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
Concept refinement, grant application, peer review, council and funding approvals.

2022-2023

2024

2026

2029

Q4 2023
Performance subawards & contracts established

May 2024
First visit of first patient

Q1 2024
IRB and FDA regulatory approvals

June 2026
Complete enrollment of n=2000

Feb 2029
Follow up imaging completed

Q2 – Q4 2024
Site qualification and training

Sep 15, 2023
Dollars awarded!

Q2 - Q4 2024
Site subawards executed
NACC Data Platform: A Modern Cloud-based Multimodal Data Integration and Harmonization Platform

Expanded Partner Data, Metadata, and Analysis Data

- CLARITI: Adv. MRI, std. MRI/PET, blood biomarker, digital NP
- SCAN/LONI: Standard MRI/PET
- NCRAD: Biospecimen & blood biomarker
- ADGC & NIAGADs: Genomic/ genetic data
- AD Knowledge Portal: Multiomics
- BDSA: Digital neuropath

Existing Data Streams
- Longitudinal clinical (UDS)
- Neuropathology
- Heterogeneous MRI/PET

Digital data & biomarkers
- Digital neuropathology
- EHR/CMS

Pilot Data Streams
Submit, view, audit, and access all of the participant data for their ADRC

Data integration and harmonization

NACC Data Platform

Scalable to new data streams
Real-time data search, visualization, and access
Ready for AI-driven discovery

Free for researchers everywhere! www.naccdata.org

NIH
NIA
IND Approval

• IND #170860 was approved by the FDA on March 6\textsuperscript{th}
• The \textit{Study May Proceed} letter available via a link on our website.
• This IND covers the following tracers that will be \textit{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 \textit{producing tracer}s (PiB, NAV4694, FTP, PI-2620) you will need to reference your local site IND.
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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

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<th>Site Readiness Checklist</th>
<th>Subaward Set-up</th>
<th>Enrolling</th>
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<td>Site Readiness Checklist</td>
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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

By 2030, Latinos and African Americans will make up nearly 40% of the 8.4 million American families affected by Alzheimer’s disease & related dementias.

https://www.usagainstalzheimers.org/learn/disparities
CLARiTI Inclusion Core

- AD/ADRD Inequities
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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 close 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
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. Adeyinka Ajayi
Project Manager, Mount Sinai

Anne Buffington, MPH
Project Manager, UW Madison

Dr. Charles Windon, Co-I
UC San Francisco

Eva Schulte, BS
CRN, UW Madison
Inclusion Core Structure

CLARiTI Leadership

CER-based Engagement & Training

• CER-based, culturally informed approach & marketing with CSPB guidance
• Digital & non-digital engagement
• Cultural competence/CER training for all CLARiTI team members

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

Inclusion Core Team

• 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

Community Partnerships

Grassroots Studies, Centers & Registries
National Community Partner Organizations
Local Community-Based Organizations

Culturally-Informed, CER Methods

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

Community-Science Partnership Board (CSPB)

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**
CLARiTI Inclusion Core

- AD/ADRD Inequities
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- Questions/Comments?
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

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.

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
CLARiTI Inclusion Core Overview

Community-Engaged Research (CER) Approach

Inclusion & Engagement Plans

CLARiTI Inclusion FAQs

Questions/Comments?
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 with our stakeholders (e.g., CSPB, ORE Cores, Study Leadership) to better understand and increase URP engagement in biomarker task completion, e.g., 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
CLARiTI Inclusion Core

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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