CLARiTI

ADRC Consortium for Clarity in ADRD Research Through Imaging

NACC Spring Meeting
CLARiTI Breakout Session
May 6, 2024

Agenda

Welcome – Sterling Johnson, PhD

- Site start up survey results

Updates and Resources from the CLARiTI Inclusion Core

- Inclusion survey results
- Discussion with ORE Core representatives

Disclosure Core

- Review of survey results
- Sharing practices across ADRC's
- Return of PET research results
- Visual Interpretation: what to expect
- Discussion

Closing - Beth Mormino, PhD

Study Aims

mPI team: Johnson, Mormino, Foroud, Rabinovici, Okonkwo, Rivera Mindt, Dickerson, Wolk, Kukull

SYNOPSIS

Vision: Accurate and comprehensive biologic diagnoses and staging to treat the multiple intersecting causes of cognitive impairment within ADRD

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 with risk factors
- Diverse representation for generalizable science
- Two time points [2-3 years apart]
- *Heterogeneity* is the focus: syndromes and multi-pathologies

CLARiTI

Component Lead Investigators (partial list of 47 investigators)

Johnson/Mormino/Biber: Admin
Rivera-Mindt/Okonkwo: Inclusion
Biber/Kukull/Toga: Image-Data informatics
Keene: Neuropath
Rabinovici: PET image reads
Shibata: MRI scoring

Rahman-Filipiak/Clark/Chin: Disclosure
Rosen/Thompson: neuropath MRI templates; AI classification
Jagust/Jack: SCAN
Villemagne: PET harmonization
Detre: Advanced MRI methods
Dage/Foroud: Biofluid mgmnt, assays

Donohue: Stats
Betthauser: Biomarker time
Jones: FDG analysis
Hohman: Data harmonization integration
Kantarci: LBD image analysis

Industry collaborators

- LMI
- Lantheus/Cerveau
- Enigma
- Lilly
- Flywheel
- GE
- Siemens
- Philips

Site start up survey results

Recruitment goals vs. CLARiTI budget

- Sites are able to enroll a total of **3,218 participants** for CLARiTI
- CLARiTI's funding will cover the enrollment of 2,000 participants
- Capacity to meet both CLARiTI and P30 requirement

CLARiTI supporting P30 obligation

- **24 sites** reported that they want CLARiTI to explore/arrange additional radioligand access in support of their P30 required ATN obligation

Flortaucipir (FTP) and Florbetapir (FBP)

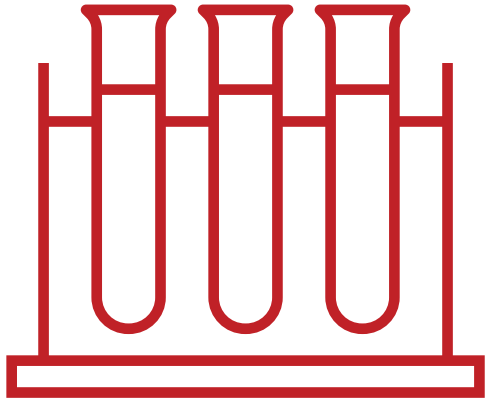
- Lilly has agreed to provide us with a number of free doses
  - 40% free doses
  - 60% commercial rate

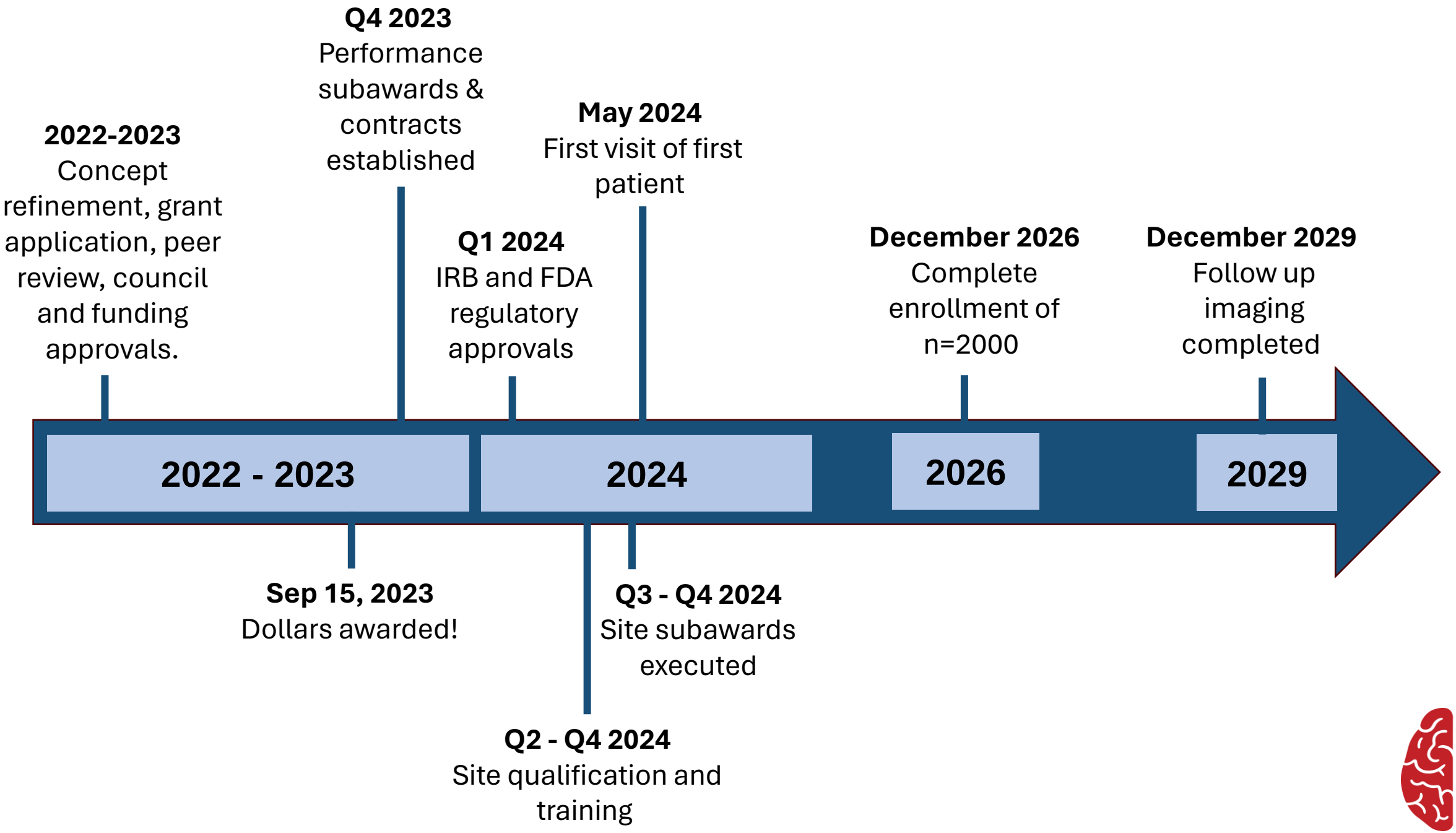
- Based on the site survey, free doses of FTP/FBP will be expended within the first year

- Subsequent doses will be charged at commercial rate of ~ $3,800/dose
  - Budgeted for $2,500/dose

Blood Collection

- **25/37 ADRC's** are collecting blood using the NCRAD ADCFB protocol
- Some sites commented they need to take **participant burden** into consideration
- **30mL** is ideal and requested
- Minimum accepted will be 10mL
- Blood is important for future assays
  - Ptau217, ab42/40, GFAP, NfL
  - TDP43
  - Alpha-synuclein
  - Other TBD assays
- **Dried blood spots are in our future**




2022-2023
Concept refinement, grant application, peer review, council and funding approvals.
Q4 2023
Performance subawards & contracts established
Q1 2024
IRB and FDA regulatory approvals
May 2024
First visit of first patient
December 2026
Complete enrollment of n=2000
December 2029
Follow up imaging completed
2022 - 2023
2024
2026
2029
Sep 15, 2023
Dollars awarded!
Q2 - Q4 2024
Site qualification and training
Q3 - Q4 2024
Site subawards executed

CLARiTI

ADRC Consortium for Clarity in ADRD Research Through Imaging

Updates and Resources from the CLARiTI Inclusion Core

Monday, May 6, 2024

CLARiTI Inclusion Core

- **CLARiTI Inclusion & Engagement Plans**
- Results from Inclusion Core Site Survey
- Inclusion Core FAQs and resources
- Questions/Comments?

