



CLARiTi

ADRC Consortium for Clarity in ADRD Research Through Imaging



**Impact of CLARiTi
National Inclusion &
Engagement Plan**

October 17, 2024



CLARiTI mPIs



Sterling Johnson



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Agenda

Scientific Impact of CLARiTI and progress report

Sterling Johnson, PhD

Beth Mormino, PhD

CLARiTI Infrastructure Updates & Impact

Sarah Biber, PhD

Study Updates

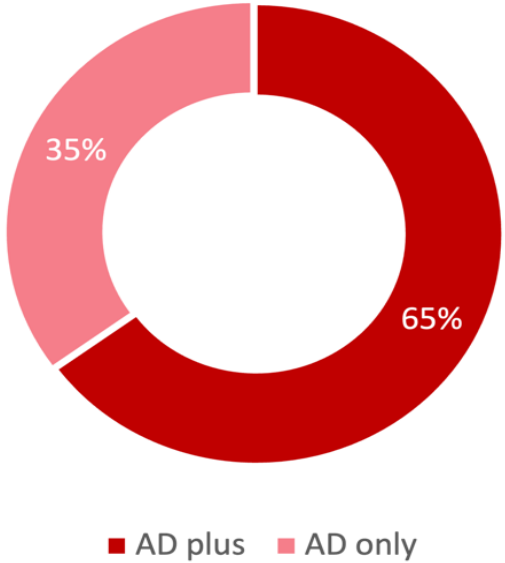
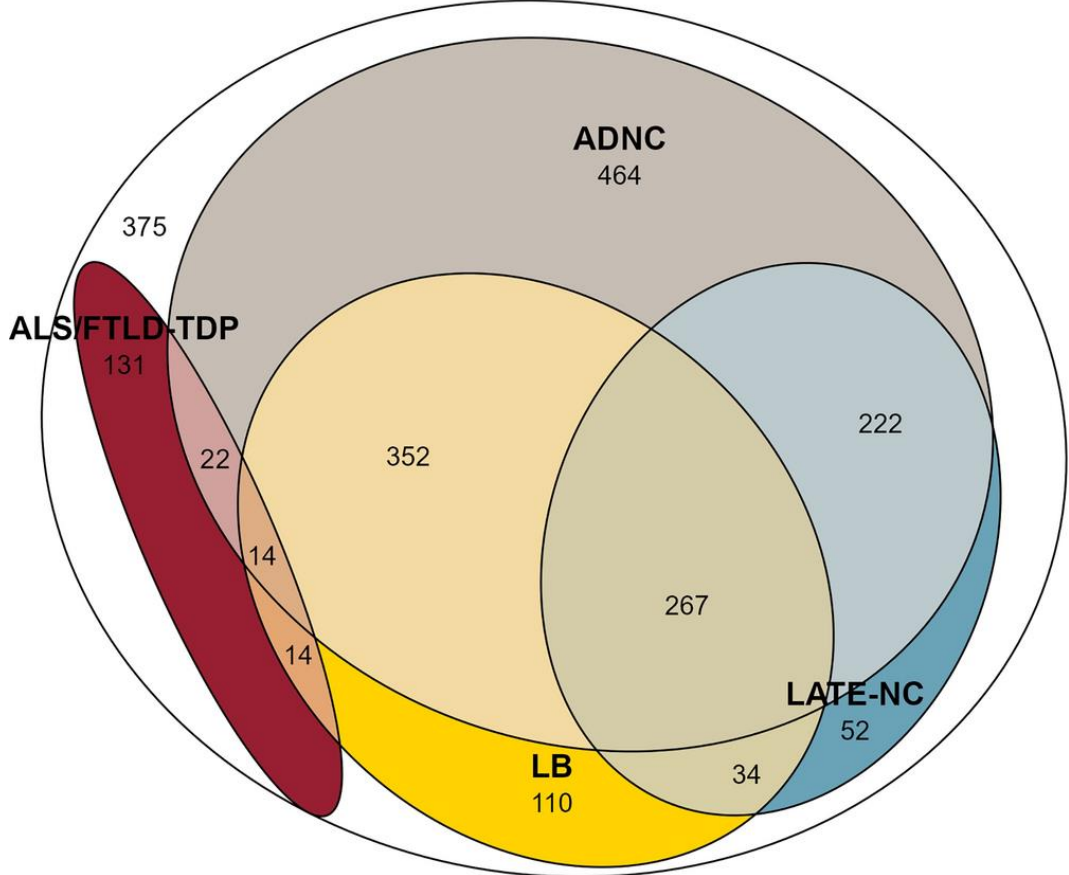
Erin Chin

CLARiTI National Inclusion and Engagement Plan

Ozioma Okonkwo, PhD

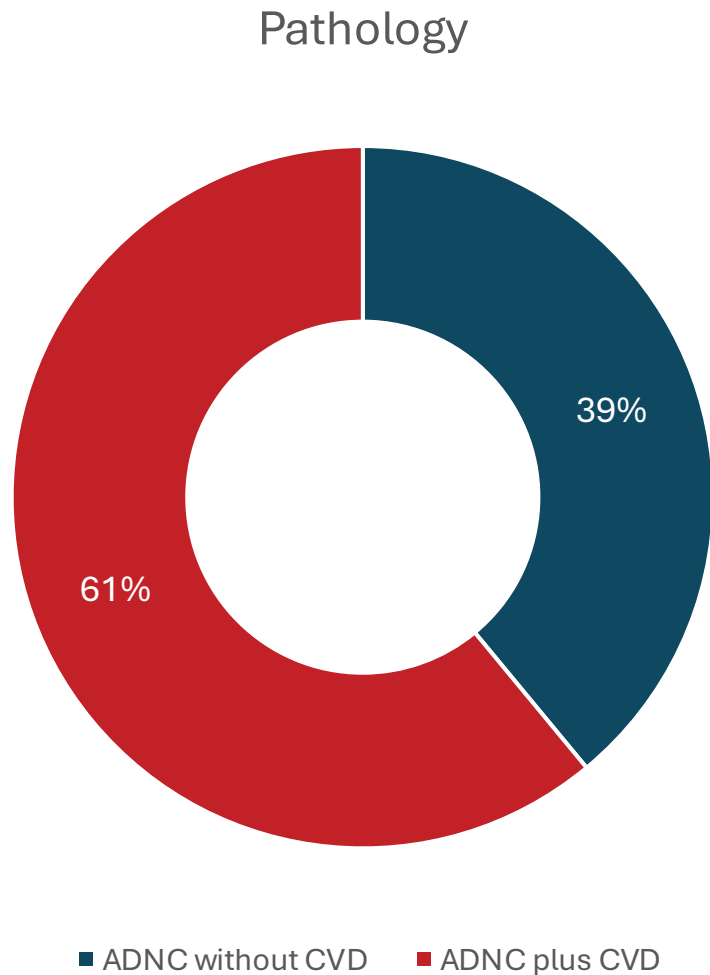
Overlap in common proteinopathies from NACC

All Participants (N=2057)



- ADNC only = 35%
- ADNC plus [TDP43, or LB, or both] = 65%
- ADNC plus LB = 46%
- ADNC plus TDP43 = 36%
- ADNC plus TDP43 and LB = 20%

ADNC co-occurs with cerebrovascular disease



- N=2423 NACC brain donors with ADNC and UDS cognitive data
 - ADNC = Braak ≥ 3
- CVD= moderate to severe arteriolosclerosis or atherosclerosis
- People with both diseases declined faster

Frank et al 2022 *Neurology*
From Boston ADRC



ATN profiles fundamental to AD research

Received: 7 February 2024 | Revised: 21 March 2024 | Accepted: 4 April 2024
DOI: 10.1002/alz.13859

Alzheimer's & Dementia
THE JOURNAL OF THE ALZHEIMER'S ASSOCIATION

RESEARCH ARTICLE

Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup

Clifford R. Jack Jr.¹ | J. Scott Andrews² | Thomas G. Beach³ | Teresa Buracchio⁴ | Billy Dunn⁵ | Ana Graf⁶ | Oskar Hansson^{7,8} | Carole Ho⁹ | William Jagust¹⁰ | Eric McDade¹¹ | Jose Luis Molinuevo¹² | Ozioma C. Okonkwo¹³ | Luca Pani¹⁴ | Michael S. Rafii¹⁵ | Philip Scheltens¹⁶ | Eric Siemers¹⁷ | Heather M. Snyder¹⁸ | Reisa Sperling¹⁹ | Charlotte E. Teunissen²⁰ | Maria C. Carrillo¹⁸

2024

CONTEMPORARY ISSUES IN PRACTICE, EDUCATION, & RESEARCH OPEN ACCESS

Challenges in a Biological Definition of Alzheimer Disease

Jemma Hazan, MBBS, MRCPsych, IBSc, Kathy Y. Liu, Harry Costello, MBBS, MSc, MRCPsych, BSc, Jeremy D. Isaacs, MA, MBBS, MRCP, PhD, Madhav Thambisetty, MD, PhD, and Robert Howard, MD

Neurology® 2024;103:e209884. doi:10.1212/WNL.0000000000209884

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J Prev Alz Dis 2024;4(11):895-896

Published online July 8, 2024, <http://dx.doi.org/10.14283/jpad.2024.141>

Editorial

On the 2024 Alzheimer's Association Criteria: Still Not Ready for Clinical Use

R.Z. Zhou¹, A. Wimo¹, B. Winblad^{1,2}

Personal View

Alzheimer's & Dementia
THE JOURNAL OF THE ALZHEIMER'S ASSOCIATION

Alzheimer's & Dementia 14 (2018) 535-562

2018 National Institute on Aging—Alzheimer's Association (NIA-AA) Research Framework NIA-AA Research Framework: Toward a biological definition of Alzheimer's disease

Clifford R. Jack, Jr.^{a,*}, David A. Bennett^b, Kaj Blennow^c, Maria C. Carrillo^d, Billy Dunn^e, Samantha Budd Haeblerlein^f, David M. Holtzman^g, William Jagust^h, Frank Jessenⁱ, Jason Karlawish^j, Enchi Liu^k, Jose Luis Molinuevo^l, Thomas Montine^m, Creighton Phelpsⁿ, Katherine P. Rankin^o, Christopher C. Rowe^p, Philip Scheltens^q, Eric Siemers^r, Heather M. Snyder^d, Reisa Sperling^s

Contributors[†]: Cerise Elliott, Eliezer Masliah, Laurie Ryan, and Nina Silverberg

2018



Clinical diagnosis of Alzheimer's disease: recommendations of the International Working Group

Bruno Dubois*, Nicolas Villain*, Giovanni B Frisoni, Gil D Rabinovici, Marwan Sabbagh, Stefano Cappa, Alexandre Bejanin, Stéphanie Bombois, Stéphane Epelbaum, Marc Teichmann, Marie-Odile Habert, Agneta Nordberg, Kaj Blennow, Douglas Galasko, Yaakov Stern, Christopher C Rowe, Stephen Salloway, Lon S Schneider, Jeffrey L Cummings, Howard H Feldman

2011

GUEST EDITORIAL

Alzheimer's & Dementia 7 (2011) 280-292

Toward defining the preclinical stages of Alzheimer's disease: Recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease

Reisa A. Sperling^{a,*}, Paul S. Aisen^b, Laurel A. Beckett^c, David A. Bennett^d, Suzanne Craft^e, Anne M. Fagan^f, Takeshi Iwatsubo^g, Clifford R. Jack, Jr.^h, Jeffrey Kayeⁱ, Thomas J. Montine^j, Denise C. Park^k, Eric M. Reiman^l, Christopher C. Rowe^m, Eric Siemersⁿ, Yaakov Stern^o, Kristina Yaffe^p, Maria C. Carrillo^q, Bill Thies^r, Marcelle Morrison-Bogorad^s, Molly V. Wagster^t, Creighton H. Phelps^u

Alzheimer's & Dementia 7 (2011) 270-279

The diagnosis of mild cognitive impairment due to Alzheimer's disease: Recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease

Marilyn S. Albert^{a,*}, Steven T. DeKosky^b, Dennis Dickson^c, Bruno Dubois^d, Howard H. Feldman^e, Nick C. Fox^f, Anthony Gamst^g, David M. Holtzman^h, William J. Jagustⁱ, Ronald C. Petersen^j, Peter J. Snyder^k, Maria C. Carrillo^l, Bill Thies^m, Creighton H. Phelpsⁿ

Alzheimer's & Dementia 7 (2011) 203-209

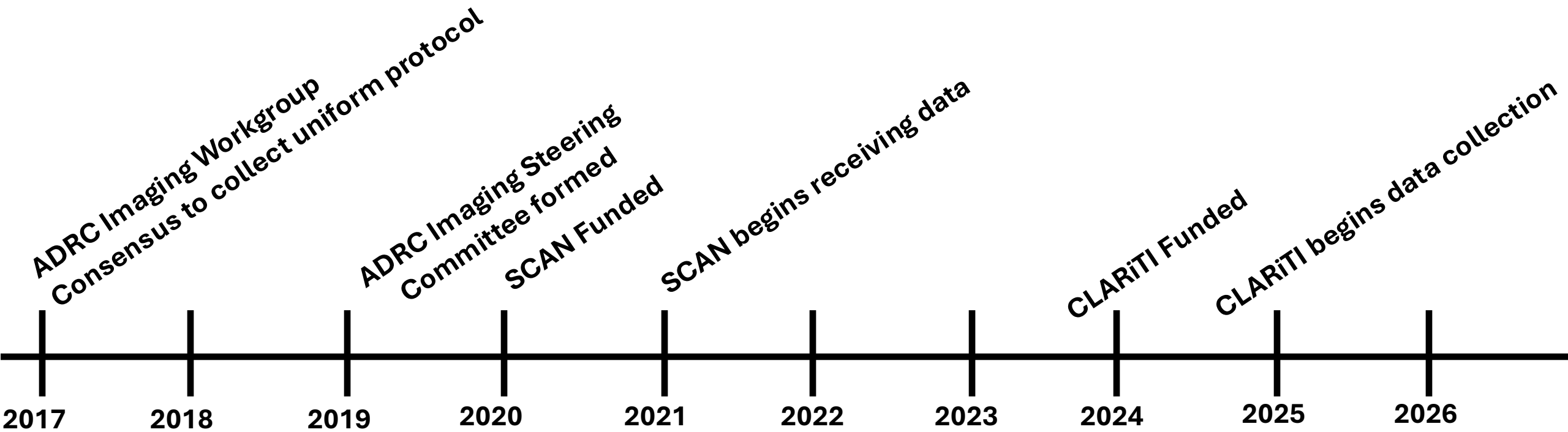
The diagnosis of dementia due to Alzheimer's disease: Recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease

Guy M. McKhann^{a,*}, David S. Knopman^b, Howard Chertkow^c, Bradley T. Hyman^d, Clifford R. Jack, Jr.^e, Claudia H. Kawas^{f,g}, William E. Klunk^h, Walter J. Koroshetzⁱ, Jennifer J. Manly^{j,k}, Richard Mayeux^{l,m}, Richard C. Mohsⁿ, John C. Morris^o, Martin N. Rossor^p, Philip Scheltens^q, Maria C. Carrillo^r, Bill Thies^s, Sandra Weintraub^t, Creighton H. Phelps^u

