CLARiTI CONNECT

December 10, 2024

CLARiTI Connect is a 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 training opportunities. Thank you for connecting!
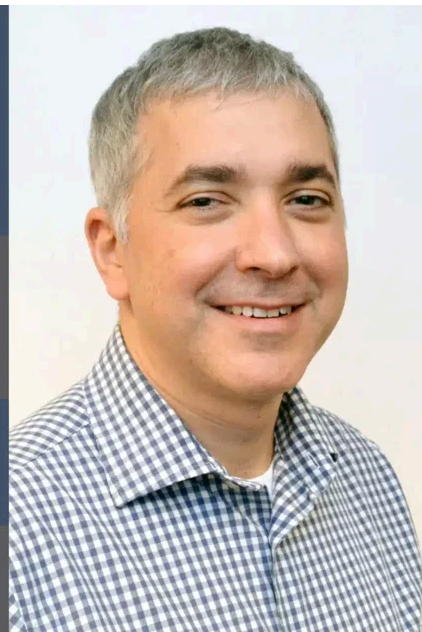
Dr. David Wolk, CLARiTI mPI, Sheds Light on LATE

During his recent presentation at the Wisconsin Alzheimer's Institute (WAI) Annual Update, Dr. Wolk shed light on discoveries around LATE (Limbic-Predominant Age-Related TDP-43 Encephalopathy) and introduced a framework for diagnosing this under-recognized condition. Dr. Wolk and his colleagues have made significant contributions to understanding LATE, a form of dementia characterized by the accumulation of TDP-43 protein in the brain. LATE is both a common mimic of Alzheimer's disease (AD), and also frequently co-occurs with AD, influencing its course and potential response to therapy. These findings emphasize the need for the research that CLARiTI is launching into multi-etiology dementia (MED), which is common but not previously the focus of major cohorts studies and clinical trials, likely slowing the discovery of new treatments. View the video.

Clinical and Imaging Features of LATE: A Diagnostic Framework

David A. Wolk, MD
Professor of Neurology

Penn | Alzheimer's Disease Research Center

Study Start Up Updates

Partial HIPAA Waiver of Authorization

CLARiTI has received approval for a partial waiver of HIPAA Authorization for all participating sites. This waiver covers access to records for subject recruitment and screening participants for enrollment into the study. Please ensure your site has this document listed on a Certificate of Action with WCG. If your site has not yet submitted to WCG, you may reference this already established waiver upon submission. **Please ensure you include this waiver in your regulatory binder.**

<div align="center">

View the Waiver

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Translation of CLARiTI Study Materials

CLARiTI study materials may be translated into other languages. WCG, our single IRB, contracts with an outside company that provides translation services, paid for by CLARiTI funding. Your site will not receive a bill. You will upload your documents and make the selection to have them translated into the language(s) of your choosing. After documents receive WCG IRB approval and a Certificate of Action is provided to your site, your site will then submit a translation request to WCG. It is best practice to submit all documents that need to be translated in one submission to avoid having multiple submissions. **WCG does not permit use of documents that are translated by outside services.** We will update the CLARiTI Study Handbook with this information in the next version. Please reach out to your project coordinator for assistance.

CLARiTI Site Initiation Visits (SIV) Updates

Congratulations to the following sites that have completed their SIV with the Central Monitoring Service (CMS): **Wisconsin ADRC, Mayo, Penn ADRC-Memory Center, Boston University ADRC, 1Florida ADRC, University of Kansas ADRC, Stanford ADRC and Johns Hopkins ADRC.** Sites with upcoming SIVs: Wake Forest ADRC and UCSD ADRC. Available upcoming SIV dates: January 31, February 10 & 28 and March 10 & 28, 2025.

- All sites must complete a SIV.
- Sites are eligible for their SIV once they have gained WCG approval and their regulatory documents are completed and filed.