Inclusion Core Mission

Ensure the inclusion/engagement of persons from Underrepresented Populations 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 (URPs, ≥ 25%) in CLARiTI

Milestone 2

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

Inclusion Core Team

Dr. Mónica 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

Alexander Robateau, MA
Study Coordinator, Mount Sinai

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

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

- Cultural competence/CER training for all CLARiTI team members

Inclusion Core Team

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

CER = Community-engaged Research

Milestone 1: URP Inclusion

- **Purpose**: Ensure the inclusion and engagement (≥ 25%) of participants from Underrepresented Populations (URPs):
  - Ethnoculturally minoritized groups
  - Low socioeconomic status (SES) (≤12 years education)
  - Individuals dwelling in rural areas

- **Inclusion Core will offer:**
  - Support for local Community Research Liaisons (CRLs)
  - Centralized Community Research Navigators (CRNs)
  - Funding for community support - up to $10k/year
  - Tailored inclusion and engagement materials
  - **Community-Scientific Partnership Board (CSPB)**

Community Research Liaison (CRL)

- Boots on the ground, in-person engagement
- Work centered on the “give” to community members & organizations
- 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

Community Research Navigator (CRN)

- Virtual engagement with centralized team members
- Work centered on the “give” to sites & participants
- Promotes pt. *engagement* (retention & task completion)
- Supports ADRC coordinators with participants’ engagement in the CLARiTI protocol
- Additional roles as determined (in collaboration with your ORE Core)

Milestone 2: Site and Core Collaboration

- **Purpose**: The Inclusion Core will partner with participating ADRCs to support their success with CLARiTI protocol. Please let us know how we can help your site!

- **Inclusion Core will offer:**
  - Training and supporting materials for CLARiTI team members (e.g., CRLs)
  - Ongoing partnership and consultation with ORE & Disclosure Cores
  - Access to resources on Community-Engaged Research (CER)
  - Monitoring and troubleshooting of inclusion efforts throughout project

Partnership with ADRC ORE Cores

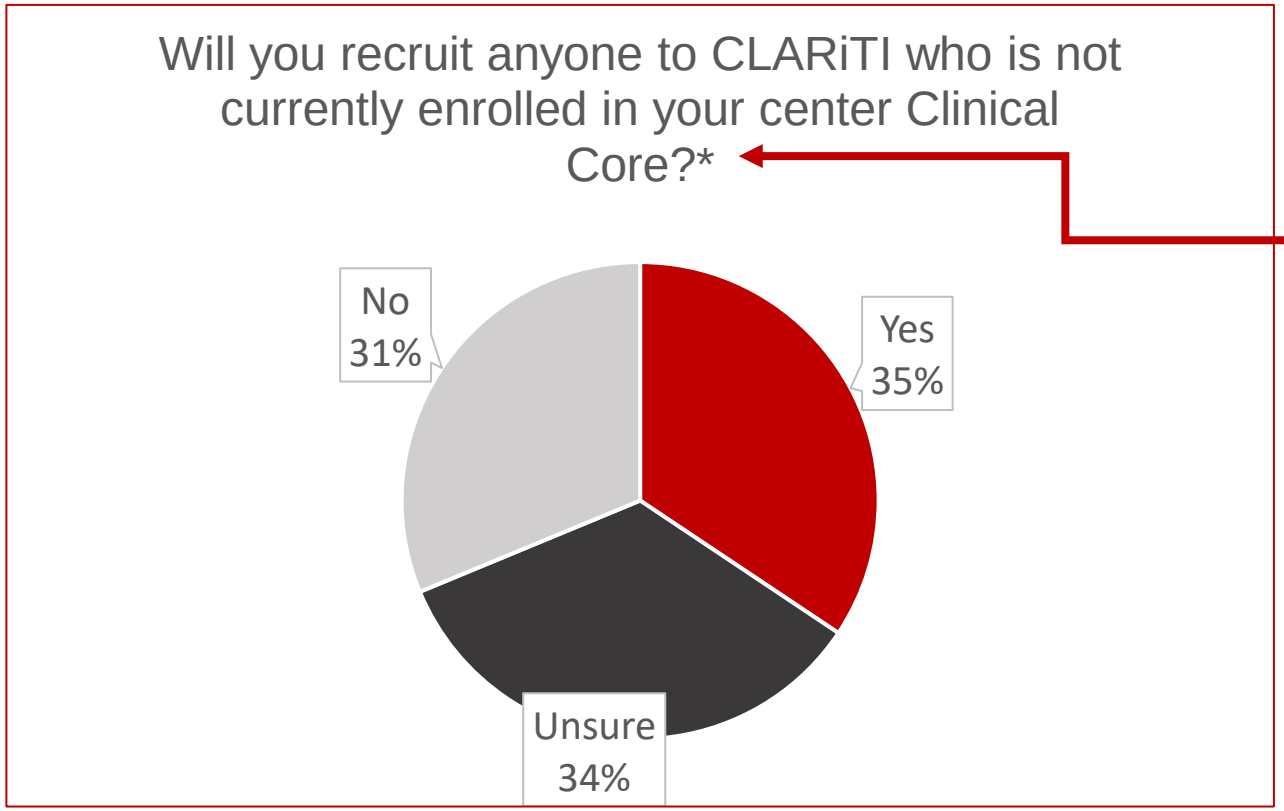
- **The success of the CLARiTI Inclusion mandate (≥25% URPs) requires close collaboration between the Inclusion Core and ADRC ORE Cores:**
  - Onboarding sessions and regular check-ins between IC and ORE Core staff
  - Consultation with ORE Core as needed to support inclusion and engagement
  - Webinars on CER training for ORE Core and all team members
  - Repository of resources and training materials for enhancing CER practices
  - Regular contact between IC leadership and ORE Core Steering Committee
  - Networking with ORE Core leaders and staff during NACC Directors meetings
  - Inclusion Core Site Survey to understand local procedures and practice

CLARiTI Inclusion Core

- CLARiTI Inclusion & Engagement Plans
- **Results from Inclusion Core Site Survey**
- Inclusion Core FAQs and resources
- Questions/Comments?

Inclusion Core Survey Results

- Survey distributed to site PIs and ORE Core leadership March 2024
- 32 sites responded



*Reminder: CLARiTI participants must be enrolled in your site Clinical Core and have a NACCID. However, you may wish to replenish your Clinical Core or increase URP representation. To do this, you may recruit CLARiTI participants from the community who are new to AD research at your center. They would need to enroll into the Clinical Core first and could then enroll into CLARiTI

Barriers to URP Inclusion

- **Participant Reluctance** towards study procedures
- **Scheduling Challenges**: Finding times that work for pts, lack of appointments outside regular working hours
- **Participant Burden**, particularly with transportation

"The most significant barrier will be convincing older adults and their adult children that blood draws, MRI, and PET scans are safe and necessary."