Revised NIA-AA criteria for the diagnosis of Alzheimer's disease: a step forward but not yet ready for widespread clinical use

Frisoni, Winblad, O'Brien

Timeline of ADRC Imaging Initiatives



scan

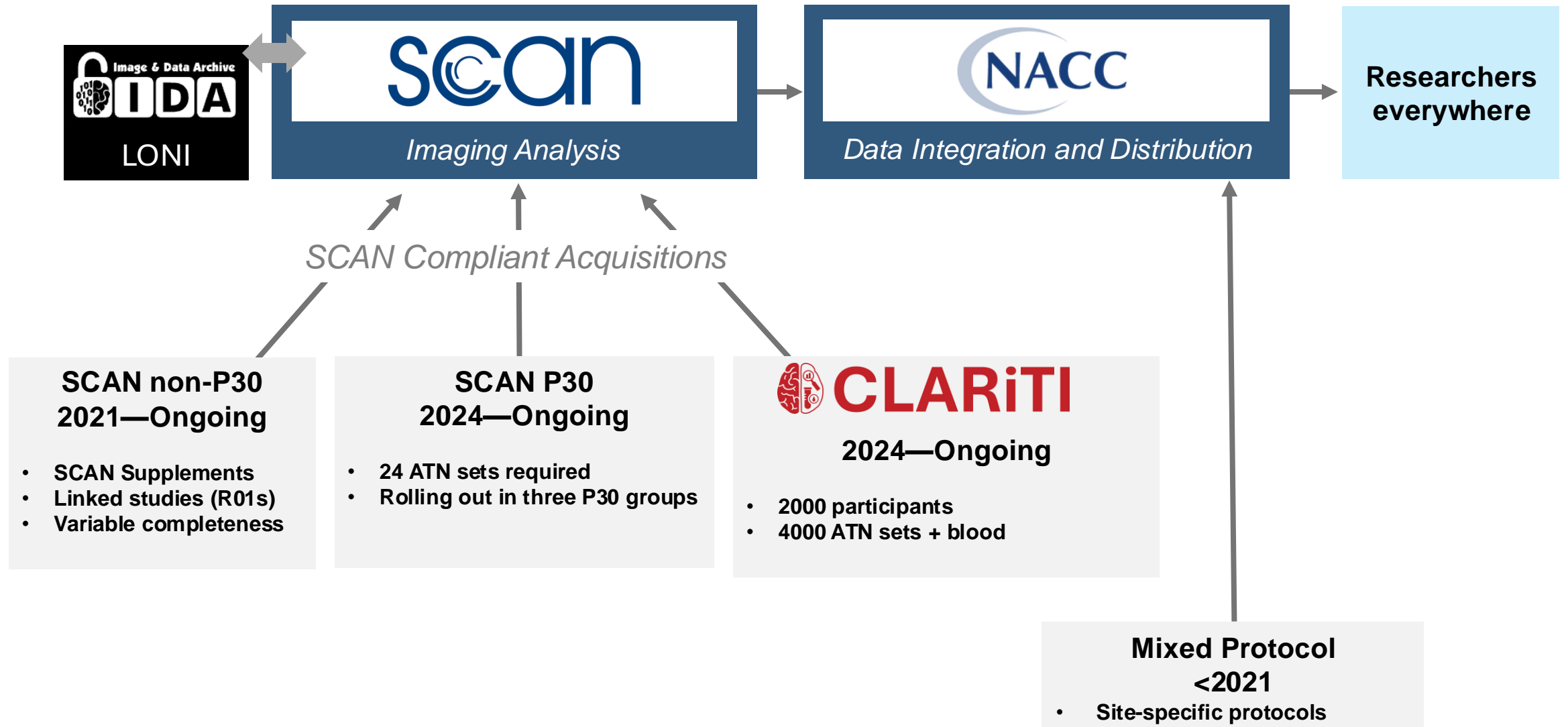
 **CLARiTI**

Agree to collect images together

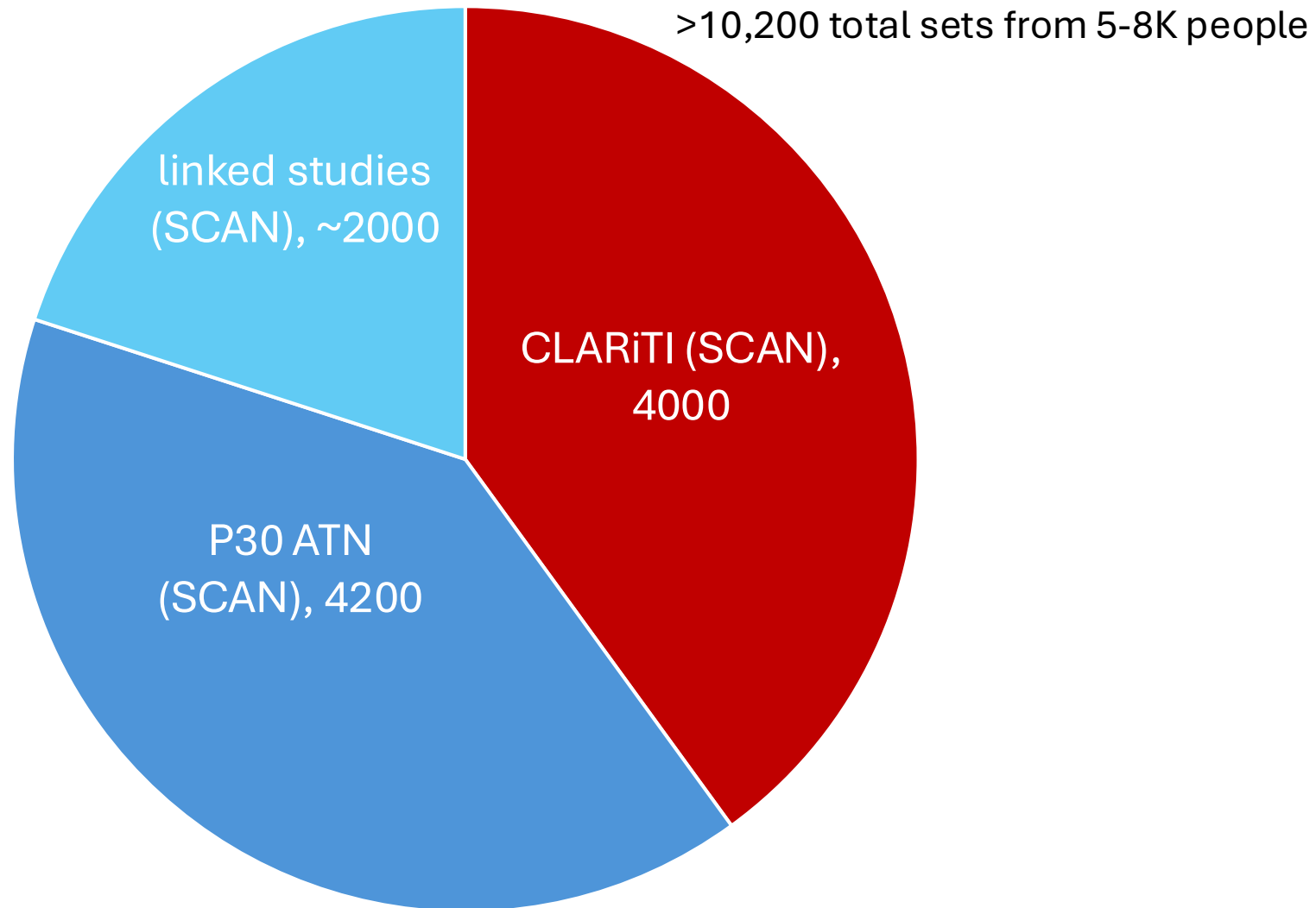
Infrastructure receive and process images

