41 1Florida ADRC	✓	✓	●																							
42 Wake Forest University, ADRC	✓		●																							
43 University of Michigan ADRC	✓		●																							
46 Nevada Exploratory ADRC	✓	✓	●																							
47 Vanderbilt Exploratory ADRC	✓		●																							
48 New Mexico Exploratory ADRC	✓		●																							
49 Duke/UNC ADRC	✓		●																							
65 Cleveland ADRC	✓		●																							
67 South Texas ADRC	✓	✓	●																							
68 UAB Exploratory ADRC		✓	●																							

NACC Subaward Update

- **Scope of Work** - *distributed to sites in the next few weeks*
- **Subaward Process Initiation** - *NACC will reach out to begin collecting documentation according to the following timeline*



CLARiTI

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Inclusion Core Processes

Co-led by Dr. Monica Rivera-Mindt and Dr. Ozioma Okonkwo

CLARiTI Inclusion Core

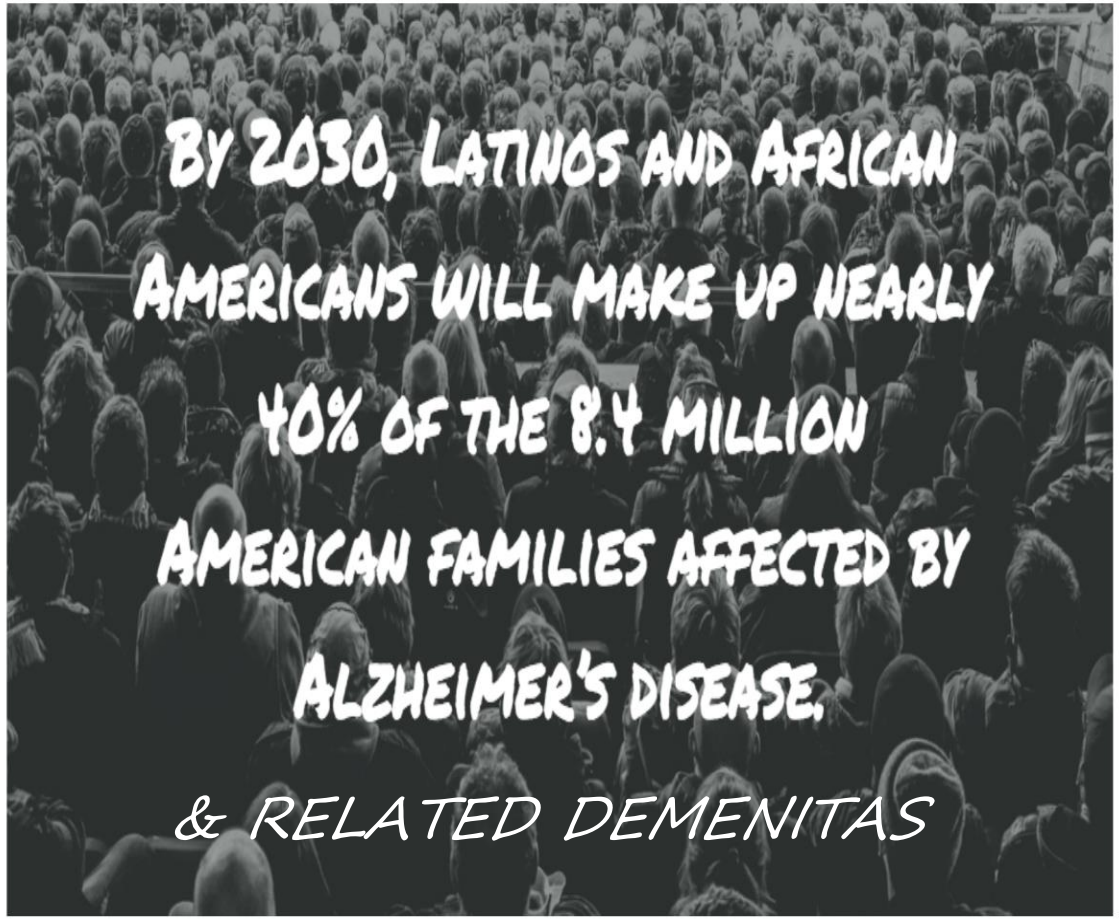
- **AD/ADRD Inequities**
- Inclusion Core Overview
- Community-Engaged Research (CER) Approach
- Inclusion & Engagement Plans
- CLARiTI Inclusion FAQs
- Questions/Comments?