Facilitators for URP Inclusion

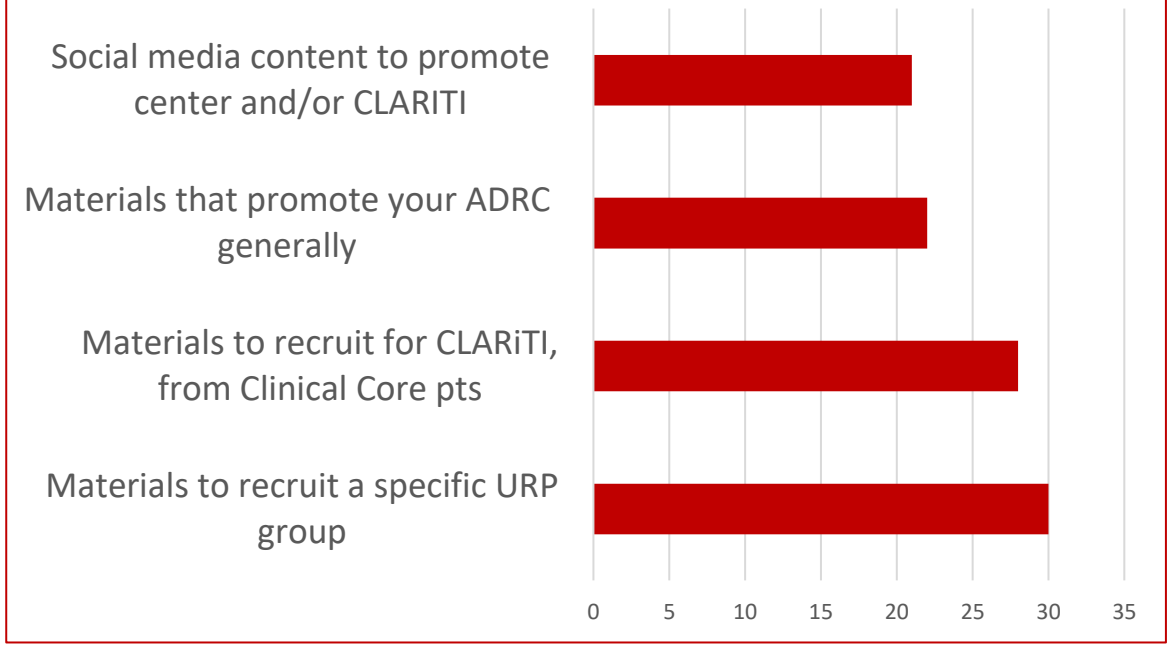
- **Significant Site Expertise:** Running community events and educational outreach
- **Successful partnerships** with local and national organizations
- **Ensuring that study staff reflect URPs**, hiring from the community

"We have found that a constant presence in the community to provide education, outreach, and support has aided in retention of all participants, but especially our URG participants."

Inclusion Core Survey Results

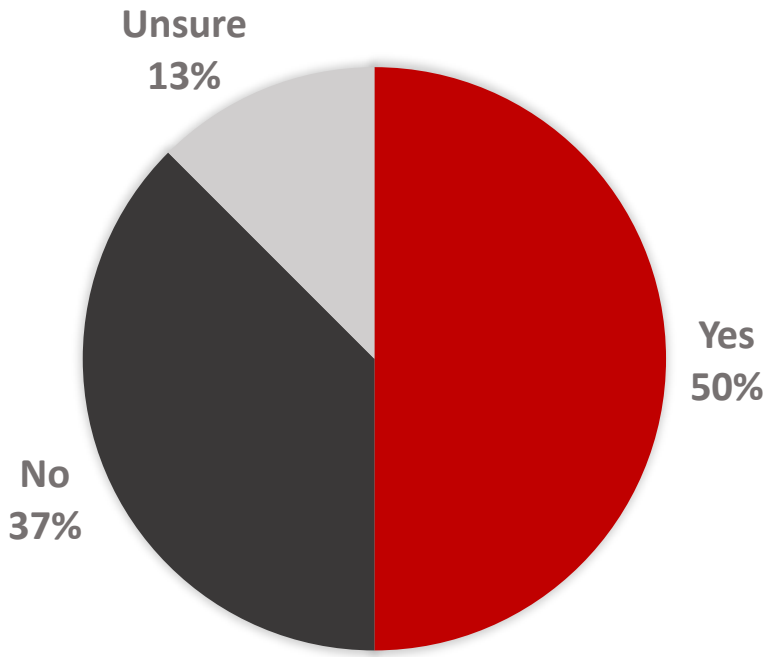
Which community engaged research training topics would be most relevant to your site?

What kind of marketing materials would be useful for your site?



Inclusion Core Survey Results

Does your center have the capacity to enroll Spanish speaking participants?



- 16/32 sites have capacity to enroll Spanish-speaking participants
- 12 sites have a bilingual neuropsychologist on staff
- 15 sites have a bilingual psychometrist on staff
- All 16 sites conduct Spanish language evaluations

CLARiTI Inclusion Core

- CLARiTI Inclusion & Engagement Plans
- Results from Inclusion Core Site Survey
- **Inclusion Core FAQs and resources**
- Questions/Comments?

Inclusion Core FAQs and Resources

- ***How will inclusion be monitored during the study?***
  - A study dashboard is being developed by NACC allowing ADRCs to view site and study-wide performance on inclusion metrics. More information to come

- ***How can I learn more about CLARiTI Inclusion plans?***
  - Please consider viewing a webinar on this topic given 3/27/24

- ***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

Thank you!

*

¡Muchas Gracias!

Questions or Comments?

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

Discussion

CLARiTI

ADRC Consortium for Clarity in ADRD Research Through Imaging

Current Disclosure Practices Across the ADRC Network

Annalise Rahman-Filipiak, PhD
Disclosure Core

NACC Spring Meeting 2024

CLARiTI Disclosure Core

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Lindsay Clark, PhD
Assistant Professor
Wisconsin ADRC

Nathaniel Chin, MD
Assistant Professor
Wisconsin ADRC

Neelum Aggarwal, MD
Professor
Rush ADRC

Brad Dickerson, MD
Professor
Harvard ADRC

Haley Kohl, BS
Disclosure Core Coordinator
Michigan ADRC

Jon Reader, MA
Disclosure Core Data Manager
Michigan ADRC

CLARiTI Disclosure Timeline

Year 1

- Draft Disclosure Protocol & Toolkit
- Survey all sites on current disclosure practices
- Consult with and pilot Disclosure Toolkit @ 5 sites
- Use pilot site + Inclusion Core feedback to update Disclosure Protocol & Toolkit

Year 2

- Develop Disclosure training materials & certification program
- Final Disclosure Protocol & Toolkit available via NACC

Year 3

Year 4

- In-Person & Virtual Disclosure Trainings (~ADRC Meeting?)
  - Evaluate effectiveness of training program
- Update Protocol & Toolkit based on preliminary feedback
- Evaluate post-disclosure outcomes data

Year 5

Purpose

- To evaluate **current interest and engagement** in return of individual research results across participating CLARiTI sites;
- To understand **infrastructure** for and **barriers** to disclosure implementation;
- To **collate disclosure practices and resources** across sites;
- To identify sites interested in participating as **pilot sites** for the Disclosure Toolkit

Methods

- Survey developed by the Disclosure Consultation Team (DCT) based on prior surveys (Roberts et al., 2021) and existing disclosure protocols.
- Surveys sent by NACC to participating sites between 01/15/2024 and 04/08/2024.
- Responses received from 37/37 sites ***(100% response rate!)***
  - *1 response invalid