Scientific questions and recruiting plan

The ADRC imaging ecosystem

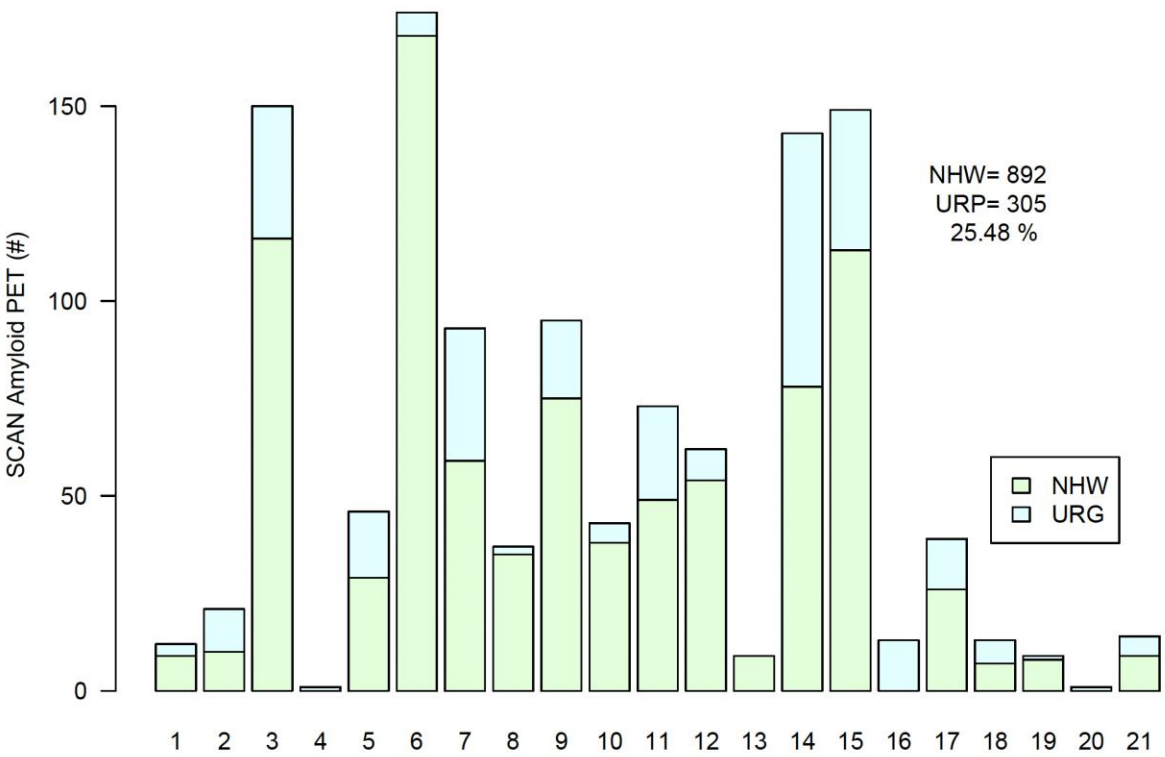


Collective impact: Estimated amyloid PET exams over next 5 years in SCAN

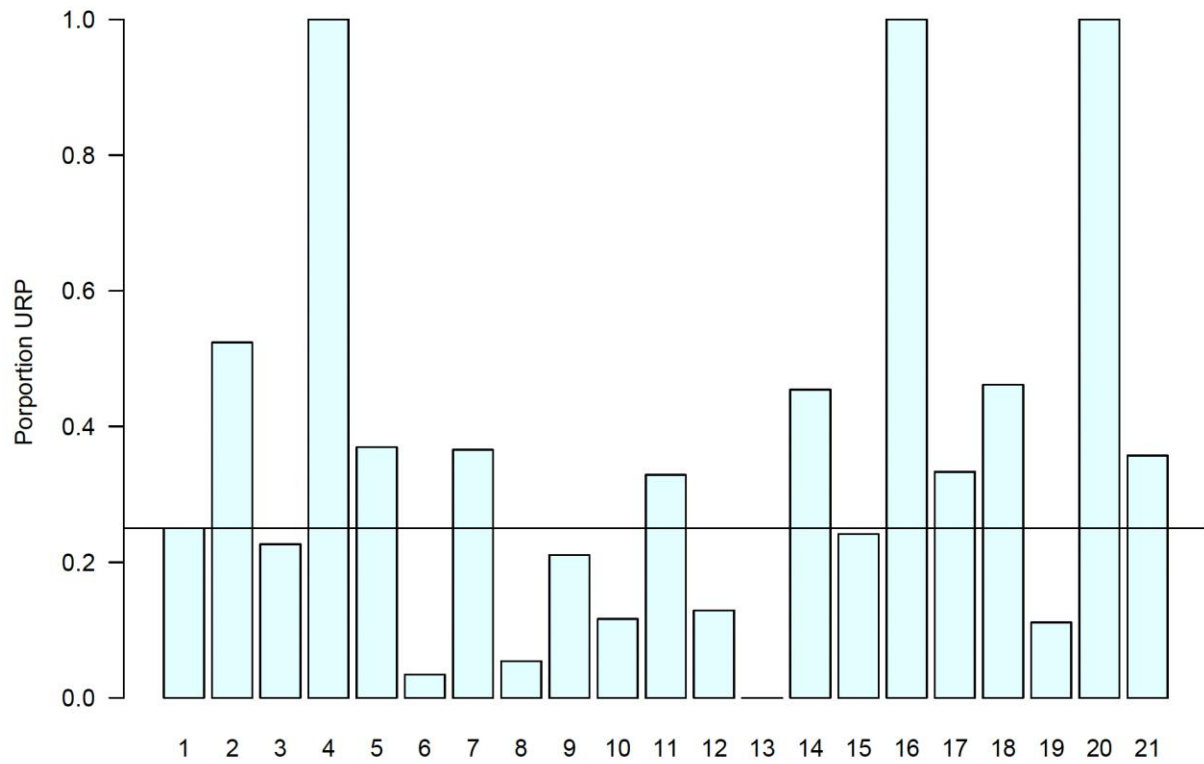


25% SCAN Amyloid data from URPs

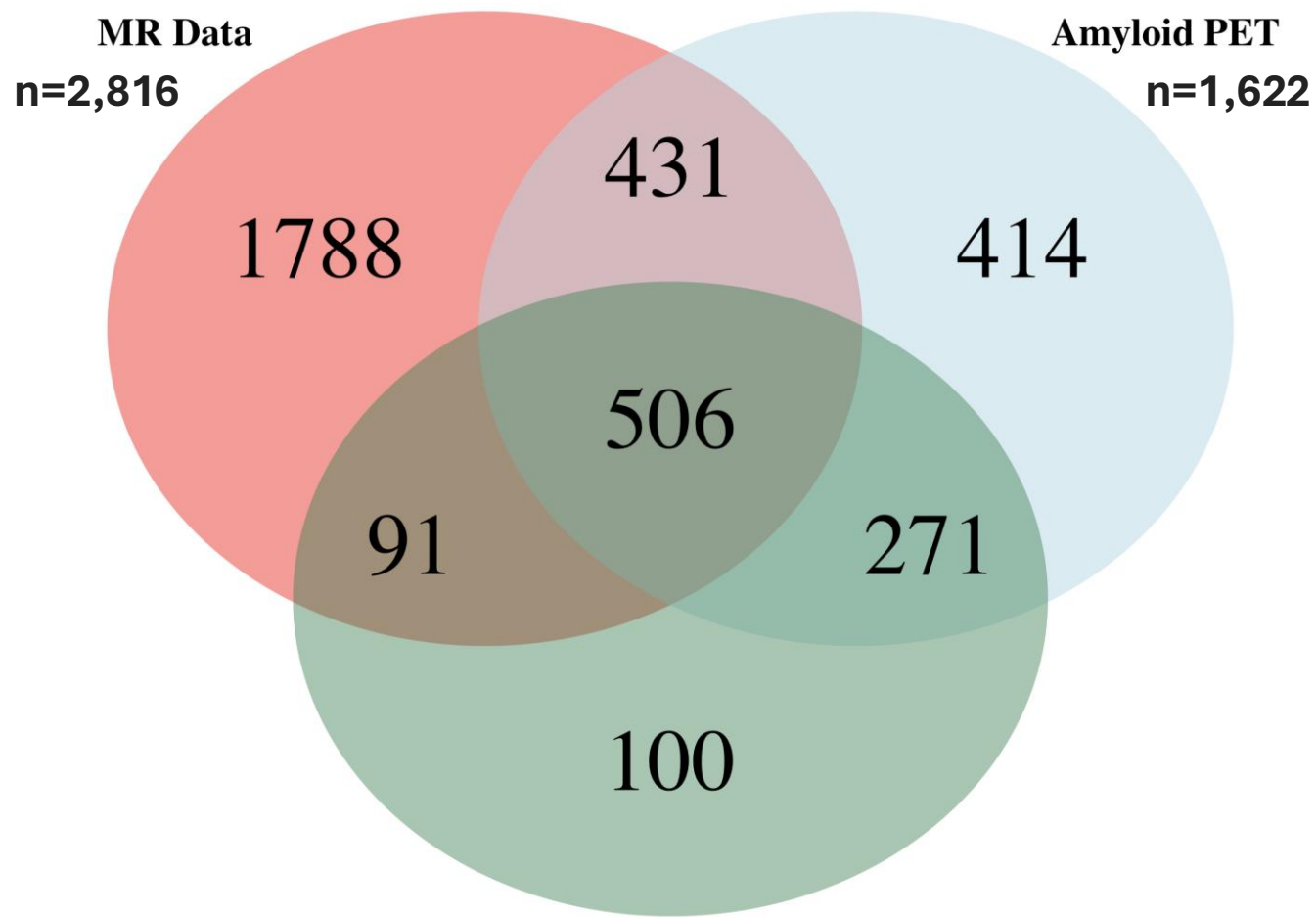
Counts by center



Proportion URG by center



3601 participants with one or more scans



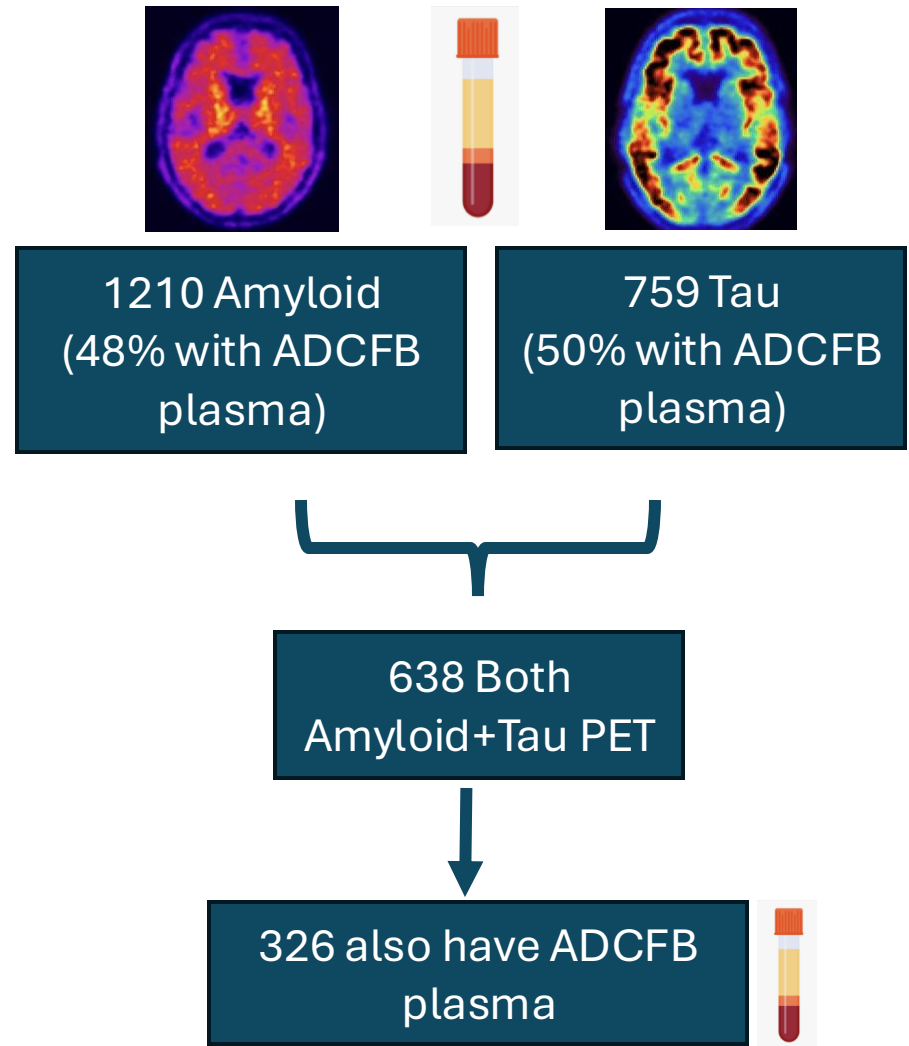
May reflect...
Site level strategies (Tau PET may not be collected in Amyloid-Impaired participants)?

Lack of resources/study protocol for collecting all 3?

Another limitation is high proportion of CU (~60%)

Venn Diagram courtesy Bill Jagust

Tau PET n=968



Flowchart courtesy
Jeff Dage

CLARiTI Aims

Infrastructure Aim: Standardized ATN+Blood acquisition

- The focus of today

Scientific Aims: Multi-etologies imaging-based signatures

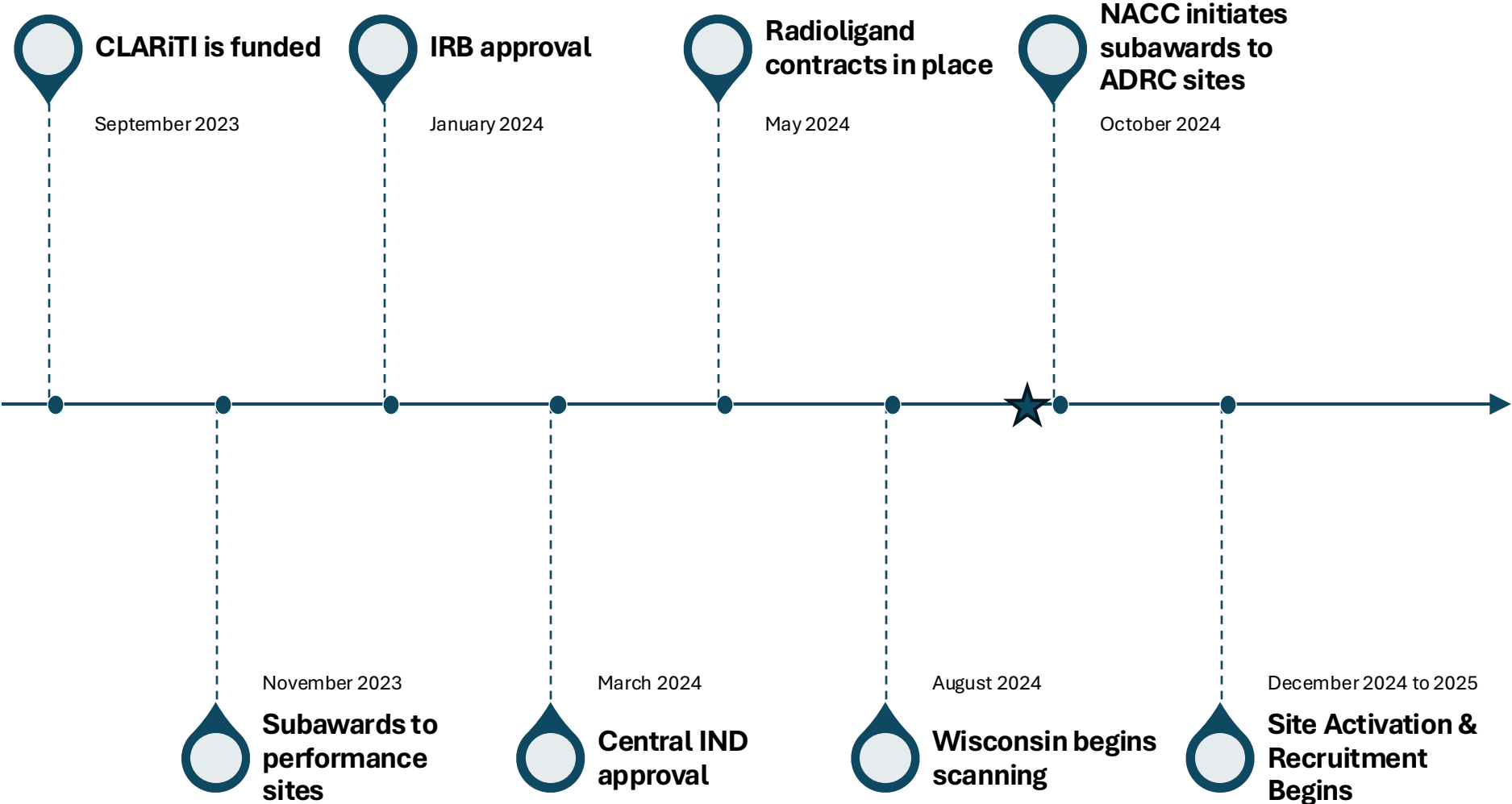
SYNOPSIS

GOAL: Create individual etiologic profiles from imaging and plasma

- ATN imaging and plasma study superimposed on existing longitudinal UDS
- **2,000 clinical core participants**; 60% impaired, 40% unimpaired
- Diverse representation for generalizable science > 25% URG
- Two time points [**4000** ATN sets] ~2 year interval
- *Embrace Heterogeneity*: syndromes and multi-pathologies



Timeline



Progress update: CLARiTI infrastructure now in place

Strategic
recruiting plan
and resources

Central IRB,
IND, regulatory,
vendors

Cores are
operational

CLARiTI portal
at LONI is
running

Informatics
established

Ready for
enrollment
when sites are



Next: Scaling up in Q4 and early 2025

Subaward phase
Nov 24

Site Activation

Site-level
dashboards with
diversity
monitoring

Core-specific
initiatives and
rollouts





Expanding NACC's Operational and Informatics Infrastructure to Amplify and Accelerate CLARiTI

Sarah Biber, PhD, NACC Executive Director

ADRC CLARiTI Session

October 17, 2024

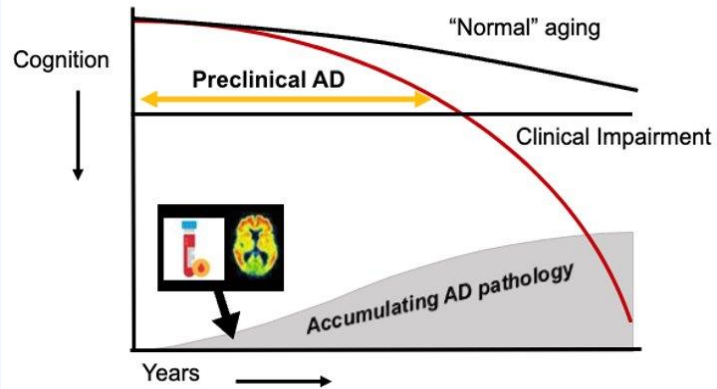
NACC serves as the data coordination hub and centralized data repository for NIA's ADRC Program

NIH National Institute on Aging (NIA) Alzheimer's Disease Research Center Program

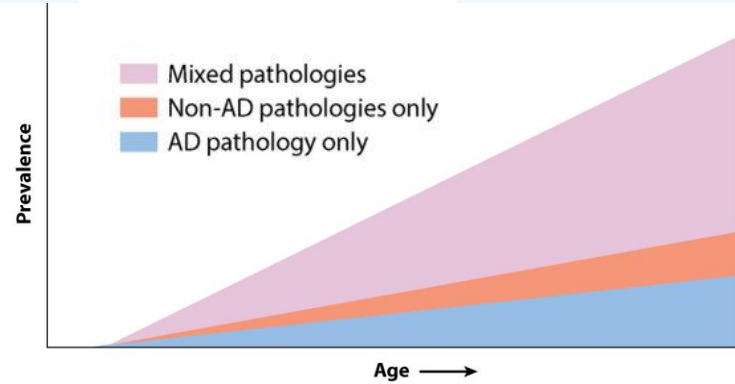


- State with NIA-Designated Center(s)
- State with Exploratory Center

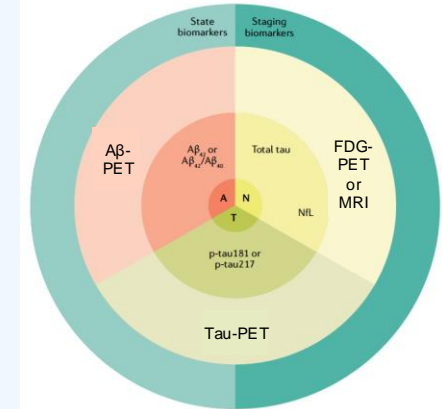
Advance Early Detection



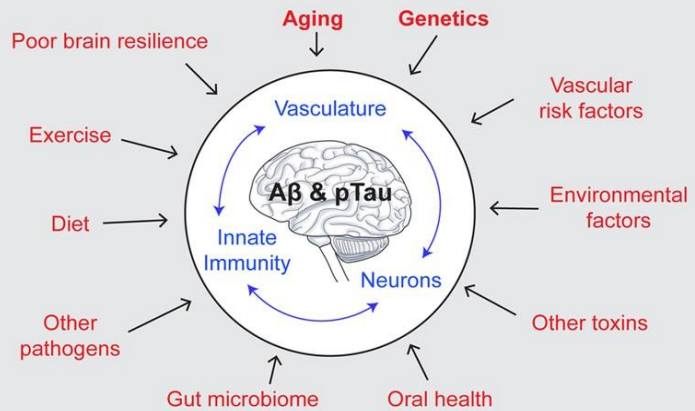
Disentangle Heterogeneity



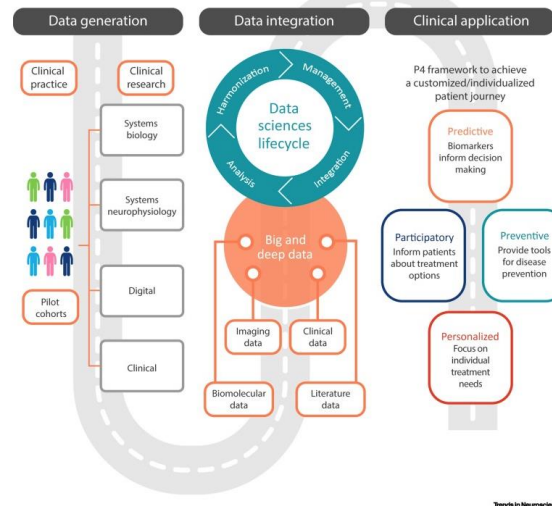
Validate Blood Biomarkers



Identify and Stratify Risk Factors and Protective Mechanisms



Precision Medicine



Improve Generalizability



Requires More Multimodal Data!