Brain Health Inequities in Alzheimer's & Disease Related Dementias (AD/ADRDs)

- **Black & Latinx adults are up to 2x as likely to develop AD/ADRDs** than non-Latinx white adults*
- **Younger age of onset**
- **Greater severity of initial cognitive symptoms**

***Note**. *Research based on primarily older adults.*
Alzheimer's Association, 2015; Campos et al., 2013

Shifting Demographics Are Placing Communities of Color in the Crosshairs of Alzheimer's



https://www.usagainstalzheimers.org/learn/disparities

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Inclusion Core Mission

Ensure the inclusion/engagement of persons from Underrepresented Populations (URPs; ≥25%) in CLARiTI by utilizing a culturally-informed, community engaged research (CER) approach, in **c**lose coordination with *all* CLARITI Cores, esp. the Admin and Disclosure Cores, and with local ORE Cores.

Milestone 1

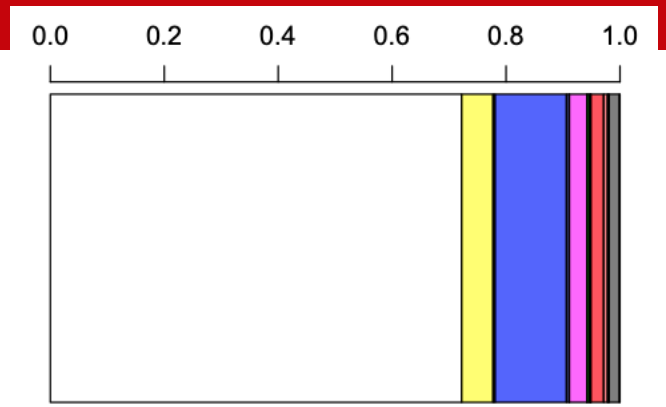
Increase the Inclusion & Engagement of Persons from Underrepresented Populations (≥ 25%) in CLARiTI

Milestone 2

Establish and Maintain Close Collaboration and Communication with other Cores to Meet Inclusion Goals

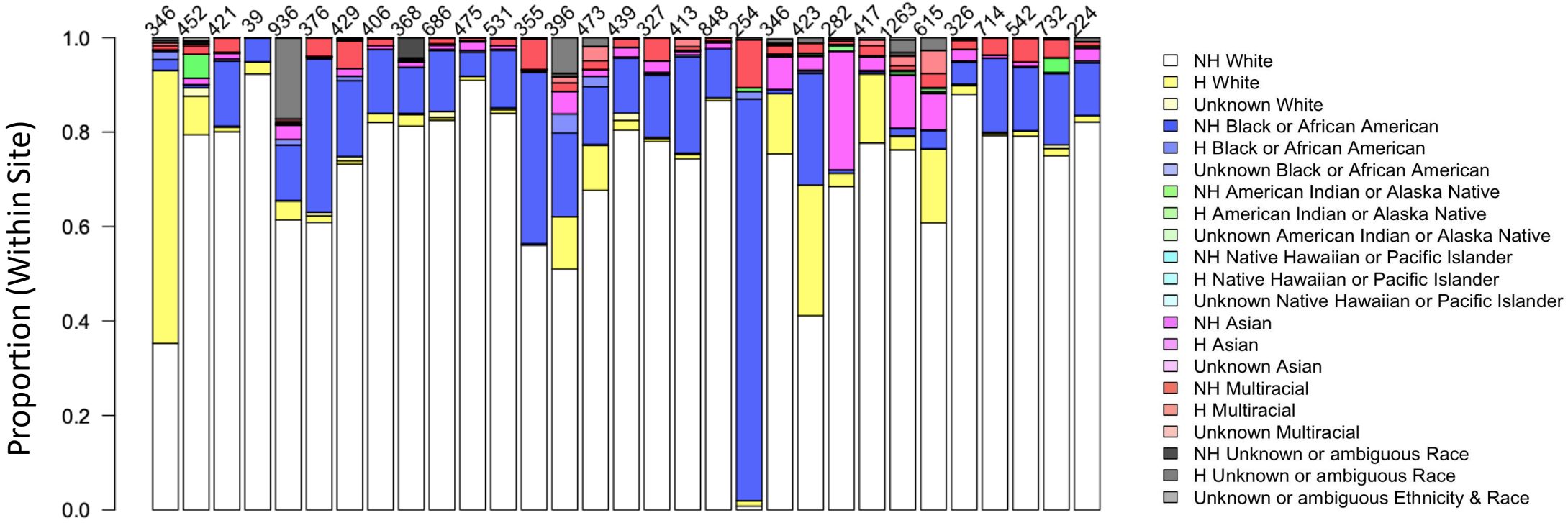
Race and Ethnicity in the ADRC Program

Proportion (collapsed across all sites)