Disclosure Progress: Comparing 2019 vs. 2024

	Type of participant			
	Dementia or MCI		Normal Cognition or SMC	
Type of information	**Roberts Survey 2019**	**CLARiTI Survey 2024**	**Roberts Survey 2019**	**CLARiTI Survey 2024**
Consensus research diagnosis	25 (83%)	**27 (75%)**	23 (77%)	25 (69%)
Neuropsychological test results	22 (73%)	27 (75%)	21 (70%)	25 (69%)
Amyloid PET results	13 (43%)	17 (47%)	8 (27%)	**16 (44%)**
MRI results	12 (40%)	**21 (58%)**	10 (33%)	**22 (61%)**
FDG PET results	8 (27%)	**6 (17%)**	6 (20%)	**4 (11%)**
Genetic test results, not APOE*	4 (13%)	**2 (6%)**	3 (10%)	2 (6%)
Tau imaging results	3 (10%)	**6 (17%)**	2 (7%)	**4 (11%)**
CSF biomarker results	3 (10%)	**8 (22%)**	1 (3%)	**5 (14%)**
APOE genetic test results	2 (7%)	**5 (14%)**	2 (7%)	**5 (14%)**

* Indicated in present survey as "Other"

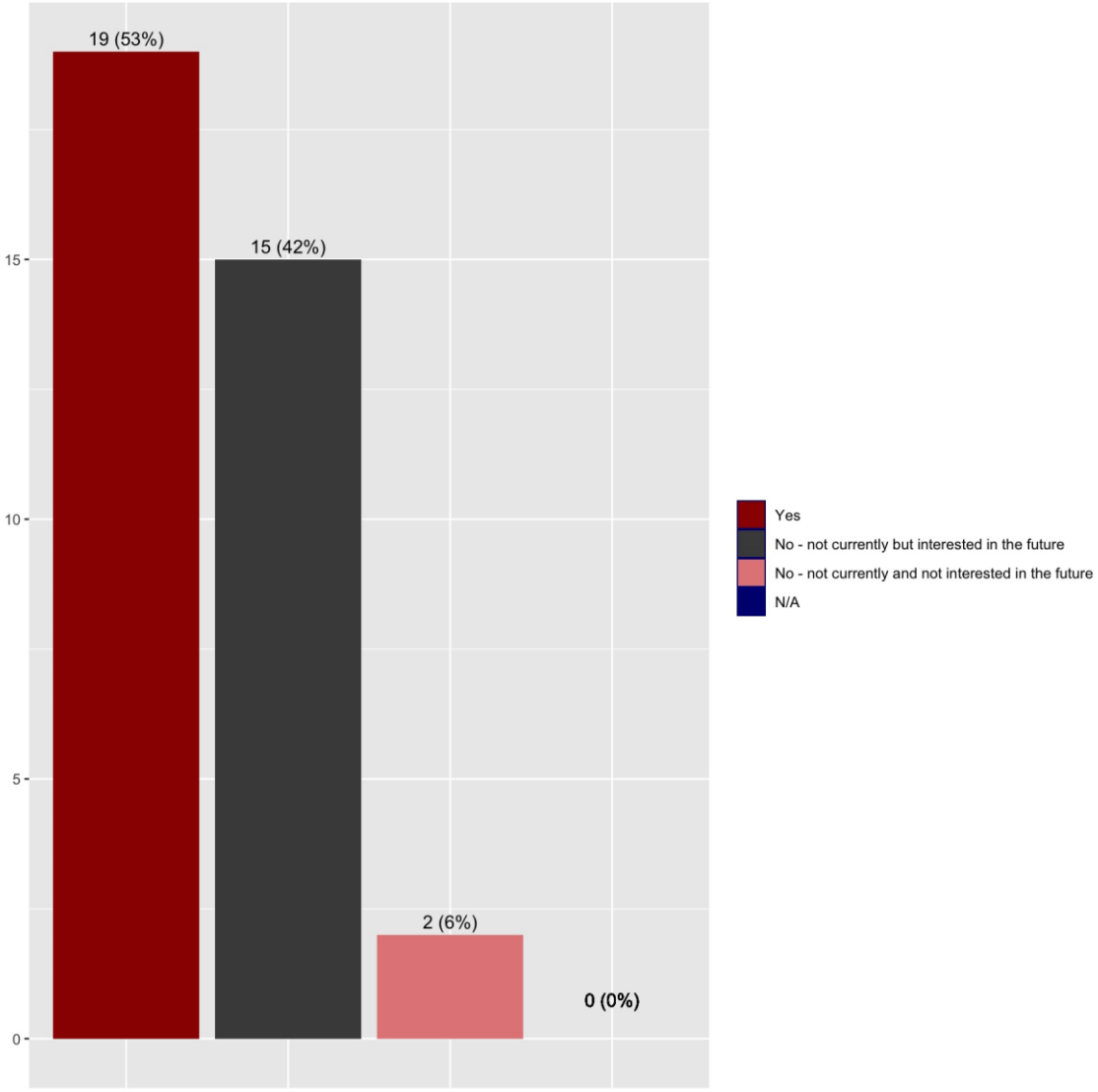
Roberts et al., 2021 N = 30

Present survey N = 36

≥ 5% increase Consistent with 2021 **≥ 5% decrease**

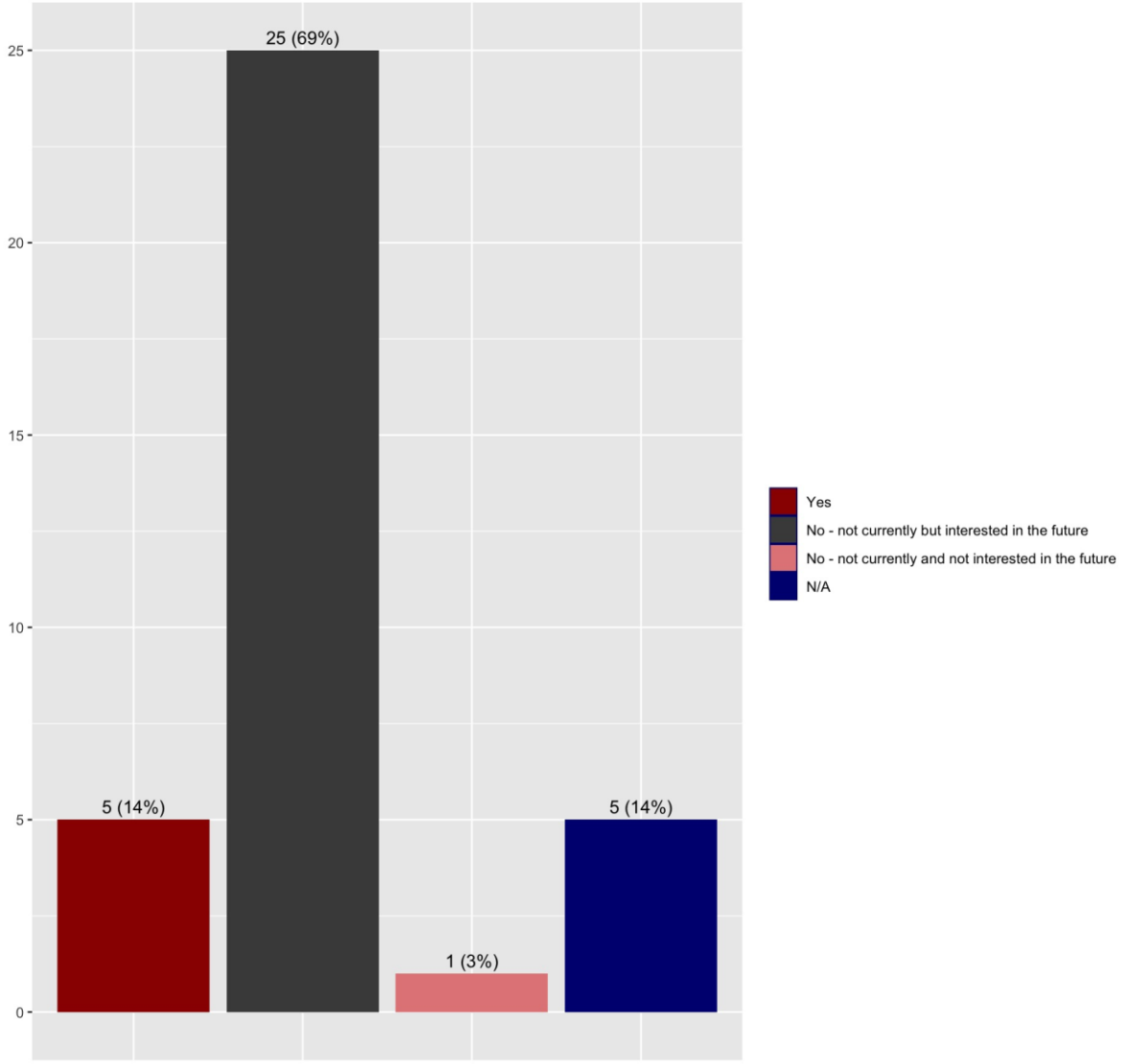
Roberts et al. (2021) A&D: TRCI

Interest/Engagement in Returning Amyloid PET Results



- **53% currently returning amyloid PET**
- 42% interested in the future.
- Of the 19 sites who disclose, 11 disclose routinely and 8 disclose sometimes.

Interest/Engagement in Returning Tau PET Results



- **5* sites (14%) already returning tau PET.**
- 69% interested in the future.
- Of the 6* sites who disclose, none disclose regularly (4 sometimes, 2 rarely).

PET Disclosure By Clinical Phenotype

With whom do you currently share results (assuming consent/assent)?

	Amyloid-Disclosing Sites (*n*=19) # (%)	Tau-Disclosing Sites (*n*=6) # (%)
Dementia	16 (84.2%)	6 (100.0%)
MCI	17 (89.5%)	6 (100.0%)
Subjective Cognitive Decline	13 (68.4%)	4 (66.7%)
Cognitively Normal	16 (84.2%)	4 (66.7%)

- Results are shared with participants and family/friends; shared with providers ~50% of the time

Returning PET Results: Session Format

Mode of Returning Results	Amyloid-Disclosing Sites (*n*=19) # (%)	Tau-Disclosing Sites (*n*=6) # (%)
In-Person	13 (68%)	5 (83%)
Phone	10 (53%)	2 (33%)
Zoom	9 (47%)	4 (67%)
Mailed Letter or Report	4 (21%)	1 (17%)
Email	0 (0%)	0 (0%)
Electronic Health Record	4 (21%)	0 (0%)

- Most sites report that PET feedback takes <30 minutes
- Physicians and advanced practice providers most frequently provide feedback; neuropsychologists, social workers, and trainees may also be involved.

Elements of Disclosure Visits

Disclosure Element	Amyloid Disclosing Sites (*n*=19) # (%)	Tau Disclosing Sites (*n*=6) #(%)
Pre-Disclosure Education	14 (74%)	3 (50.0%)
Summary Report	10 (53%)	3 (50.0%)
Visual aids/Images of Result (slices)	5 (26%)	2 (33%)
Recommendations/Action Steps	17 (90%)	5 (83%)
Clinical Referral	13 (68%)	3 (50%)

- Separate consent often used

Maps onto NACC Best Practice Guidelines for Biomarker Disclosure:
https://files.alz.washington.edu/best-practices/biomarker-disclosure.pdf

Returning PET Results: Result Format