Researchers need to be able to readily access increasing amounts of multimodal data that are high-quality, harmonized, and integrated to advance the field



Socio-demographic



Neurocognitive tests



Neuro-pathology



Imaging (MRI/PET)



Biomarker



Genetic & genomic



EHR & Claims

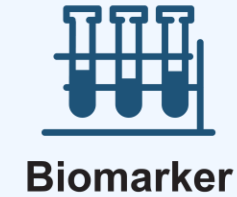
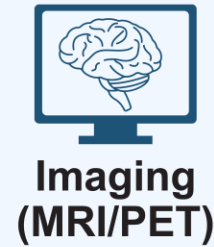


Digital data



Multomics data

Requires More Multimodal Data!



NACC's Expanded Mission and Role

NACC is providing advanced informatics an operational infrastructure, implementing new frameworks to facilitate impactful communication and collaboration, and supporting the next generation of researchers across the ADRC Program

Data Coordination & Centralized Repository

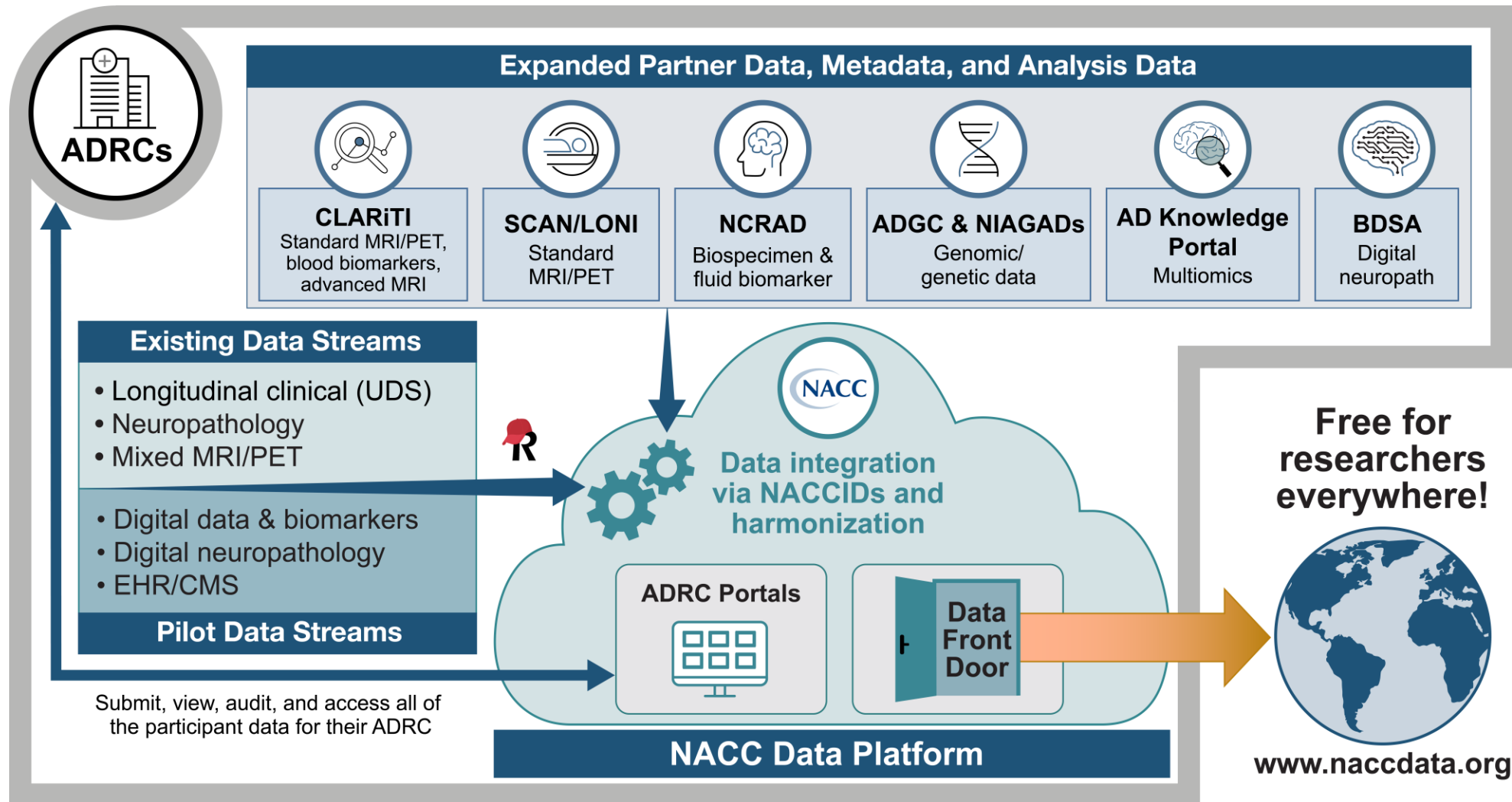


Communication & Collaboration Hub



New Investigator Support

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





Operational Advances

Supporting ADRC groups and initiatives



Strategic Planning



Project Management



Group Facilitation



Surveys & Analysis



Webinars & Forums

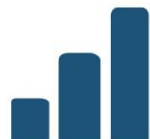
Convening the ADRC Program through biannual meetings

ADRC MEETING

Sharing the value of NACC and the ADRC Program to key stakeholders



Dynamic Website



Reports



Newsletters



Social Media



Podcasts

Facilitating collaboration through a real-time NACC Directory



Community Forum



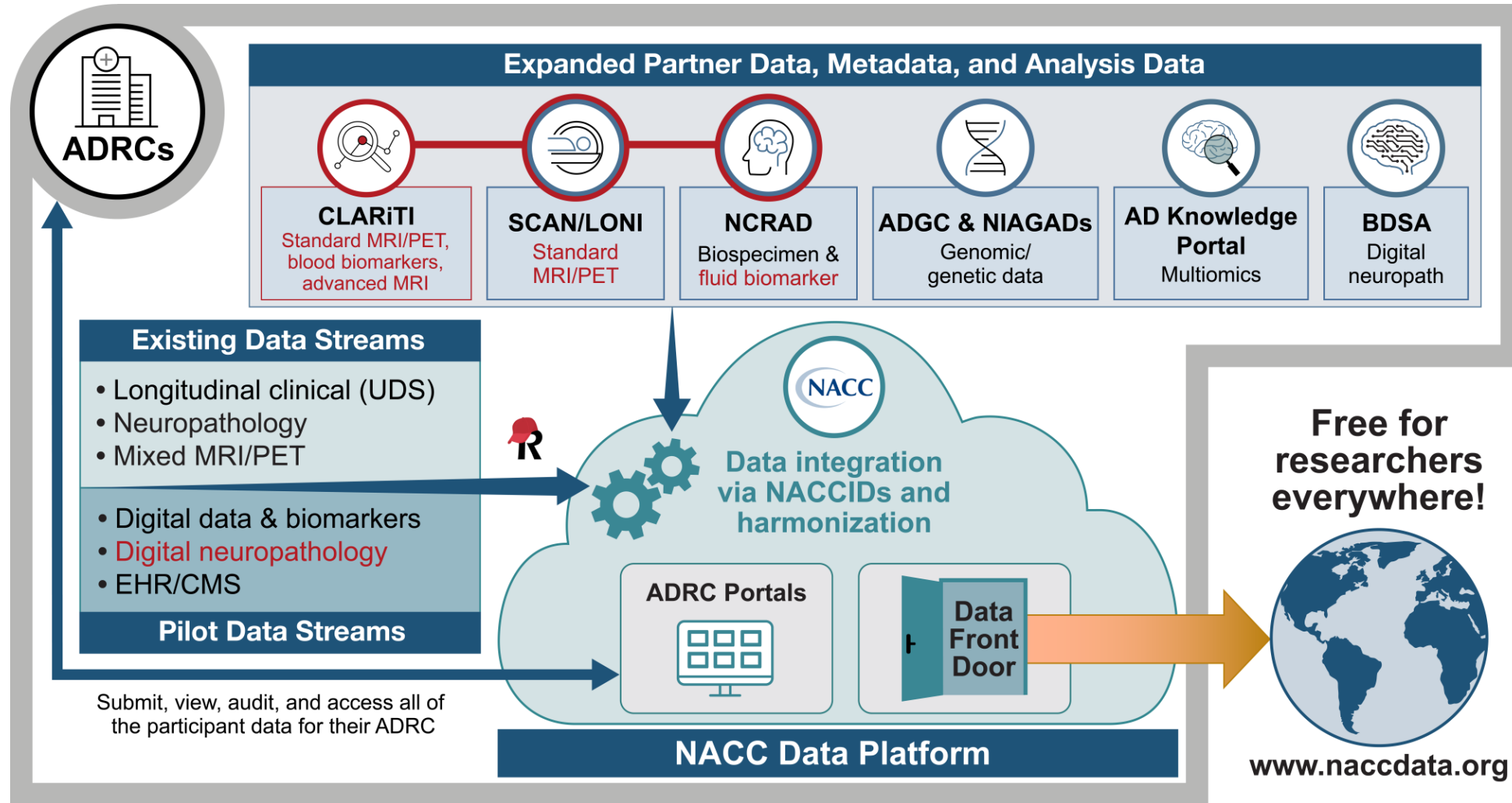
NACC Directory



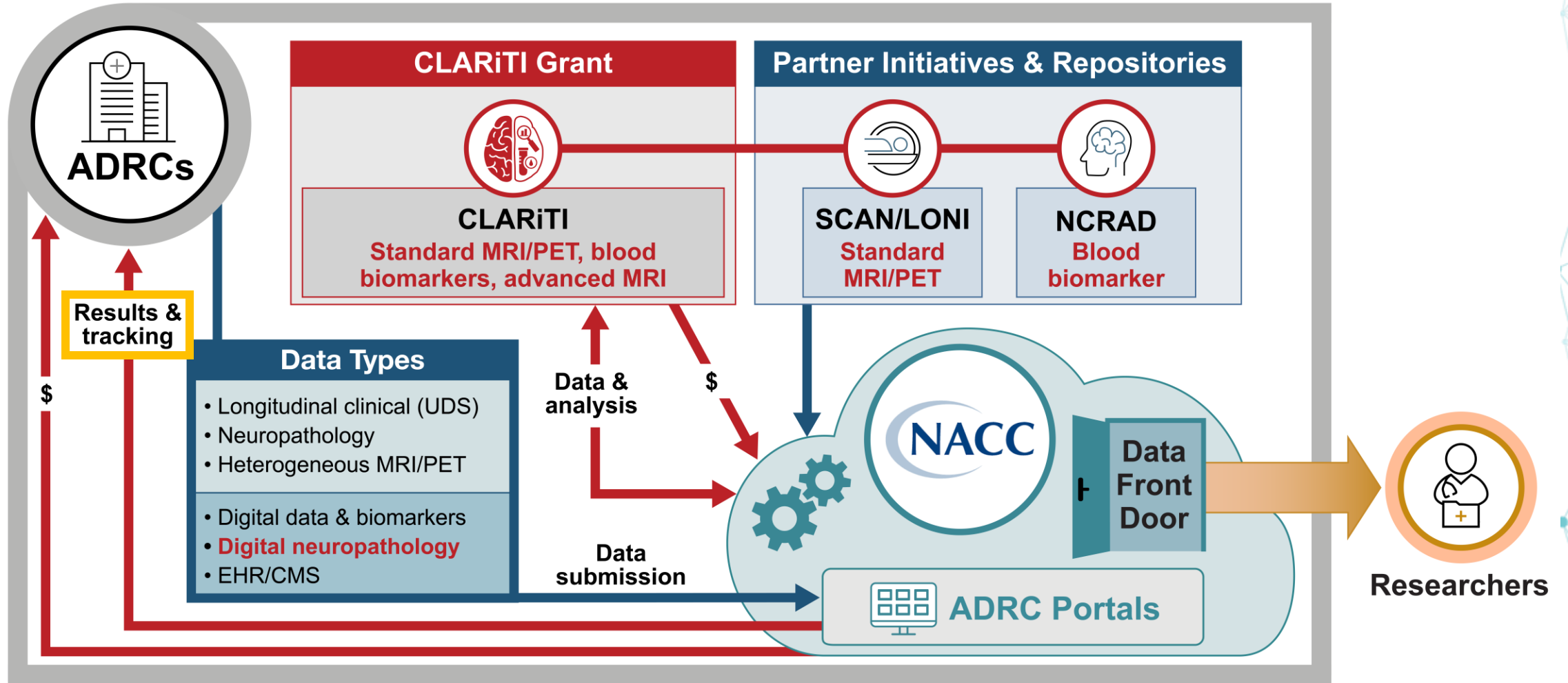
CLARiTI

NACC

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



NACC Data Platform: CLARiTI



NACC's Expanded Mission and Role

NACC is providing advanced informatics infrastructure, implementing new frameworks to facilitate impactful communication and collaboration, and supporting the next generation of researchers across the ADRC Program

Data Coordination & Centralized Repository



Communication & Collaboration Hub



New Investigator Support

Informatics Support

Data Submission and Tracking

- Data submission interface
- EDC system with case report forms
- Site-level dashboards
- Program-wide dashboards

Electronic Data Capture



ADRC Portals



Building key data pipelines

- MRI/PET
- Digital Neuropathology
- Fluid Biomarker
- Multimodal data integration via NACCID

Data Pipelines



Data Integration



Data Sharing

- Real-time form error checks
- Data Front Door: One-stop-shop for CLARiTI data

Data Integration



Data Front Door



A decorative background featuring a network diagram with teal and light blue nodes and connecting lines, spanning the top and bottom of the slide.