- After you receive approval from Central Monitoring Service (CMS) and a Site Activation letter from CLARiTI, you may begin study activities.
- The expectation is that sites will be ready to begin study activities shortly after the SIV, if site study start-up is delayed, a refresher SIV may be necessary.

Plan Ahead!

It is essential that all regulatory documents are filed in advance of the SIV. SIVs are scheduled for five hours to accommodate time for questions. The site PI is required to be there for the first 2 hours. There is an additional PI debrief (30 min) scheduled after the SIV. Please be in contact with your CLARiTI Administrative Team (CAT) Project Coordinator to make sure your site has been given the greenlight to schedule your SIV. Once your site is approved, you may reach out to the CAT regulatory team to secure a date.
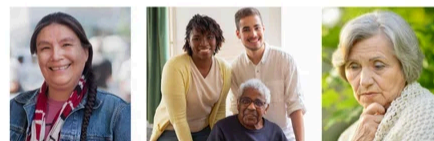
Review the SIV Agenda

Return of Results Brochure Now Available

The Return of Results (RoR) Core has released the first component of the RoR Toolkit for site implementation: Brain Amyloid Imaging - Learning My Results Brochure. This brochure is designed to provide educational material about amyloid imaging, the meaning of possible amyloid PET results, potential risks and benefits of learning results, and additional considerations. This material has been WCG approved and is available for sites to use as they begin consenting participants to the study.

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IRB Approved at the
Protocol Level
Nov 05, 2024

CLARiTI

Brain Amyloid Imaging PET Scan
Should I learn my test results?

This brochure is designed to help CLARiTI participants decide whether they wish to receive the results of their brain amyloid imaging scan. Please review this brochure and, if you wish, discuss it with your loved ones or doctors. Please let our study team know if you have any questions before making your decision. You may change your mind at any time.

The RoR Core has intentions to provide sites with professionally printed versions of the brochure; keep an eye out for updates regarding this effort! In the interim, the brochure is available on the CLARiTI website, as well as, the CLARiTI public Box folder. Finally, the initial version of the RoR Toolkit is scheduled for launch during the first quarter of 2025. We are continuing to incorporate feedback and look forward to sharing our efforts with the ADRC consortium.

Subaward Progress Update

We're thrilled to announce that the University of Washington has signed the subaward agreement from the University of Wisconsin.

With this approval, NACC has begun submitting requests to the University of Washington's Office of Sponsored Programs (OSP) to draft and issue subawards for participating sites. Thanks to your collaboration, we've made significant progress - 20 out of 33 sites have been submitted by NACC to University of Washington OSP, marking a key milestone.

Next Steps:
The University of Washington OSP will be reaching out to your grants offices with any questions as we move toward issuing the subawards.

What You Can Do:
If your site has not received confirmation from naccgrants@uw.edu that your subaward agreement has been submitted for approval, this indicates that NACC is pending receipt of required documentation from your site. Please ensure your site is ready for submission and respond promptly to any questions from NACC, and/or University of Washington OSP.

Timeline:
The submission and review process will take approximately 6-8 weeks. We anticipate issuing the first subawards in January, with most being processed by Q1 2025.

If you have any questions, don't hesitate to reach out to us at naccgrants@uw.edu. Thank you for your continued support and efforts as we move forward!

Communications Updates

CLARiTI Directory Launched: Your Research Network Hub

The CLARiTI Directory was recently launched. This study-specific directory serves as a focused subset of the NACC Directory, specifically designed to connect our 597 active CLARiTI collaborators. While the NACC Directory remains the comprehensive source for all 2,000+ ADRC members, the CLARiTI Directory is the primary database used to send CLARiTI-specific communications.

The CLARiTI Directory is automatically updated by your member profile in the NACC Directory. Your member profile enables targeted CLARiTI communications and depending upon your project role, access to the new CLARiTI online discussion group on the ADRC Program Community Forum.