	Amyloid-Disclosing Sites (*n*=19) # (%)	Tau-Disclosing Sites (*n*=6) # (%)
Quantitative Data	3 (16%)	1 (17%)
Categorized/Labeled Data	18 (95%)	4 (67%)
Personalized Risk Estimates Incorporating Results	1 (5%)	0 (0%)
Other	2 (11%)	3 (50%)

- PET Results are most frequently given an interpretive label (e.g., “Elevated” vs. “Not Elevated”)
- Few sites disclose raw/quantitative data or personalized risk estimates
- Other: participants’ scan images

Reasons to Return PET Results

Reason for Disclosure	Amyloid-Disclosing Sites (*n*=19) #(%)	Tau-Disclosing Sites (*n*=6) #(%)
Participant or Family Requested Results	17 (89%)	6 (100%)
Participant's Physician Requested Results	10 (53%)	2 (33%)
Inform Participant's Healthcare or Medical Decision-Making	15 (79%)	3 (50%)
Thanking Participants for Their Contribution to Research	17 (89%)	4 (67%)
Retention of Participants in Research	17 (89%)	4 (67%)
Ongoing Disclosure-Specific Study	11 (58%)	2 (33%)

Reasons NOT to Return PET Results

Reason not to Disclose	Sites Not Disclosing Amyloid (*n*=17) #(%)	Sites Not Disclosing Tau (n=30) #(%)
Information not Useful/Actionable	3 (16%)	5 (17%)
Financial Burdens	2 (11%)	3 (10%)
Time Burdens for Staff	4 (21%)	6 (20%)
Personnel Shortage	3 (16%)	6 (20%)
Participants Not Interested	0 (0%)	0 (0%)
Lack of Expertise in Disclosing Results	5 (26%)	5 (17%)
Not Part of Original Study (or in Consent)	11 (58%)	11 (37%)
Results Do Not Meet Clinical Regulations	3 (16%)	8 (27%)
Potential for Unintended Harms to Participants	6 (32%)	7 (23%)
Concerns About Legal Liability	2 (11%)	2 (7%)
Other	6 (32%)	4 (13%)

Additional Disclosure Barriers

- Exploratory compounds that are not FDA approved and/or without established cutoffs
- Lack of radiologic read
- Tau collected as part of a specific subpopulation (e.g., CTE in AD); concerns about validity of cutoffs/meaning of result
- Lack of resources, time, and pathways for clinical follow-up for distressed participants

Survey Limitations

- N/A variable – unclear if not currently collecting these data, or other reason
- Unclear whether sites conducting disclosure are doing so as part of ancillary study (e.g., LEADS) versus longitudinal cohort.

Future Directions

- Pilot site selection & consultations
- Develop disclosure training materials & certification program
- Final Disclosure Protocol & Toolkit available via NACC – YEAR 2

Acknowledgements

- **Thank you to:**
  - Teams who took time to respond to our many CLARiTI surveys!

  - Jon Reader (CLARiTI Disclosure Core Data Analyst)
  - Erin Chin (CLARiTI)
  - Brittany Hale & Heather O’Connell (NACC)

CLARiTI

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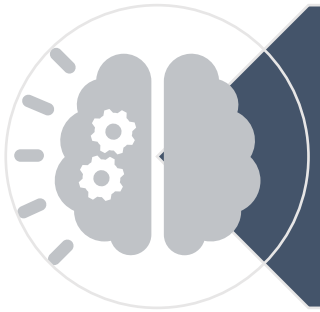
Disclosure Core Introduction and Goals

Lindsay Clark, PhD
Disclosure Core
NACC Spring Meeting 2024

Disclosure Core Goals



Develop and adapt a flexible biomarker disclosure toolkit

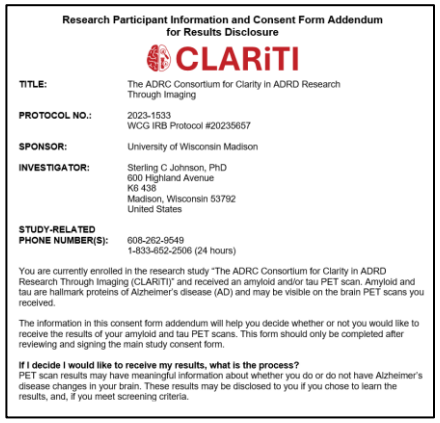
Develop training resources and materials