Data Submission and Tracking

NACC ADRC Portals

ADRCs can submit, view, audit, access,
and manage their CLARiTI participant data

ADRC Portals



CLARiTI

Submit Data



View, Audit, Track, and
Access Participant Data



Program-Wide
Dashboards and Reports



NACC ADRC Portals

ADRCs can submit, view, audit, access,
and manage their CLARiTI participant data

ADRC Portals



CLARiTI

Submit Data



View, Audit, Track, and
Access Participant Data

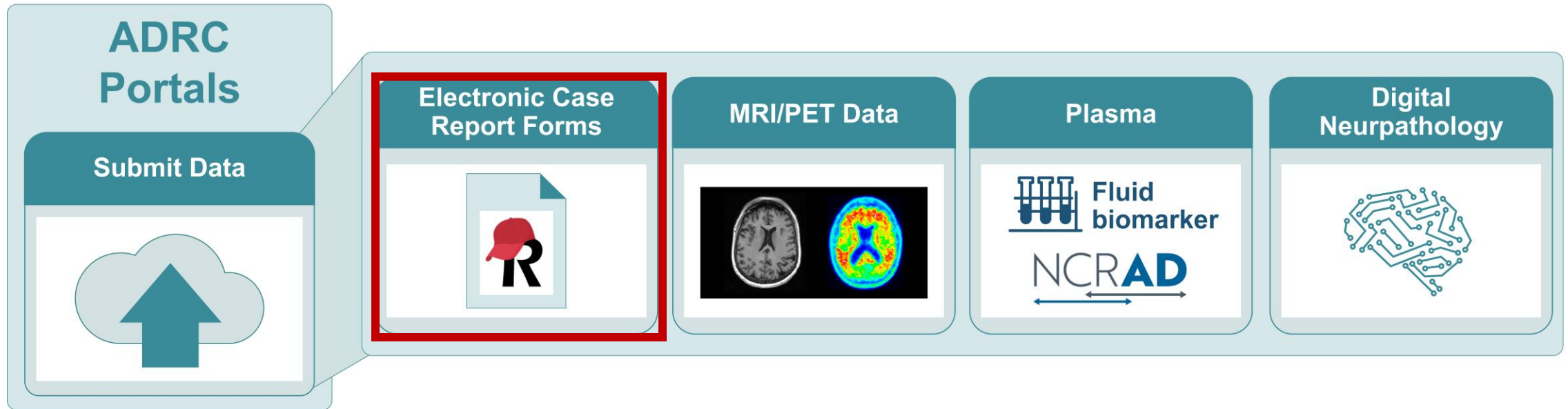


Program-Wide
Dashboards and Reports



NACC ADRC Portals: Submit Data

Data Submission



NACC ADRC Portals

Submit CLARiTI Protocol Data via REDCap EDC CRFs

CLARiTI EDC #10 25

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Legend for status icons:

- Incomplete ● Incomplete (no data saved) ?
- Unverified ● Many statuses (all same)
- Complete ● Many statuses (mixed)

Dashboard displayed: [Default dashboard] Create custom dashboard

Displaying Data Access Group: -- ALL --

Displaying record: Page 1 of 2: "CL33_1" through "CL37_50" of 200 records 100 records per page

+ Add new record

Displaying: Instrument status only | [Lock status only](#) | [All status types](#)

Record ID	Identifiers		Study Participation		Baseline					Return of Results			Follow-up Visit					
	A - CLARiTI Identifiers CRF	B1 - CLARiTI Eligibility Screening CRF	B2 - CLARiTI Participant Consent Status CRF	C1 - CLARiTI ADCFB Bio-Sample Collection CRF	C2 - CLARiTI Amyloid Scan CRF	C3 - CLARiTI Tau PET CRF	C4 - CLARiTI PET PET CRF	C5 - CLARiTI MRI and Advanced MRI CRF	C6 - CLARiTI Amyloid PET Visual Read CRF	C7 - CLARiTI MR Visual Read CRF	E1 - CLARiTI PET Return of Results CRF	E2 - CLARiTI PET Return of Results CRF	E3 - CLARiTI PET Post-Visit Follow-up CRF	C1 - CLARiTI ADCFB Bio-Sample Collection CRF	C2 - CLARiTI Amyloid PET Scan CRF	C3 - CLARiTI Tau PET CRF	C4 - CLARiTI PET PET CRF	C5 - CLARiTI MRI and Advanced MRI CRF
CL33_1 Center: Arizona NACCID:	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
CL33_2 Center: Arizona NACCID:	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
CL33_3 Center: Arizona NACCID:	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
CL33_4 Center: Arizona NACCID: Rock	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
CL33_5 Center: Arizona NACCID:	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

CLARiTI EDC #10 24

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) Views: Basic data entry

B1 - CLARiTI Eligibility Screening CRF

Data Access Group: Arizona

Editing existing Record ID CL33_1 - Center: Arizona NACCID

Event: Study Participation

Record ID: CL33_1

CLARiTI Research Program

Screening and Eligibility Case Report Form

0. Name of staff filling out this form:

Participant ADR ID# (PTID): 987654321

Participant NACCID # (if available):

ADC Name: Arizona ADRC

ADC Site ID#: 33

0a. Date of Screening:

0b. Select the UDS form version you will be using to complete the participant's CLARiTI Eligibility and Screening Case Report Form:

UDSv3 UDSv4

Attention Research Staff: Please fill out this form using information from the participant's most recently completed NACC Uniform Data Set (UDS) form.

For guidance on where to find the questions in UDSv3 please refer to the CLARiTI Screening and Eligibility Case Report Form UDSv3 Appendix in Box: <https://sawmadison.box.com/s/y9fao7c3d0cm18cto013se042quw>

Cognitive Decline

1a. Does the participant have normal cognition (global CDR-sb) and/or neuropsychological testing within normal range) and normal behavior (i.e., the participant does not exhibit behavior sufficient to diagnose MCI or dementia due to FTLD or LBD)?

No, cognitively impaired Yes, cognitively unimpaired

1b. Does the participant meet the criteria for dementia?

No Yes

1c. Does the participant meet the criteria for MCI?

No Yes

NACC ADRC Portals

ADRCs can submit, view, audit, access,
and manage their CLARiTI participant data

ADRC Portals



CLARiTI

Submit Data



View, Audit, Track, and
Access Participant Data

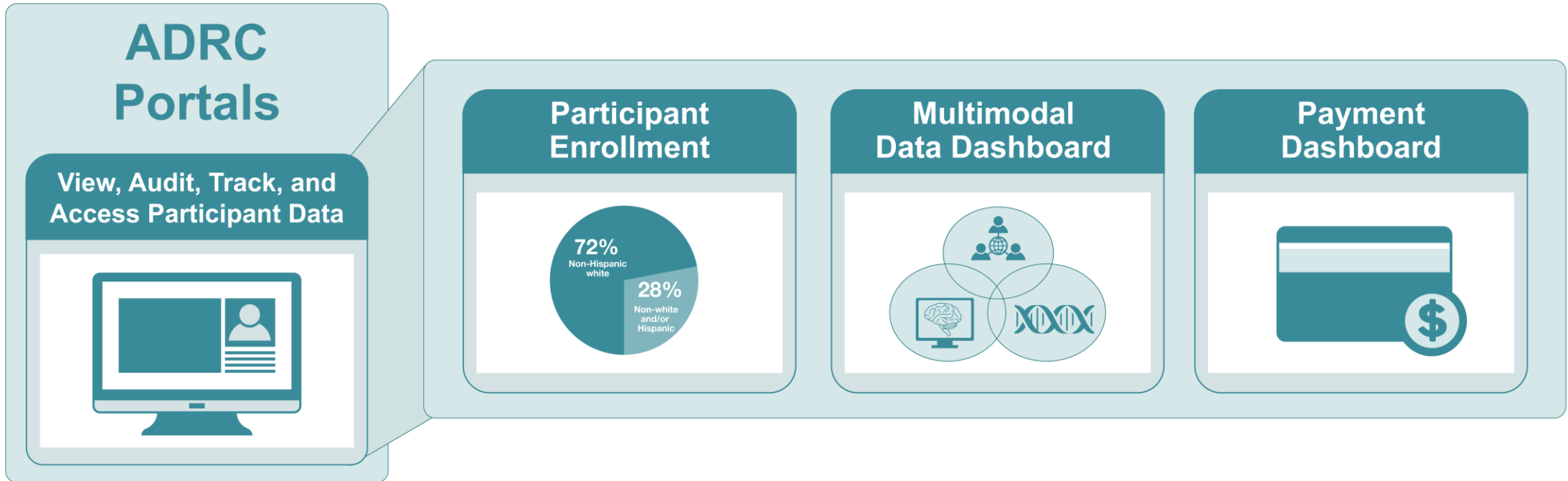


Program-Wide
Dashboards and Reports



NACC ADRC Portals

Site-Level View, Audit, and Access



NACC ADRC Portals

ADRCs can view and download
Program-Wide Dashboards and Reports

ADRC Portals



CLARiTi

Submit Data



View, Audit, Track, and
Access Participant Data



Program-Wide
Dashboards and Reports



NACC ADRC Portals: Program-Wide Dashboards

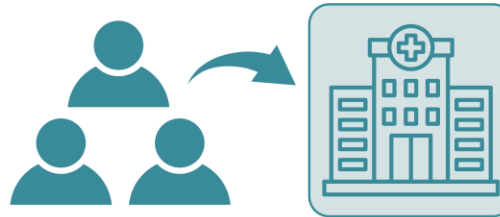


ADRC Portals

Program-Wide Dashboards & Reports



CLARiTI Recruitment and Enrollment



Multimodal Data Dashboard



A decorative background featuring a network diagram with teal lines and dots of varying sizes and colors (teal and light grey) connected in a complex web pattern.

Building Key Data Processing Pipelines



scan

Imaging Analysis



Data Integration and Distribution

**Researchers
everywhere**

SCAN Compliant Acquisitions

**SCAN non-P30
2021—Ongoing**

- SCAN Supplements
- Affiliated R01s
- Site specific scanning schedules & eligibility

**SCAN P30
2023—Ongoing**

- ADRC P30 Budget
- Site specific scanning schedules & eligibility
- 24 ATN sets required
- Expect 600 participants/year



CLARiTI

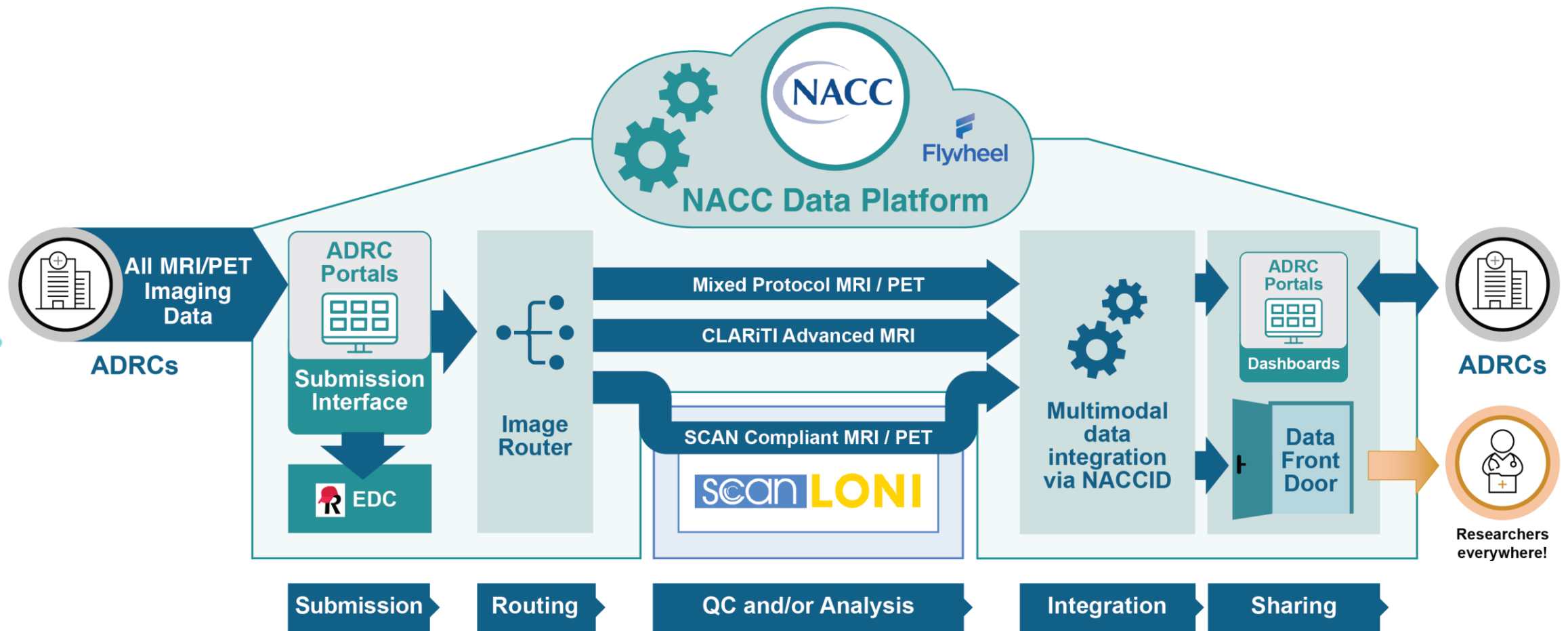
**CLARiTI
2023—Ongoing**

- CLARiTI Performance Site Budget
- CLARiTI scanning schedule and eligibility
- 2000 participants over 5 years

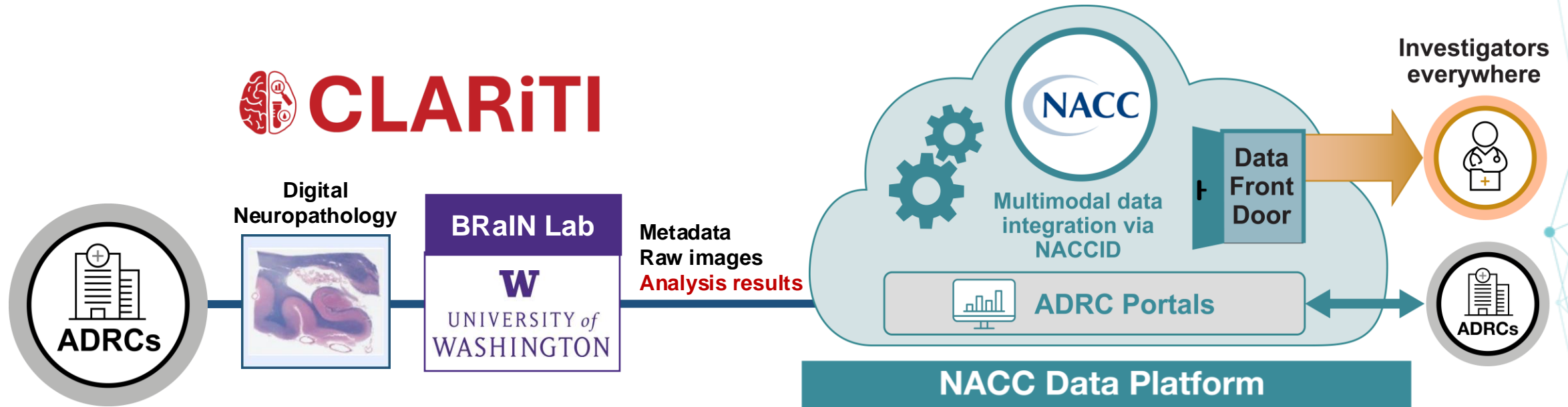
Mixed Protocol

- Site-specific protocols

MRI / PET Pipeline

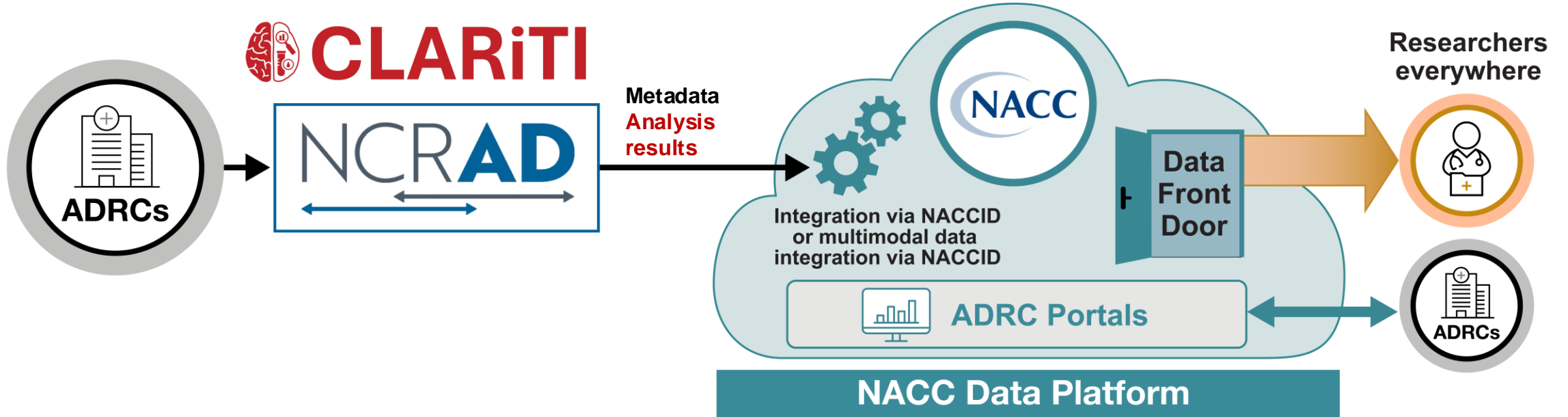


Digital Neuropathology Pipeline



Dirk Keene, MD, PhD
CLARiTI Neuropathology Lead
Chair of Neuropathology,
University of Washington