Total Active=14854

~3700 URM



* NACC Data Freeze March 2020 (to eliminate effect of covid)

Inclusion Core Team

Dr. Monica Rivera-Mindt, Co-Lead
Fordham University/Mount Sinai

Dr. Ozioma Okonkwo, Co-Lead
University of Wisconsin, Madison

Dr. Desiree Byrd, Co-I
CUNY, Queens College

Dr. Vanessa Guzman, Co-I
Mount Sinai

Dr. Charles Windon, Co-I
UC San Francisco

Dr. Adeyinka Ajayi
Project Manager, Mount Sinai

Anne Buffington, MPH
Project Manager, UW Madison

Eva Schulte, BS
CRN, UW Madison

Inclusion Core Structure

CLARiTI Leadership

Community-Science Partnership Board (CSPB)

CLARiTI Inclusion Core (Co-Leads: Okonkwo & Rivera-Mindt)

CER-based Engagement & Training

Inclusion Core Team

Community Partnerships

Culturally-Informed, CER Methods

- CER-based, culturally informed approach & marketing with CSPB guidance
- Digital & non-digital engagement

- Cultural competence/CER training for all CLARiTI team members

- Co-Is w/CER & brain health equity expertise
- ~5 Community Research Navigators (CRNs) - ***part of Inclusion Core***
- Community Research Liaison (CRL) ***at each site***
- ***Partnering* w/ ORE Core leaders & team members**

Grassroots Studies, Centers & Registries

National Community Partner Organizations

Local Community-Based Organizations

- True community partnership
- CSPB Guidance
- Less restrictive inclusion/exclusion criteria

CER = Community-engaged Research

Community Research Navigator (CRN)

- Centralized team members (virtual engagement)
- Work centered on the "give" to participants (pts.) & study partners
- Promotes pt. *engagement (retention & task completion)*
- Supports ADRC coordinators with participants/study partners' engagement in the CLARiTI protocol.
- Additional roles to be determined

Community Research Liaison (CRL)

- Boots on the ground (in-person engagement)
- Work centered on the "give" to community members & local sites
- Promotes *inclusion* by supporting community partnerships & liaising with community clinicians, community-based organizations (CBOs), and community members
- Coordinates local inclusion/engagement events/efforts with local ADRC leadership & ORE Core team
- Participates in community events

We want to hear from you!

- On 03/25/24: NACC distributed a **Site Survey** re: inclusion plans to site PIs and ORE Core Leaders
- Please share your thoughts!
- We want to provide training and resources tailored to your needs!
- **Please submit by 04/15**

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Community Engaged Research (CER) Approach

Pivotal to successful inclusion & engagement (e.g., retention, study task completion) of ppl from URPs in AD/ADRD clinical research:[1,2,3]

- **culturally-informed, community-engaged research methods**
- **more intensive personal contact & genuine community partnership**

1. Gilmore-Bykovsky et al., 2019; 2. Ashford et al., 2022; 3. Okonkwo*, Rivera Mindt* et al., In Press

Community Engaged Research (CER) Approach

Pivotal to successful inclusion & engagement (e.g., retention, study task completion) of ppl from URPs in AD/ADRD clinical research:[1,2,3]

- **culturally-informed, community-engaged research methods**
- **more intensive personal contact & genuine community partnership**

By providing greater personal connection & community partnership, CRNs and CRLs will be pivotal to the implementation & success of the Inclusion Core's mission.

1. Gilmore-Bykovsky et al., 2019; 2. Ashford et al., 2022; 3. Okonkwo*, Rivera Mindt* et al., In Press

Key CER Principles

- Recognizes community as a unit of identity
- Builds on strengths and resources of the community
- Facilitates collaborative partnerships in all phases of research
- Integrates knowledge and action for mutual benefit of all partners
- Promotes a co-learning empowering process that attends to social inequalities
- Involves a cyclical and iterative process
- Addresses health from positive and ecological perspectives
- Shares findings and knowledge gained to all partners

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Inclusion Core Efforts

- **Purpose**: Ensure the inclusion/engagement (≥25%) of ppl from Underrepresented Populations (URPs) in CLARiTI:
  - **Ethnoculturally minoritized groups**: Black/African American, Latinx, Asian, American Indian or Alaska Natives, Native Hawaiians, and other Pacific Islanders.
  - **Low socioeconomic status (SES):** ≤ 12 years education
  - **Geography**: Individuals dwelling in rural areas