Investigate disclosure feasibility, safety, and satisfaction

Flexible biomarker disclosure toolkit

- If sites already have return of results processes, can continue to use those processes for CLARiTI participants
- **For sites who do not currently return biomarker results, or want to supplement current processes:**

Consent form language



Research Participant Information and Consent Form Addendum for Results Disclosure

CLARiTI

TITLE: The ADRC Consortium for Clarity in ADRD Research Through Imaging

PROTOCOL NO.: 2023-1533
WCG IRB Protocol #20235657

SPONSOR: University of Wisconsin Madison

INVESTIGATOR: Sterling C Johnson, PhD
600 Highland Avenue
K6 438
Madison, Wisconsin 53792
United States

STUDY-RELATED PHONE NUMBER(S): 608-262-9549
1-833-652-2506 (24 hours)

You are currently enrolled in the research study "The ADRC Consortium for Clarity in ADRD Research Through Imaging (CLARITI)" and received an amyloid and/or tau PET scan. Amyloid and tau are hallmark proteins of Alzheimer's disease (AD) and may be visible on the brain PET scans you received.

The information in this consent form addendum will help you decide whether or not you would like to receive the results of your amyloid and tau PET scans. This form should only be completed after reviewing and signing the main study consent form.

If I decide I would like to receive my results, what is the process?
PET scan results may have meaningful information about whether you do or do not have Alzheimer's disease changes in your brain. These results may be disclosed to you if you chose to learn the results, and, if you meet screening criteria.

Educational materials

What You Need to Know about Amyloid PET Results

A guide for research participants

For people with mild cognitive impairment or dementia

What does an "elevated" or "positive" test result mean?

- An elevated test result means the scan detected amyloid plaques in your brain.
- An elevated test result cannot definitively confirm or diagnose the cause of your cognitive impairment; however, it does support the likelihood that Alzheimer's disease is a cause.
- If you have mild cognitive impairment, you have an increased risk for developing dementia due to Alzheimer's disease. It does not mean you will definitely develop dementia from Alzheimer's disease.

What does a "non-elevated" or "negative" test result mean?

- A non-elevated test result means the scan did not detect amyloid plaques in your brain. This result means brain changes indicative of Alzheimer's disease were not detected.
- It is possible that amyloid plaques are present but not at an elevated level.
- An individual may still develop elevated amyloid or dementia due to Alzheimer's disease in the future.
- A non-elevated result does not change the fact that you have mild cognitive impairment or dementia; it does mean that the cause is likely something other than Alzheimer's disease.

For people who are cognitively unimpaired

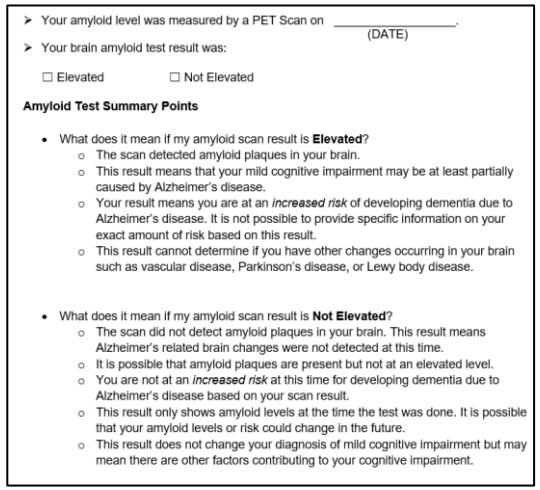
What does an "elevated" test result mean?

- An elevated test result means the scan detected amyloid plaques in your brain and therefore you have one of the protein abnormalities that defines Alzheimer's disease.
- An elevated test result means that you are at higher risk of developing cognitive changes and eventual dementia in the future. However, it does not mean that you definitely will.

What does a "non-elevated" test result mean?

- A non-elevated test result means the scan did not detect amyloid plaques in the brain. This result means brain changes indicative of Alzheimer's disease were not detected.
- It is possible that amyloid plaques are present but not at an elevated level.
- You may still develop amyloid plaques in the future.

Participant result summary report



- Your amyloid level was measured by a PET Scan on _____ (DATE).
- Your brain amyloid test result was:

☐ Elevated ☐ Not Elevated

Amyloid Test Summary Points

- What does it mean if my amyloid scan result is **Elevated**?
  - The scan detected amyloid plaques in your brain.
  - This result means that your mild cognitive impairment may be at least partially caused by Alzheimer's disease.
  - Your result means you are at an *increased risk* of developing dementia due to Alzheimer's disease. It is not possible to provide specific information on your exact amount of risk based on this result.
  - This result cannot determine if you have other changes occurring in your brain such as vascular disease, Parkinson's disease, or Lewy body disease.
- What does it mean if my amyloid scan result is **Not Elevated**?
  - The scan did not detect amyloid plaques in your brain. This result means Alzheimer's related brain changes were not detected at this time.
  - It is possible that amyloid plaques are present but not at an elevated level.
  - You are not at an *increased risk* at this time for developing dementia due to Alzheimer's disease based on your scan result.
  - This result only shows amyloid levels at the time the test was done. It is possible that your amyloid levels or risk could change in the future.
  - This result does not change your diagnosis of mild cognitive impairment but may mean there are other factors contributing to your cognitive impairment.

Staff training manual

Forms/Scripts

- ✓ Assessing readiness
- ✓ Conducting disclosure visits
- ✓ Resources for next steps

Disclosure toolkit development

- Develop and test with pilot sites
- Collaborate with Inclusion Core for participant input
- Finalize toolkit and disseminate through NACC
- Add tau PET disclosure materials once available
- Update toolkit materials based on preliminary feedback

Biomarker Disclosure Process

Before	Return of Results	After
Pre-test education and informed consent Assess for readiness (reason for learning result, brief psychological screening, answer questions)	Assess what person knows about AD and biomarker tests. Confirm readiness to learn results. Return the result (nontechnical words, pauses, verbal and written report of result) Ensure comprehension and assess initial reaction to result Prepare for next steps	Follow-up within a couple of weeks to check-in Possible mental health or research questionnaires

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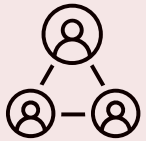
NACC Biomarker Disclosure Guidance: https://files.alz.washington.edu/best-practices/biomarker-disclosure.pdf
Largent et al., 2023 Testing for AD Biomarkers and Disclosing Results Across the Disease Continuum.

Disclosure Core

Training Resources

Training manual

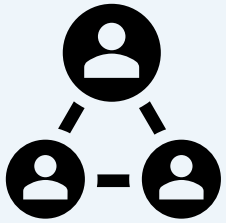
Training sessions
or webinars



Individual
consultation

Evaluate training
effectiveness
and needs

Research outcomes



Feasibility

Safety
Comprehension

Satisfaction

Thank you!

Questions or Comments?