Fluid Biomarker Pipeline

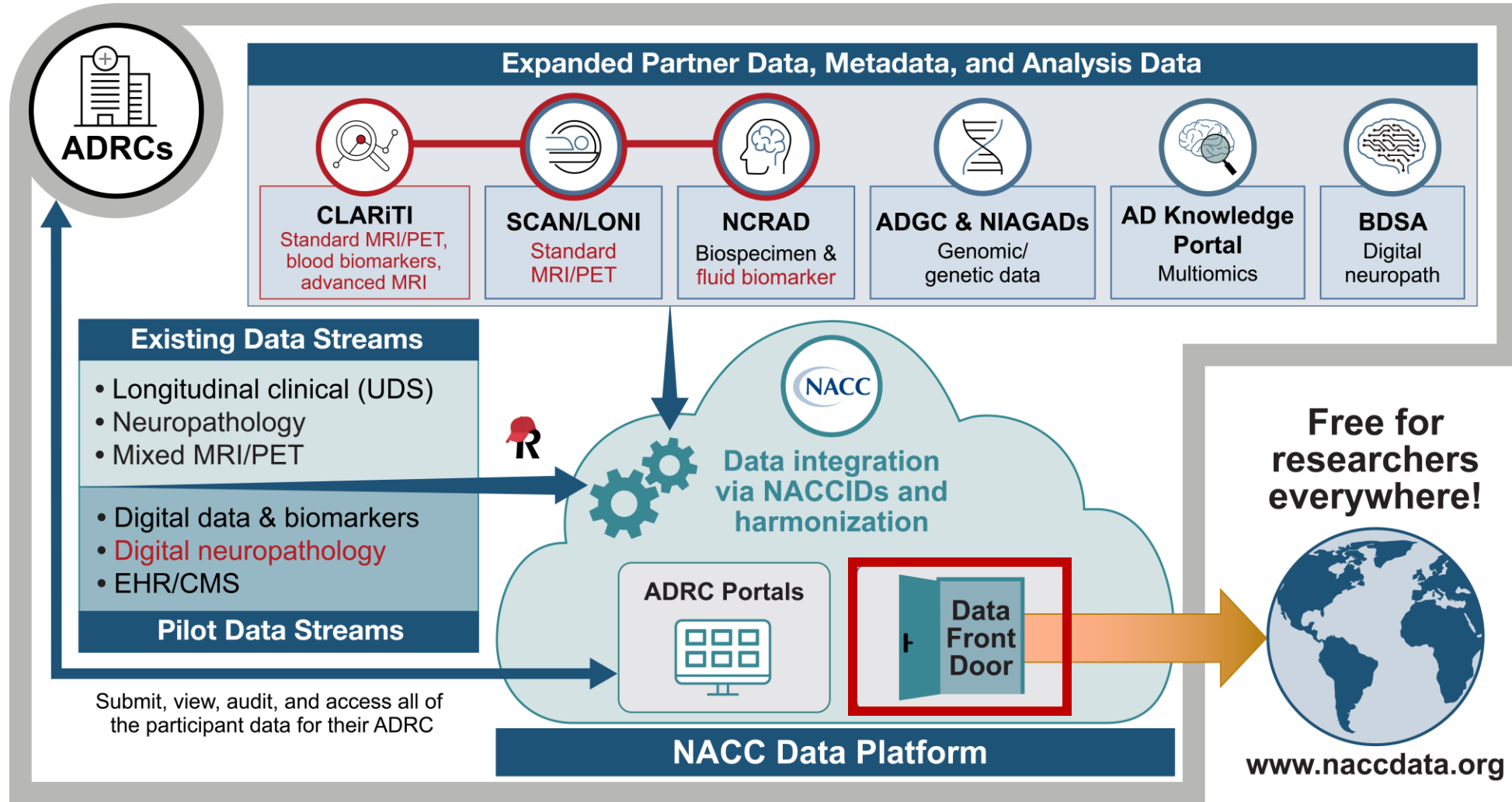


Tatiana Foroud, PhD
CLARiTI Plasma Biomarkers Lead
Executive Associate Dean for Research Affairs,
Indiana University School of Medicine

A network diagram background consisting of a complex web of light blue lines connecting various nodes. Some nodes are represented by solid teal circles, while others are smaller, semi-transparent grey circles. The lines are thin and create a dense, interconnected pattern across the entire page.

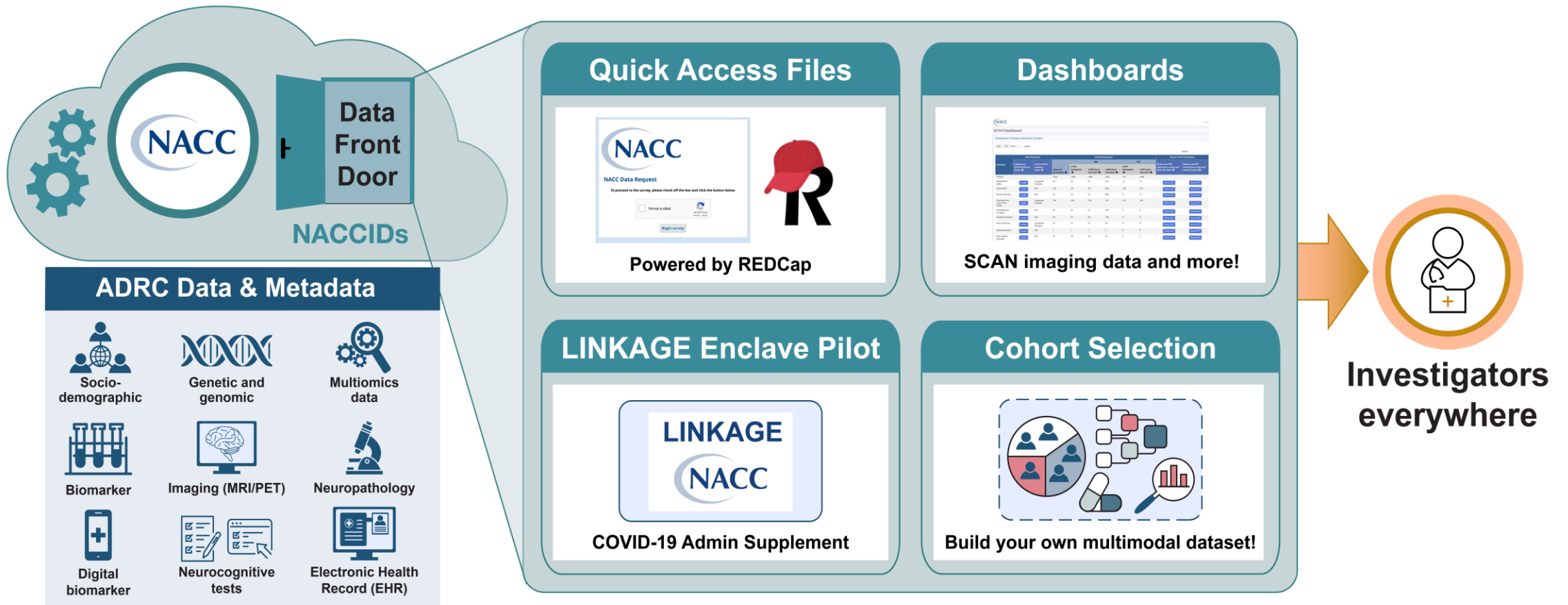
NACC Data Front Door: A One-Stop-Shop for CLARiTI Study Data

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



Data Front Door: Advanced Data Search, Visualization, & Access

One-Stop-Shop for All ADRC Data



NACC's Expanded Mission and Role

NACC is providing advanced informatics infrastructure, implementing new frameworks to facilitate impactful communication and collaboration, and supporting the next generation of researchers across the ADRC Program

Data Coordination & Centralized Repository



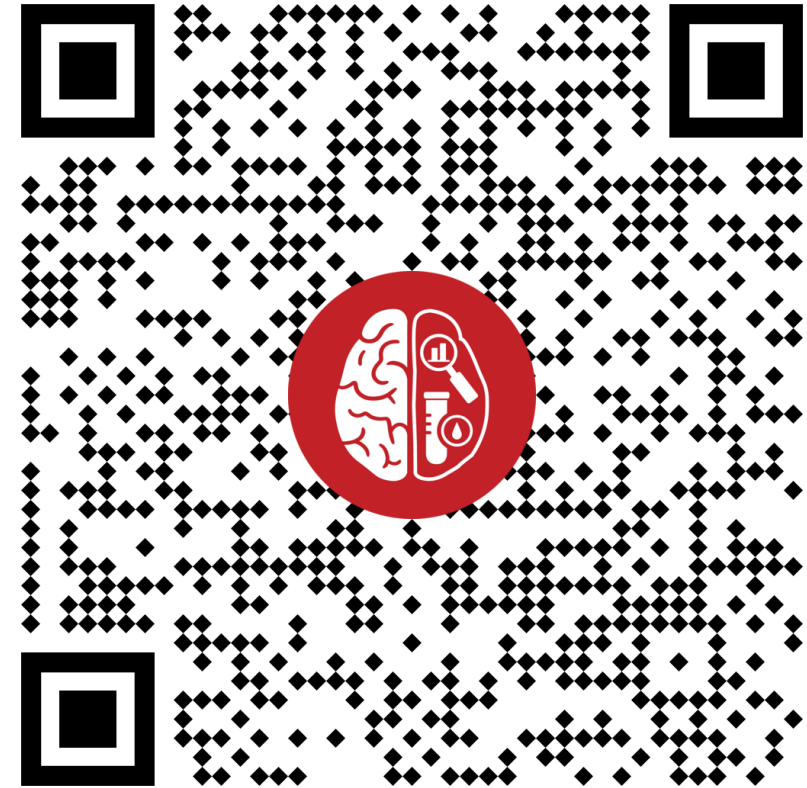
Communication & Collaboration Hub



New Investigator Support

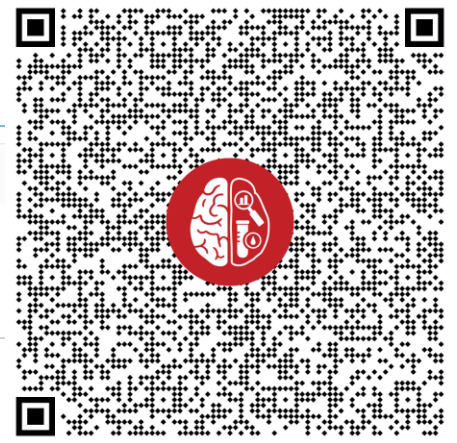
Operations Support: NACC-hosted website

The screenshot shows the homepage of the CLARiTI website. At the top left is the NACC logo and the text "THE NIA ALZHEIMER'S DISEASE RESEARCH CENTERS PROGRAM National Alzheimer's Coordinating Center". A yellow "PORTAL" button is in the top right. Below is a navigation bar with links: "NACC collaborations", "Requesting data", "Data Analysis", "Publishing", "NACC productivity", "Data collection", "ADRC resources", and a search box. The main header features the CLARiTI logo (a brain with a microscope) and the text "CLARiTI" in large red letters, with "ADRC Consortium for Clarity in ADRD Research Through Imaging" below it. A secondary navigation bar includes: "NEWS & STUDY UPDATES", "ABOUT", "WEBINARS & EVENTS", "MEET THE TEAM", "PARTNERS", "TOOLKITS & RESOURCES", "FAQS", and "CONTACT US". The "News & Study Updates" section is active, showing a carousel of brain scan images with the headline: "University of Washington plays key role in \$150M CLARiTI study for Alzheimer's and related dementias research".