CLARiTI Directory

Is this person actively involved in the CLARiTI project?	○ Yes ◉ No	ⓗ 💬 reset
Would Amy Young like to receive communications about the CLARiTI Initiative?	◉ Yes ○ No	ⓗ 💬 reset

Keeping Your Member Profile Current:

NACC recently sent out a Member Profile Survey. Please check your email for "NACC Action needed: Update Your NACC Directory Profile" and use your unique survey link to update your NACC Directory profile.

Can't find the email? ADRC members can contact their ADRC Administrator for a new survey link. If you believe you should be in the NACC Directory but aren't currently included, please contact your Center Administrator.

Non-ADRC members should reach out to the CLARiTI Communications Manager directly at clariti@medicine.wisc.edu. Keeping your profile current ensures you stay connected with relevant CLARiTI initiatives and collaborators.

CLARiTI Group on the ADRC Program Community Forum

The ADRC Program Community Forum, powered by Discourse, has launched to all ADRC members. If you are an ADRC member or in a CLARiTI imaging role, you should have received an email titled **"Invitation to Join the ADRC Program Community Forum"** sent by the NACC Team <hello@naccdata.org> on November 19.

This exciting new platform offers a dynamic communication channel for CLARiTI by providing a centralized hub for questions and collaboration among ADRC members through a moderated community forum. You will automatically be added to the

appropriate CLARiTI Groups in the Forum based on your assigned role in the NACC Directory, according to the table below. Each group has access to a private discussion category for CLARiTI. The CLARiTI groups are moderated by CLARiTI staff to address inquiries. All members are encouraged to participate and respond to each other to facilitate collective learning.

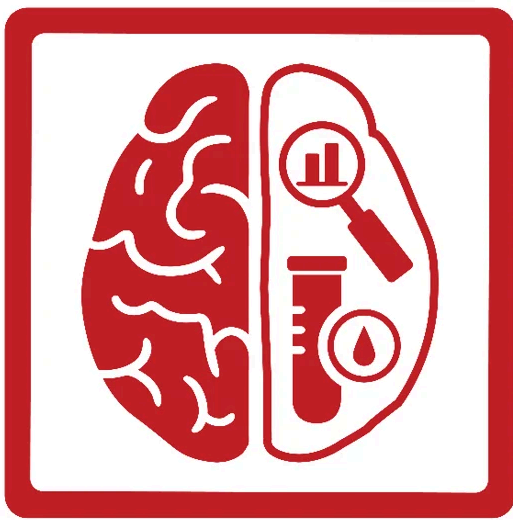| ADRC Community Forum Group Name	Roles Assigned to Group
CLARiTI Regulatory	CLARiTI Regulatory Coordinator CLARiTI Study Coordinator/Project Manager
CLARiTI Inclusion	CLARiTI Primary Site ORE Core Leader CLARiTI Community Research Liaison/CRL/Outreach specialist
CLARiTI Visual Reads & Return of Results	CLARiTI Site Principal Investigator CLARiTI Study Coordinator/Project Manager
CLARiTI Imaging	CLARiTI Site Physicist CLARiTI Additional Imaging Contact
CLARiTI Study Coordination	CLARiTI Study Coordinator/Project Manager
CLARiTI Data Management	CLARiTI Study Coordinator/Project Manager

Click on the link below to learn more about the ADRC Program Community Forum, get instructions on how to access and use the Forum, and find other helpful resources. If you have any questions, please contact Community Forum Online Help.

Learn about the Community Forum

CLARiTI Design Toolkit for Style, Graphics, Templates

A new toolkit is now available for cores and ADRC teams that includes guidance on branding, design tools and templates, including:

- CLARiTI style guide
- Logos and graphics
- PowerPoint template
- Zoom backgrounds
- Photo library resources
- Video clips from recent press
- And more...

Our Inclusion Core will also role out a suite of materials for participants in 2025. Please be in touch with **Phoebe Frenette**, CLARiTI's Communications Specialist, if you have any questions or to consult on other CLARiTI-related communications projects and needs.