Email us at:
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ADRC Consortium for Clarity in ADRD Research Through Imaging

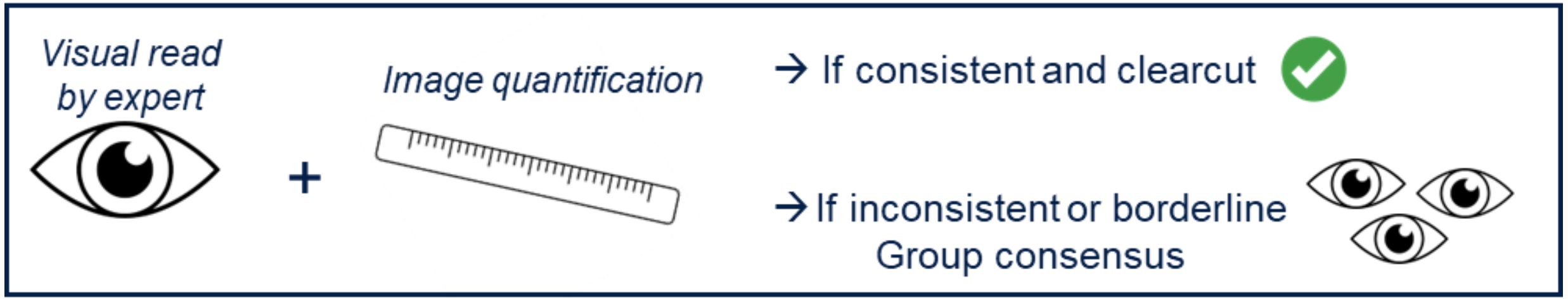
Clinical Read Approach

Gil Rabinovici, MD
UCSF ADRC
Image Reads Core Lead

NACC Spring Meeting 2024

Clinical Read Approach: Amyloid PET

Visual interpretation method developed for LEADS, ADNI-4



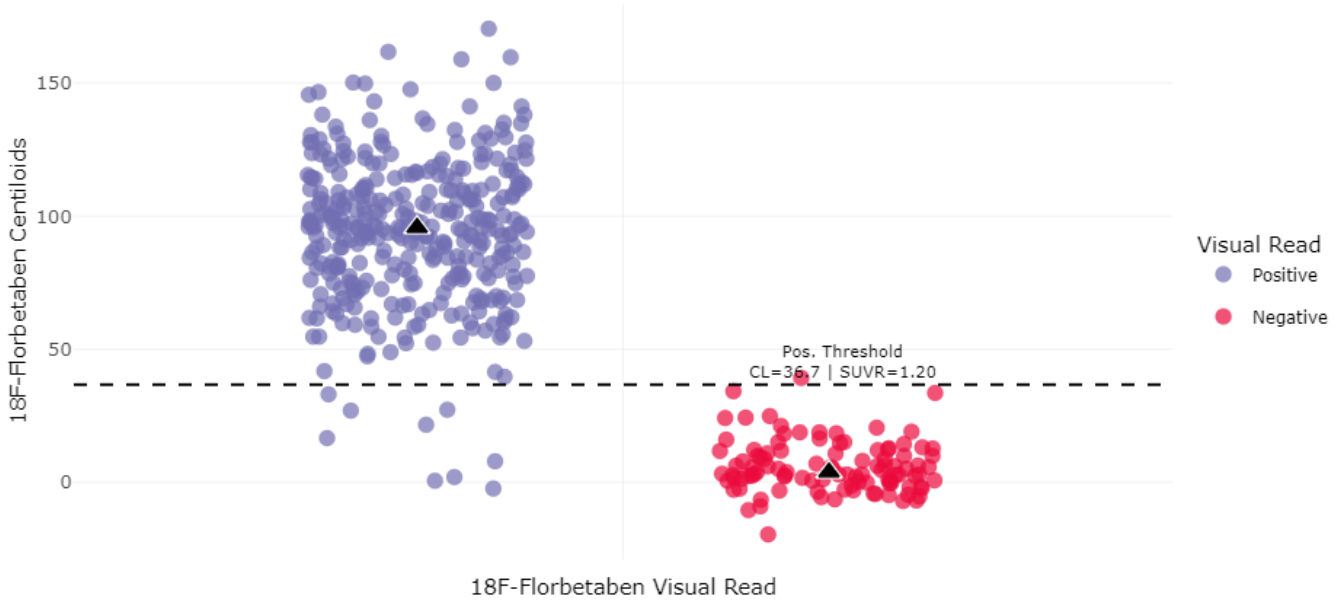
- Visual read based on FDA-approved methodology (when available)
- ADNI tracer-specific SUVR thresholds (18-20 CL)
- Final binary read (elevated/non-elevated)
- Regional pattern
- Additional reader notes

- Developing tau PET read methodology
  - FTP, MK-6240, PI-2620
  - Tau staging conforming to new criteria: MTL only, moderate neocortical, high neocortical