<https://bit.ly/CLARiTI>

Operational Support: Study Start-up Dashboard



<https://bit.ly/CLARiTI-Startup-Dashboard>

CLARiTI Study Start-up PID 237

Data Exports, Reports, and Stats

[VIDEO: How to use Data Exports, Reports, and Stats](#)

[+ Create New Report](#)
[My Reports & Exports](#)
[Other Export Options](#)

Number of results returned: **36**

Total number of records queried: 37

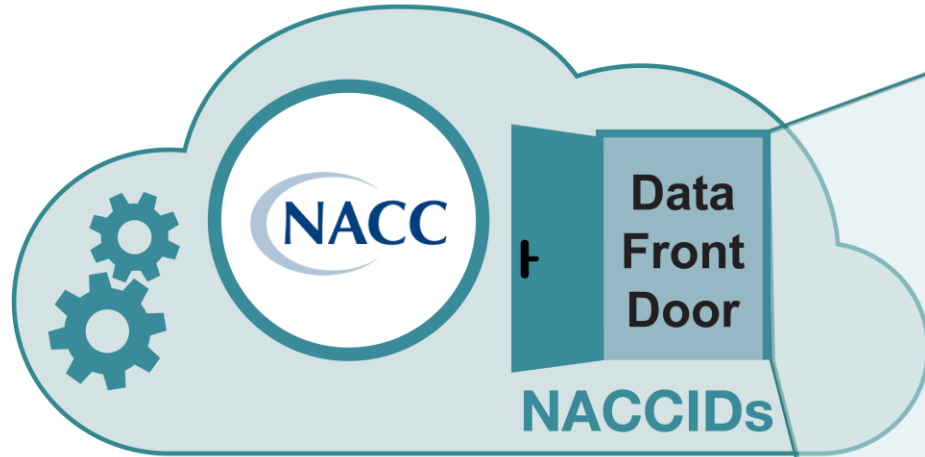
Report execution time: 0.1 seconds

[Public](#)
[Stats & Charts](#)
[Export Data](#)
[Print Page](#)

Live filters: [ADRC Affiliation]

CLARiTI Study Start-up Dashboard - ranked by points

ADRC Affiliation	Site Initiation Meeting Completed	Site CLARiTI Study Coordinator Designated	Site CLARiTI Outreach Specialist Designated	NACC Subaward Executed	IRB Review Ceded To WCG	WCG Approval	SCAN Qualified Site for CLARiTI	Radiotracers Selected	Manufacturer SOW Filed	Regulatory Documents Completed	UWisc Central Monitoring SIV	LONI Access	ADCFB Protocol Training With NCRAD	Blood Collection Kits Ordered	Site Recr Strat Final
Wisconsin ADRC	Complete	Complete	Complete	Complete	Complete	Complete	Complete	Complete	Complete	Complete	Complete	Complete	Complete	Complete	Complete
Boston University ADRC	Complete	Complete	Complete	In Progress	Complete	Complete	Complete	Complete	Not Started	Complete	In Progress	Complete	Complete	Not Started	In Progress
Mayo Clinic ADRC	Complete	Complete	Complete	In Progress	Complete	Complete	Complete	Complete	In Progress	Not Started	In Progress	Complete	Not Started	Not Started	Not Started
1Florida ADRC	Complete	Complete	Complete	In Progress	Complete	Complete	In Progress	Complete	In Progress	Not Started	In Progress	Complete	Not Started	Not Started	Not Started
South Texas ADRC	Complete	Complete	Complete	In Progress	Complete	Complete	In Progress	Complete	Not Started	Not Started	In Progress	Complete	Not Started	Not Started	Not Started
University of Kansas ADRC	Complete	Complete	Complete	In Progress	Complete	Complete	Not Started	Complete	In Progress	Not Started	In Progress	Complete	Not Started	Not Started	Not Started
Wake Forest University, ADRC	Complete	Complete	Complete	In Progress	Complete	Not Started	Complete	Complete	In Progress	Not Started	Not Started	Complete	Not Started	Not Started	Not Started
Rush University Alzheimer's Disease Center	Complete	Complete	Not Designated	In Progress	In Progress	Not Started	Complete	Complete	In Progress	Not Started	Not Started	Complete	Not Started	Not Started	Not Started
Stanford ADRC	Complete	Complete	Not Designated	In Progress	Complete	Complete	Complete	Complete	Not Started	Not Started	In Progress	Complete	Not Started	Not Started	Not Started
University of Michigan ADRC	Complete	Complete	Not Designated	In Progress	Not Started	Not Started	Not Started	Complete	Not Started	Complete	Not Started	Complete	Complete	Not Started	Not Started
University of Washington ADRC	Complete	Complete	Not Designated	In Progress	Complete	Not Started	Not Started	Complete	Not Started	Not Started	Not Started	Complete	Complete	Not Started	Not Started



NACC Data Platform

 Socio-demographic	 Neurocognitive tests	 Neuro-pathology
 Imaging (MRI/PET)	 Biomarker	 Genetic & genomic
 EHR & Claims	 Digital data	 Multiomics data

Key AD/ADRD Challenges & Opportunities

- Advancing Early Detection
- Disentangling Heterogeneity
- Validating Blood Biomarkers
- Identifying & Stratifying Risk Factors & Protective Mechanisms
- Providing Precision Medicine
- Improving Generalizability

NACC's CLARiTI Team

CLARiTI Leadership (mPIs)



WALTER KUKULL, PHD
PI/Director, NACC
Professor,
Epidemiology



SARAH BIBER, PHD
Executive Director

CLARiTI Management & Operations Support



HEATHER O'CONNELL
CLARiTI
Program Manager



HANNAH KOENIG
CLARiTI Data Manager

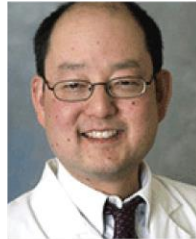


BRITTANY HALE
Project Manager

Co-Investigators



**KWUN CHUEN
GARY CHAN, PHD**
Associate Director
Prof., Biostatistics,
Health Systems &
Population Health



DEAN K. SHIBATA, MD
Co-investigator, NACC;
Professor, Radiology



YEN-CHI CHEN, PHD
Co-investigator, NACC
Assistant Professor,
Statistics



MARK BAUER, EDD
Manager of
Communications



AILEEN IDA, MA
Communications
Specialist



**HANNAH
ROSENTRETER**
Events & Collaborations
Manager



JANE XIA, MHA
Grants & Finance
Manager



VALERIE HOCKENS
Program Operations
Specialist



EMILY ALMEDA
Administrative
Coordinator

Communications & Events Support

Grants & Finance Support

CLARiTI Technical Support



**SHILPA
ALLIMATTI, MS, MBA**
Technology Lead



DAN PETERSON
Software Engineer



EMILY CHENG, BS
Software Engineer



LAURA MCLEOD
Senior REDCap
Administrator



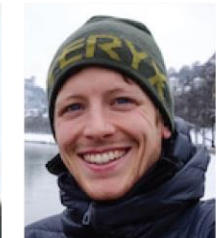
ZACH STARK, BBA
Software Engineer



BEN KELLER, PHD
Software Engineer



JANENE HUBBARD, BS
Research Consultant



BRENDAN SMITH, BS
Software Developer



CLARiTI

ADRC Consortium for Clarity in ADRD Research Through Imaging



CLARiTI Study Updates
October 17, 2024

CLARiTI Subawards Update

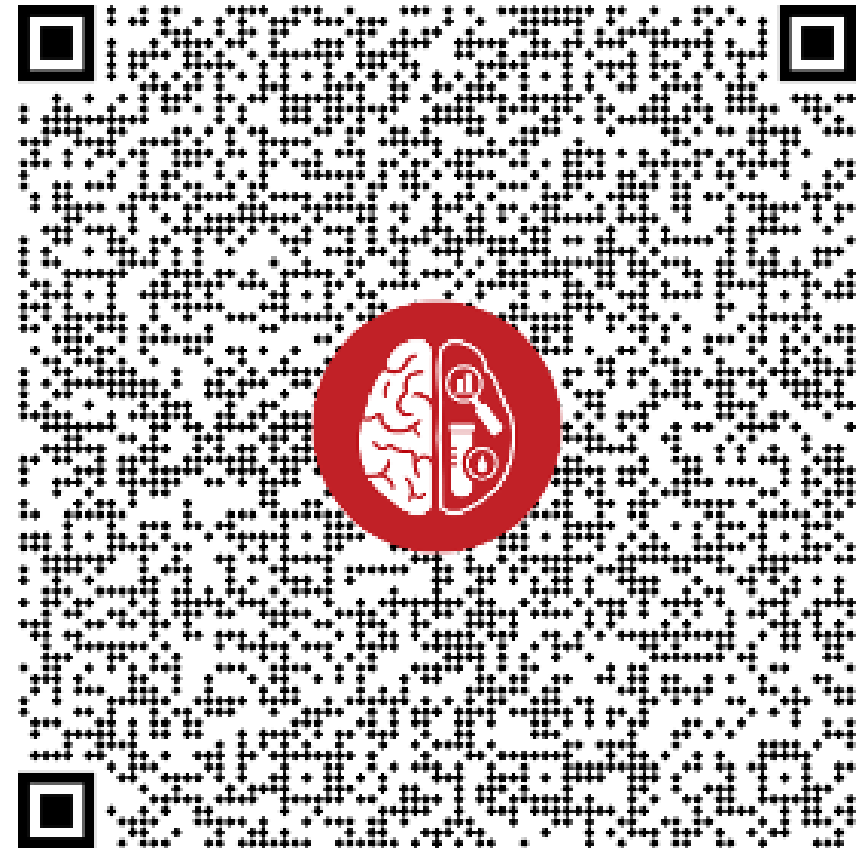
- Budget period 9/1/2024 - 8/31/2025
 - Email with details was sent 9/12/2024
 - Pre-award expenses are allowed up to 90 days (>June 3, 2024)
- Subaward documentation reviews are underway
 - ADRCs will be receiving site-specific communications from NACC regarding status of their subawards over the course of the next few weeks.
 - Priority is based on site readiness; WCG approval, Site Initiation Visit (SIV) with Central Monitoring Service



What you can do

- Respond to subaward correspondence promptly
 - Coordinate with your local RSP office
- Continue working on site readiness
 - WCG approval
 - Site Initiation Visit with CMS
 - Onboarding with radioligand companies
- Inclusion Core Launch Call

Visit the Study Start-Up
Dashboard



Central Monitoring

- [University of Wisconsin Central Monitoring Service](#)
- Sponsor compliance; standardized monitoring
- Benefit for CLARiTI sites
- Site Initiation Visit (SIV)
 - CLARiTI regulatory team will reach out upon WCG IRB approval
 - Documents needed for CLARiTI ebinder will be required *in advance* of the scheduled SIV
- Interim Monitoring Visits (IMV)



Site Communications

- CLARiTI Website
- CLARiTI Connect Newsletter
- Study Handbook
- Webinars
 - Next webinar will be presented by SCAN
 - November 22, 12pm CT
- CLARiTI Concierge
- Office Hours
- CLARiTI group within the NACC Community Forum



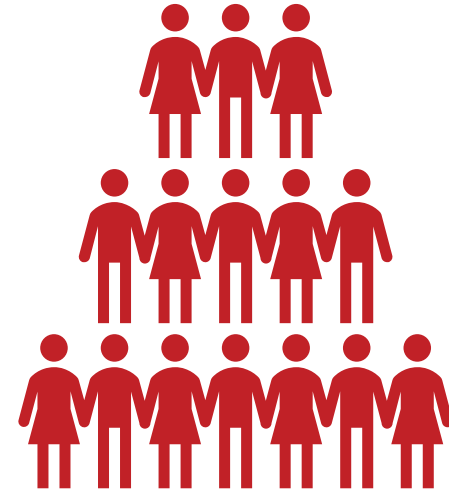
Return of Results Toolkit

- Gathered information from 4 pilot sites
 - Interests and needs
- Gathered information from 3 expert sites
 - Workflows, resources, tools
- Next steps:
 - Finalize Toolkit
 - Lead a training webinar in early 2025
 - Develop and publish supplemental training videos to support rollout



Inclusion

- Inclusion Core launch call with individual sites
- Diversity Dashboard within ADRC Portal
- Participant facing website
- CRN Support
- Culturally tailored materials and resources



Thank you!



**CLARiTI's first participant scanned at the Wisconsin ADRC, is thanked by Dr. Sterling Johnson, mPI.
(Photo used with permission)**



ADRC Consortium for Clarity in ADRD Research Through Imaging





CLARiTI

ADRC Consortium for Clarity in ADRD Research Through Imaging

CLARiTI National Inclusion and Engagement Plan

Mónica Rivera Mindt, PhD, ABPP-CN & Ozioma Okonkwo, PhD

Thursday, October 17, 2024



CLARiTI Inclusion Core

- Introduction to Inclusion Core Team and CLARiTI Engagement Goals
- Culturally-Informed Community-Engaged Research (CI-CER) Overview
- CI-CER Approach in CLARiTI
- Next Steps
- Questions/Comments?



CLARiTI Inclusion Core Team



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



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



Dr. Desiree Byrd, Consultant
CUNY, Queens College



Dr. Stephen Cubbellotti, Data Scientist
Mount Sinai



Dr. Vanessa Guzman, Co-I
Mount Sinai



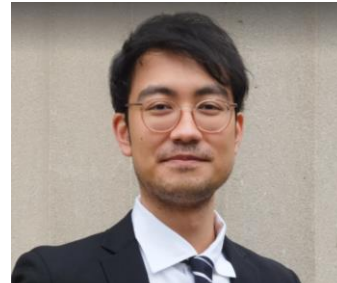
Dr. Charles Windon, Co-I
UC San Francisco



Dr. Adeyinka Ajayi
Project Manager, Mount Sinai



Anne Buffington, MPH
Project Manager, UW Madison



Alexander Robateau, MA
Study Coordinator, Mount Sinai



Eva Schulte, BS
CRN, UW Madison



Emily Weiler, MSW
CRN, Mount Sinai

Inclusion Core Mission

Ensure the inclusion and engagement of persons from Underrepresented Populations (URPs) in CLARiTI by utilizing a culturally-informed community-engaged research (CI-CER) approach, in close coordination with all CLARiTI Cores, esp. the Admin and Return of Results Cores, and with local ORE Cores.

Milestone 1:

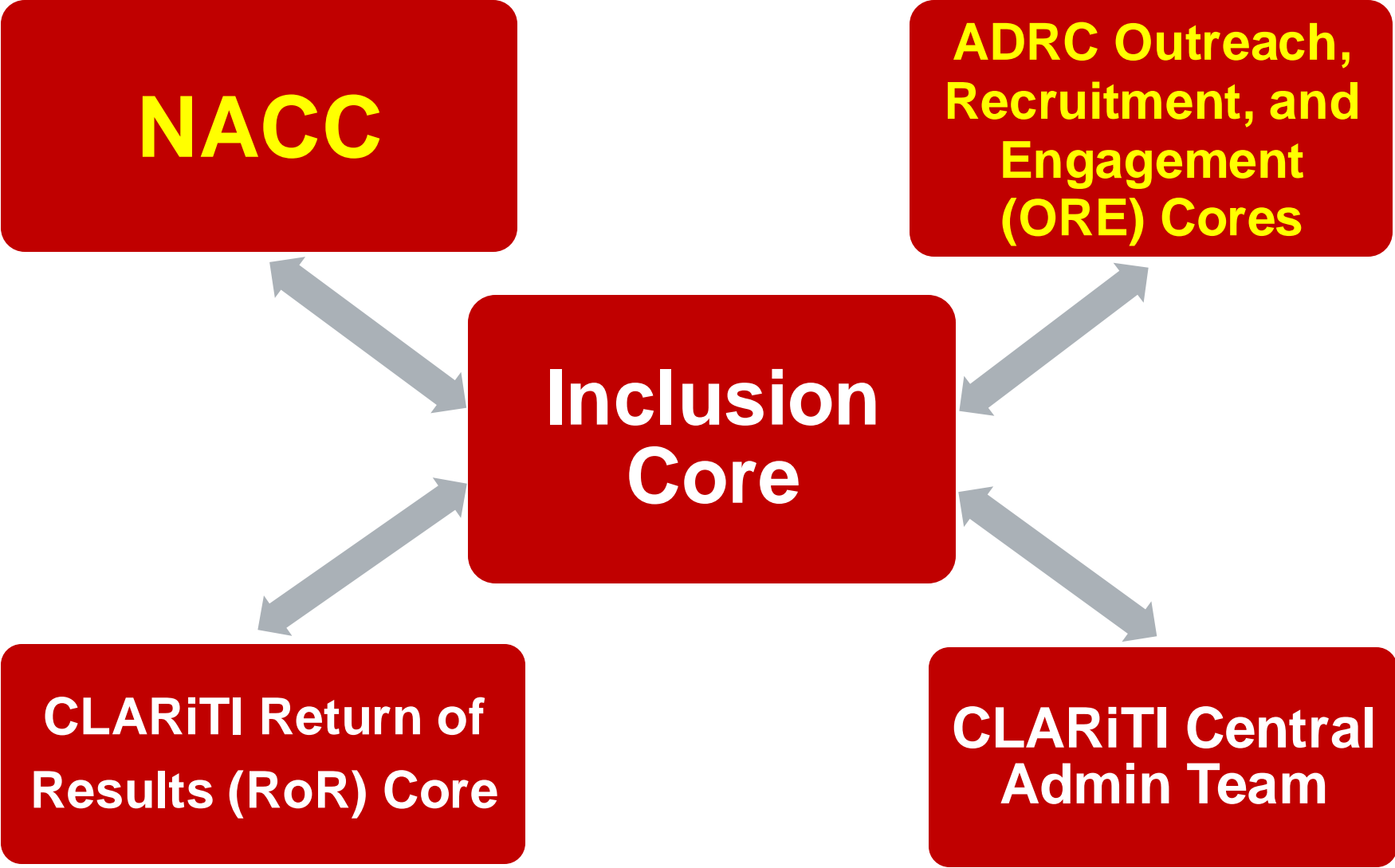
Increase the inclusion & engagement of persons from URPs to $\geq 25\%$ in CLARiTI.