Visit the CLARiTI Design Toolkit

Webinars & Events

CLARiTI WEBINAR

Study Start-up Updates
Wednesday, January 22, 2025
4:00-5:00pm ET

CLARiTI Webinar: CLARiTI Study Start-up Updates

Wednesday, January 22, 2025 at 4:00 pm ET | 3:00 pm CT | 1:00 pm PT

Please join us for this hour-long webinar. CLARiTI study leaders will provide updates on the status of study start-up and operationalization. We will discuss site initiation information, the CLARiTI group on the ADRC Program Community Forum, and cover other important study essentials. NACC will provide updates on data pipelines in development. Inclusion will also be spotlighted to share the latest updates from the core's start-up activities. We will conclude with an open Q&A. Register today!

CLARiTI Webinar: Updates on the SCAN Project & Plans for SCAN2

November 22, 2024

Review the webinar recording for study guidelines for SCAN PET and MRI data acquisition, examples of available data and results and information about SCAN renewal (SCAN2), with Drs. William Jagust and Cliff Jack.

Watch the Recording

SAVE THE DATE

CLARiTI Webinar: NACC Updates on CLARiTI Infrastructure

Thursday, February 20, 2025 at 3:00 pm ET | 2:00 pm CT | 12:00 pm PT

Inclusion Corner

Inclusion Core Site Onboarding Calls

Inclusion Core is excited to report that we have begun **Site Onboarding Calls.** These onboarding calls are scheduled within six weeks of the Site Initiation Visit with CLARiTI Admin Team. During the onboarding calls, Inclusion Core will discuss site inclusion goals, assess site readiness for participant recruitment, and provide information on available resources and support services. The goal of these calls is to establish a collaborative partnership to increase the inclusion and engagement of underrepresented populations. We look forward to connecting with your site!

Welcoming new Inclusion Core Member

Reagan Schoenholz, Community Research Navigator

Reagan Schoenholz has recently joined the CLARiTI Inclusion Core and is a Community Research Navigator with a background in cognitive science. She received her Bachelor's of Science and Art at McGill University. After moving to New York, she worked as a Clinical Research Coordinator with the Sleep Medicine Research Group at Mt. Sinai. Before joining the Rivera Mindt Lab, Reagan completed the post-baccalaureate Premedical program at Columbia University.

In her free time, Reagan loves to knit, hike, read, and spend time with her friends.

Meet the NACC CLARiTI Data Team

Hannah Koenig, MPH, CLARiTI Data Manager

Hannah is the CLARiTI Data Manager at NACC and works with all things data spanning from REDCap project creation and monitoring, data exports, preparing tools and instruments for data collection, and any other CLARiTI data needs. She has worked in various aspects of health research as a Biostatistician for both the US Navy in San Diego and patient research in Seattle, and as a Data Manager for UW in the Dept. of Laboratory Medicine, Pathology. When not working she enjoys reading, crafting, cooking/baking, and exploring the outdoors with her border collie.

Dan Peterson, Software Engineer

Dan Peterson is a software engineer at NACC, working on the Data Platform. He has experience developing and deploying image processing pipelines in the cloud for medical research - both in academia and industry. He lives in Seattle with his partner, Lizzie and their 6-year-old son, Arthur. He enjoys contemporary art, and games of all kinds.

Emily Cheng, Software Engineer

Emily Cheng is a software engineer at NACC, supporting development and delivery of informatic services. Emily has worked in the companion diagnostics space developing bioinformatic pipelines and related infrastructure for liquid biopsy assays. Outside of work she enjoys hiking, visiting local art markets, making art and fostering cats.

Submissions for CLARiTI Connect

Please share your CLARiTI related news, job postings, etc., with Phoebe Frenette, CLARiTI Communications Specialist.

Contact Us:

Email: clariti@medicine.wisc.edu