- **Approach**: Culturally-informed, community-engaged research (CER) methods

- **Inclusion Core will offer:**
  - Tailored inclusion and engagement materials
  - Training for CLARiTI team members & consulting for ORE Core members
  - Community Research Liaisons (CRLs) provide engagement w/ local community
  - Participant navigation support via Community Research Navigator (CRN) Program
  - Community-Scientific Partnership Board (CSPB)
  - Monitoring/refining of inclusion and engagement efforts among URPs throughout project
  - **Community Support:** Flexible annual $ for local efforts *(up to* $10K; e.g., support/ partnership w/ community org's; outreach/engagement events)

Questions about URP recruitment at your site? Ideas for Inclusion Core programming?

Please contact us at clariti-inclusion@medicine.wisc.edu

Inclusion Plans

- **Inclusion of participants from URP backgrounds**:
  - The inclusion plan (recruitment & enrollment) will follow the local ADRC processes and the Inclusion Core is available to support your success – please let us know how we can help!
  - Community Research Liaison (CRL) role designed to assist with inclusion efforts

- **Participant compensation**:
  - Compensation for participation is by procedure, per time-point
  - The payment method is flexible and it is determined by the site
  - Participants may be offered additional payments for travel, lodging, or parking

- **Marketing team**:
  - Inclusion Core partnering with a marketing agency to produce tailored inclusion materials

Engagement Plans

- **Retention**
  - **Community Research Navigator (CRN)** role designed to assist with retention efforts
  - **Community outreach/engagement funding (10k/site/year)** can be used for retention efforts (e.g., community health events, participant appreciation events, swag)
  - **Marketing team**: Our marketing agency can also produce tailored retention/engagement materials
- **Study Task Completion (i.e., MRI, PET)**
  - We will work w/ our stakeholders (e.g., CSPB, ORE Cores, Study Leadership) to better understand and increase URP engagement in biomarker task completion, es. neuroimaging protocols

Partnership with ORE Cores at the ADRCs

- **The success of the CLARiTI Inclusion mandate (≥25% URPs) will require close collaboration between the Inclusion Core and ORE Cores at the ADRCs:**

  - Onboarding sessions with ORE Core
  - Networking with ORE Core leaders and staff during the fall and spring NACC Directors meeting
  - Inclusion Core check-ins with ORE Core staff
  - Regular contact between Inclusion Core leadership and ORE Core Steering leadership
  - Provide ORE Core with a repository of resources and training materials for enhancing CER practices
  - Distribute the Inclusion Core Survey to ORE Core to understand local procedures and practices
  - Webinars to provide CER training to ORE Core
  - Consultation with ORE Core as needed to support recruitment and engagement

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CLARiTI Inclusion Core FAQs

- ***How can I reach the Inclusion Core?***
  - Please contact us at: clariti-inclusion@medicine.wisc.edu

- ***I have questions, concerns or ideas about engagement of participants from URPs- who can I share this with?***
  - Please contact us at clariti-inclusion@medicine.wisc.edu

REMINDER

ADRC Leaders (esp ORE Core Leaders) and Staff

NACC distributed a site survey about inclusion plans on 3/25, with the **deadline of 04/15**

Please share your thoughts with us so we can provide training and resources tailored to your needs!

Thank you!

¡Muchas Gracias!

Questions or Comments?

Email us at:
clariti-inclusion@medicine.wisc.edu

Announcements

- **CLARiTI Breakout Session at NACC Spring Meeting**
  - Save the date: Monday, May 6th, 11:35-1:05pm CT
  - Lunch will be provided for those attending in person
  - In person invite will be extended to CLARiTI site investigators and ORE Core Leaders. Anyone can attend virtually!
  - Agenda will include presentations by the CLARiTI Disclosure and Inclusion Cores with time for open discussion.

Announcements

- **Next Webinar** will be held on June 20, 10 AM CT/8 AM PT
  - Blood & Biomarkers/NCRAD
- **CLARiTI Connect newsletter**
  - Distributed by the CLARiTI administrative teams at UW Madison and the National Alzheimer's Coordinating Center. CLARiTI Connect contains current information about study progress, operations updates, news, and more!
- **Stay in touch!**
  - Email: clariti@medicine.wisc.edu
  - Web: https://naccdata.org/nacc-collaborations/clariti

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