Milestone 2:

Establish and maintain close collaboration and communication with other Cores to meet inclusion goals.



Inclusion Core's *Primary** Partnerships



*But we are happy to collaborate with all Cores, just let us know how we can be of help!

Partnership with ADRC ORE Cores



Success of the CLARiTI Inclusion mandate ($\geq 25\%$ URPs*) requires close collaboration bet. Inclusion Core & ADRC ORE Cores:

- Regular meetings between Inclusion Core (IC) Leadership and ORE Core Steering Leadership
- Regular check-ins between IC Study Team and ORE Core Team Members
- Consultation with ORE Core (*and other Cores*) as needed to support URP inclusion and engagement
- Networking with ORE Core leaders and team members during NACC Directors Meetings!



*URPs: Underrepresented Populations

Inclusion Core Collaboration with NACC

The Inclusion Core thanks NACC for their partnership on two key initiatives:

- **CLARiTI's Public-Facing Website**
 - Connect with public
 - Give back with brain health education
 - Portal for inclusion into CLARiTI
- **'Diversity Dashboard'**
 - Track key inclusion and engagement metrics





CLARiTi Inclusion Core

- Introduction to Inclusion Core Team and CLARiTi Engagement Goals
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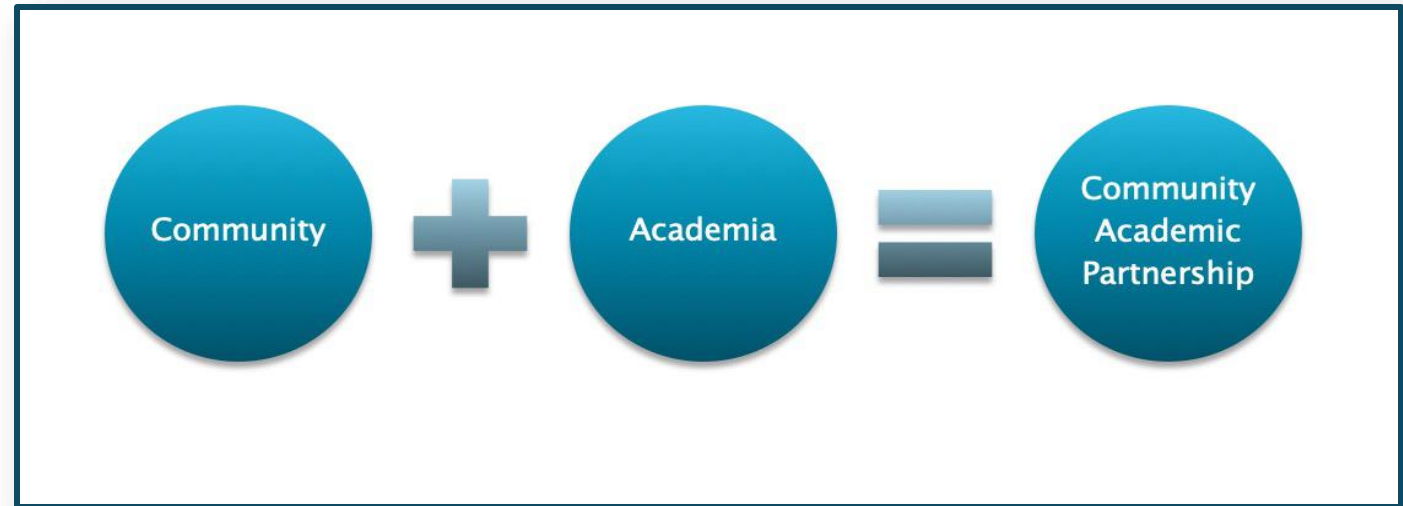
Culturally-Informed Community-Engaged Research (CI-CER): Why?

- **Improves the quality and validity of research** by drawing upon the knowledge and lived experiences of the people involved.
- **Involves communities** that have historically been harmed or excluded.
- **Examines potential harms of research** with the intent to reduce and eliminate it.
- **Acknowledges the effects that research may have on policy.**



CI-CER Key Principles

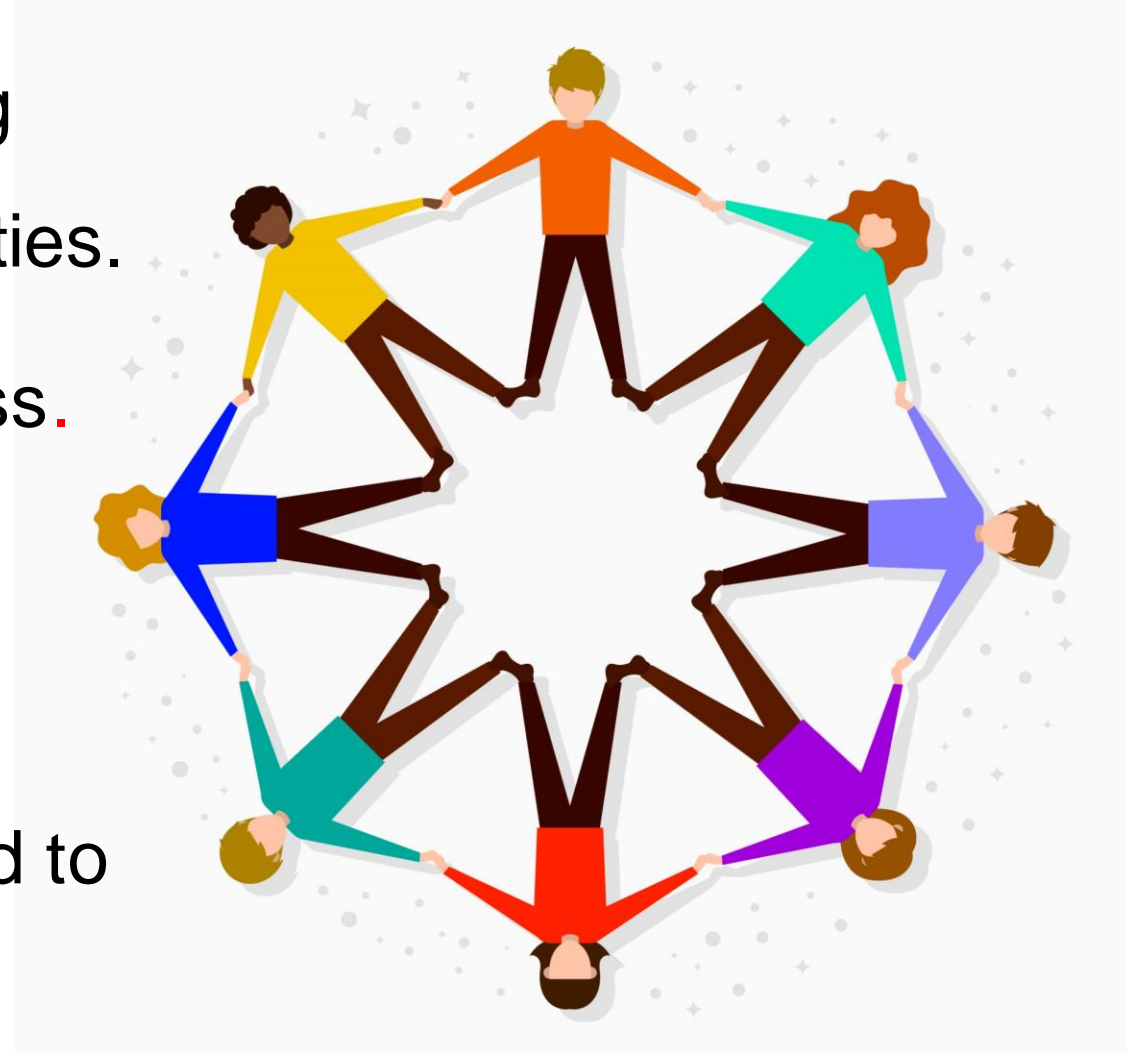
- Recognizes community as a unit of identity.
- Builds on the strengths and resources of the community.
- Facilitates collaborative partnerships in all phases of research.
- Integrates knowledge and action for mutual benefit of all partners.



- **Sweat equity, time, credibility, trust**
- **Meaningful URP inclusion, engagement, and characterization**
- **Institutional support of faculty/investigators/team members**

CI-CER Key Principles, Continued

- 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.



Why is CI-CER Important for AD Research?

Impact of CI-CER in AD research

- ADNI3 Diversity Taskforce found “...initial evidence supporting a culturally informed community-engaged approach for increasing inclusion of Black and Latinx older adults in Alzheimer disease cohort studies.”^{1,2}
- A systematic review of AD studies offered some support for improved representation of URPs with community outreach efforts, however, more research is needed.³
- **Takeaway for CLARiTI:** CI-CER approach is an important evidence-based approach for URP inclusion, though more study is needed to inform best practices.



¹Okonkwo*, Rivera Mindt*, Ashford* et al., 2024 (*Co-First Authors)

²Rivera Mindt et al., 2024

³Gilmore-Bykovskyi et al., 2019



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CI-CER Approach in CLARiTI

- **Guidance from the Community-Science Partnership Board (CSPB)**
- **Culturally Competent Research Team**
 - Community Research Liaisons (CRLs)
 - Community Research Navigators (CRNs)
- **Culturally-Informed Outreach Materials**
- **Community Outreach Funds**
- **Ongoing CI-CER Support for Sites**



Community-Science Partnership Board (CSPB)

- **Goal**: To work together in partnership as scientists and community members, to develop strategies, based on the preferences, priorities and voices of community members with cultural humility at the forefront of decision making.
- **CLARiTI CSPB**
 - 12 members: Community members + scientists
 - Meets quarterly
- **First meeting was held 9/9/24!**



Community Research Liaisons (CRLs)

- **Boots on the Ground:** CRLs provide in-person engagement.
- **“Study Buddy”:** Support URP visits; meet participants “at the curb” to welcome them to the study and help them navigate study visits.
- **The Give:** Work centered on the “give” to community members & organizations.
- **Promote *Inclusion*:** Support community partnerships & liaise with community clinicians, community-based organizations (CBOs), and community members.
- **Coordinate:** Local inclusion/engagement events/efforts with local ADRC leadership & ORE Core team.
- **Participate** in community events!



Community Research Navigators (CRNs)

- CRNs are a part of Inclusion Core team and will virtually engage with staff at each Center.
- Guide and support the community engagement work of CRLs, based on CI-CER principles.
- Act as a knowledge-sharing resource for CRLs and local center staff.
- Additional roles as determined (in collaboration with your ORE Core).



Culturally-Informed Outreach Materials

- Culturally-informed materials will be produced in collaboration with a Latina-owned marketing agency, including:
 - Facebook (*Meta*) ads.
 - CLARiTI pamphlets and brochures.
- CLARiTI Community Science Partnership Board (CSPB) will review and inform **all** outreach materials.



Community Outreach Funds

- **\$10k/year to support community outreach**
- **Funds can be used for:**
 - Building relationships with local Community-Based Organizations.
 - Community outreach events.
 - Advisory boards/councils- stipends or meeting expenses.
 - Participant appreciation initiatives, swag and gifts.
 - Local printing and advertising expenses.
 - We welcome other uses of this outreach funding!



Ongoing CI-CER Support

- **Bi-annual training webinars** on CI-CER for CLARiTI staff
- **Presentations** at Spring and Fall ADRC meetings
- **Collaboration** with ORE Core Steering Committee
- **Repository** of resources and training materials for enhancing CI-CER practices
- **Certification & ongoing training** on CI-CER methods for CRLs
- **Additional CI-CER support** at the request of Centers

Notes. **CI-CER** = Culturally Informed Community Engaged Research; CRL = Community Research Liaison





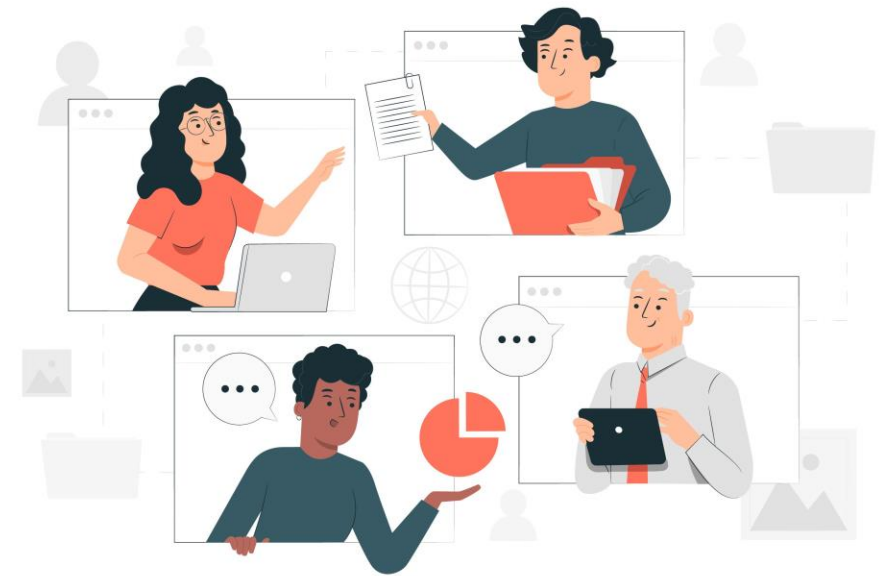
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Next Steps: Inclusion Core Onboarding Calls

- Inclusion Core will hold *brief* onboarding calls with each site within 6 weeks of their CAT Site Initiation Visit.
- **Purpose:** Provide sites with information about Inclusion Core's resources and establish collaborative consultation.
- **Content:** Onboarding calls will discuss:
 - Site inclusion goals
 - Site readiness
 - Inclusion Core's resources and support services
- **Attendees:** Calls will be held with each Site's CLARiTI PI, ORE Core leader, study coordinator, and Community Research Liaison (CRL, if applicable).



Key Take Aways for Moving Forward

- **Sustained community engagement** will be crucial for CLARiTI to meet inclusion and engagement goals.
- **Inclusion Core will work directly with Centers** to support their inclusive outreach and engagement strategies.
- **Outcomes of CRL work will be tracked and engagement metrics disseminated** so that Centers can understand the impact of this work and its potential utility in other projects.





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Thank you!

*

¡Muchas Gracias!



Questions or Comments?

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