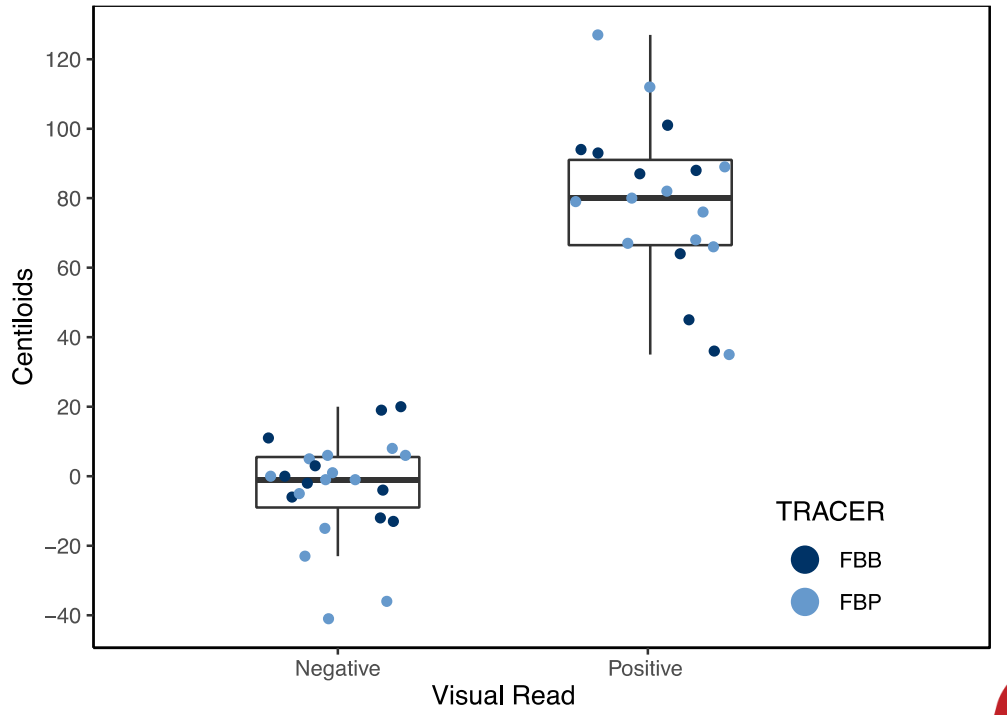
UCSF

Visual Reads vs. Quantification

LEADS, N=467, 96% concordance



ADNI-4, N=42, 98% concordance



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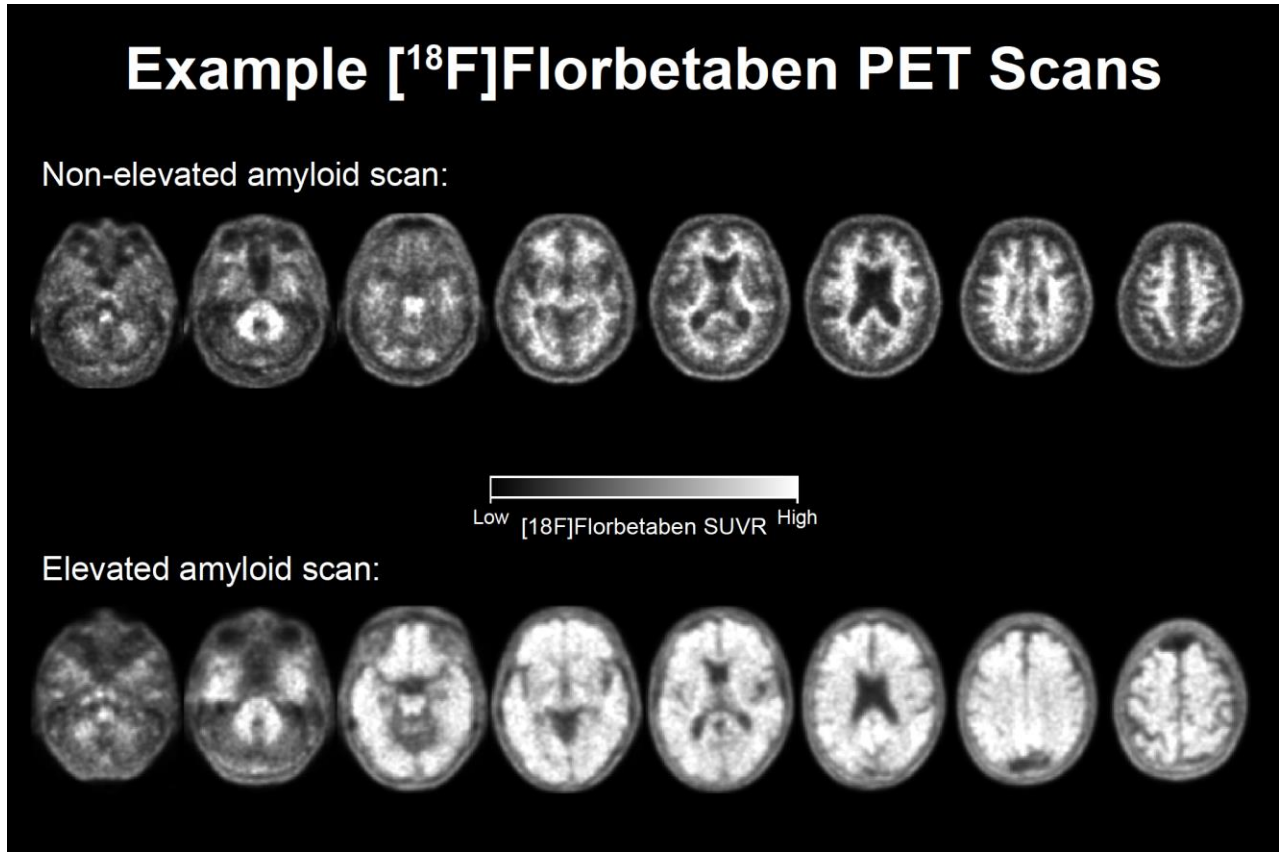
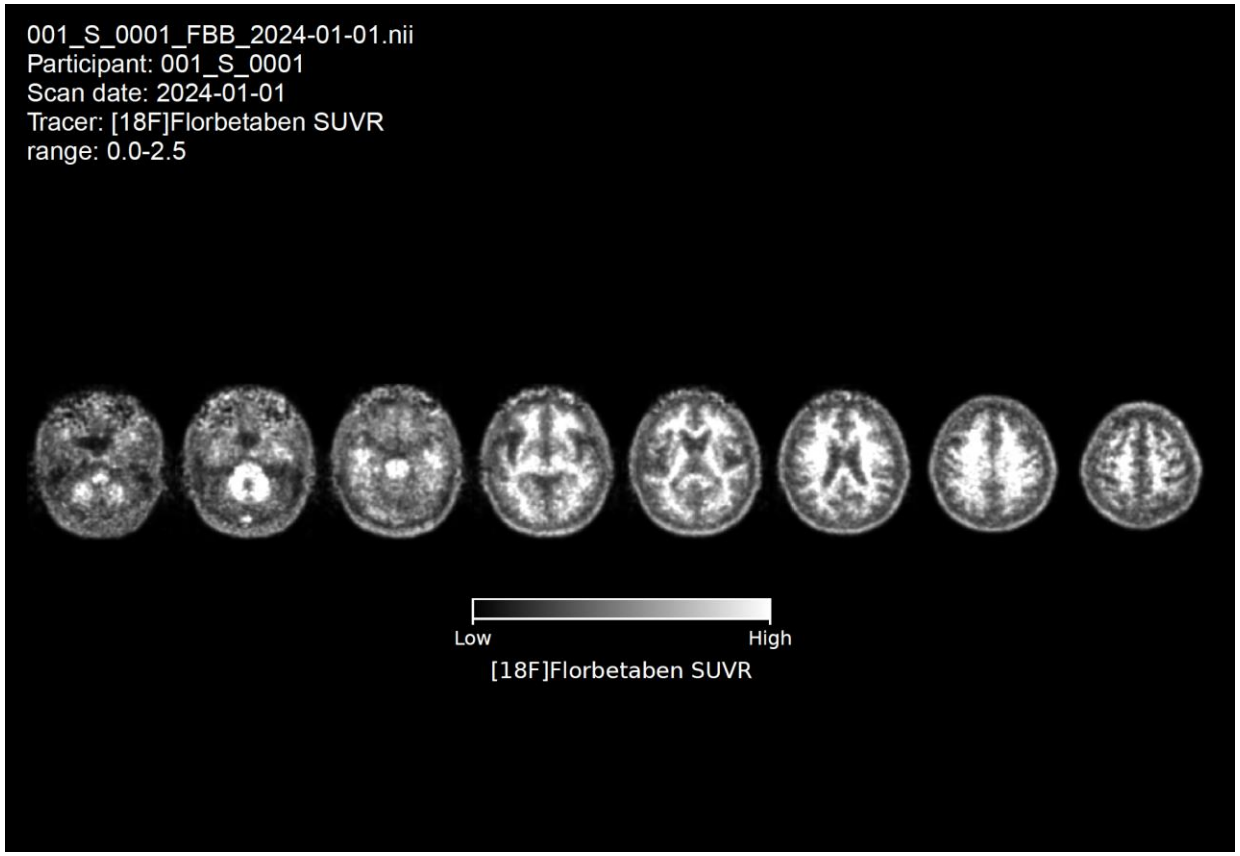
Standardized Image Display



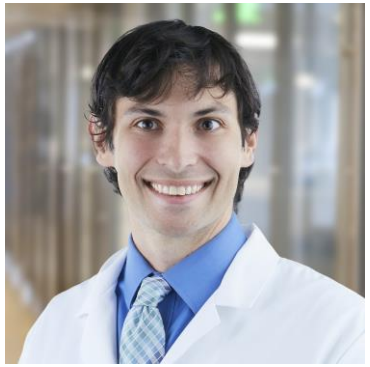


CLARiTI Image Reads Team

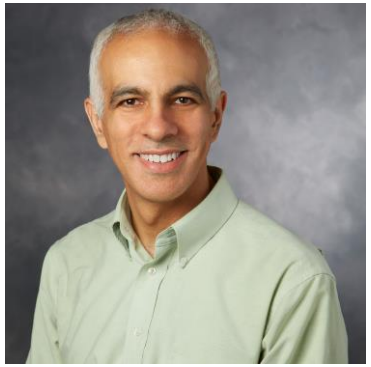
Visual Readers

Gil Rabinovici, MD
UCSF ADRC

David Soleimani-Meigooni, MD
UCSF ADRC



Jeremy Tanner, MD
South Texas ADRC



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Pittsburgh ADRC

Researchers

Ganna Blazhenets, PhD
UCSF ADRC

Zoe Lin
UCSF ADRC

Not pictured: Carol Soppe

Discussion

Announcements

- **Visit us at our booth!**
  - Meet members of the CLARiTI Administration team
- **Next webinar is on June 20, 10 AM CT**
  - Blood & Biomarkers/NCRAD
- **Stay in touch.**
  - Email CLARiTI Administrative Team: clariti@medicine.wisc.edu
  - Email CLARiTI Inclusion Team: clariti-inclusion@medicine.wisc.edu
  - Website: https://naccdata.org/nacc-collaborations/clariti

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Thank you for attending!

scan for breakout session slide deck and resources