

New NIA/NIH Alzheimer Disease Consortium

The National Institutes of Health (NIH) announced on December 11 the funding of a new clinical trials consortium that is expected to accelerate and expand studies for therapies in Alzheimer disease (AD) and related dementias. The infrastructure of 35 U.S. sites, called the Alzheimer's Clinical Trial Consortium (ACTC), will address the time frame, complexity, and expense of the recruitment process and site activation for AD trials looking for new and effective ways to treat or prevent AD and other neurodegenerative diseases.

The ACTC will be led jointly by research teams from the University of Southern California (USC) Alzheimer's Therapeutic Research Institute (ATRI; San Diego), the Harvard-affiliated Brigham and Women's Hospital and Massachusetts General Hospital (Boston), and the Mayo Clinic (Rochester, MN). Funds were awarded by the National Institute on Aging (NIA) at NIH, which leads the federal effort in AD research. NIA will also provide scientific input to the ACTC under a cooperative agreement.

The award for support of the consortium is expected to total nearly \$70 million over 5 years, pending availability of funds. Specific trials would be funded separately, under a process by which investigators will collaborate with the consortium to undertake research. Funding opportunity announcements for specific ACTC trials are expected to be released in early 2018 and will be open to all qualified investigators. It is anticipated that the ACTC will have the capacity to handle 5–7 trials during the 5-year award period.

Developing effective treatments for AD and related dementias has proven extremely challenging. With recent advances in basic science and identification of promising therapeutic targets, the number and types of possible therapies for testing have grown and are expected to increase significantly. At the same time, early intervention and development of methods for prevention are growing foci. With current technologies, however, studies require screening of thousands of volunteers to identify eligible participants. Other challenges facing AD clinical trials include development of more sensitive cognitive assessment and neuroimaging analyses, data management, and bioethics considerations. "We have reached a critical juncture in Alzheimer's and related dementias research, with new and exciting opportunities to build upon what we have learned," said NIA Director Richard J. Hodes, MD. "The ACTC will provide vital infrastructure, centralized resources, and shared expertise to help us more rapidly and optimally test new treatments."

The ACTC experts and infrastructure will support the design and conduct of trials across the full spectrum of AD and related dementias, from prevention initiatives to combination trials for advanced symptomatic stages. Specific objectives of the consortium include: creating infrastructure with expert leadership to streamline implementation of trials; developing innovative trial design methods, outcomes, and analysis strategies; maintaining trial site quality standards during and between trials; developing and implementing cutting-edge participant recruitment and retention strategies, especially in diverse populations; using a centralized Institutional Review Board; developing and running capture systems for data pertinent to the ACTC; securing centralized tissue banking for specimens; providing centralized imaging, biostatistics, bioinformatics, and data management and analysis support; and facilitating and managing public/private partnerships.

Trials would be conducted under the guidance of ACTC leaders, an executive committee, and an external advisory board, which will include a patient advocate. The ACTC principal investigators are: Paul Stephen Aisen, MD, director of the ATRI at the Keck School of Medicine of USC; Reisa A. Sperling, MD, director of the Center for Alzheimer Research and Treatment at the Brigham and Women's Hospital and professor of neurology, Harvard Medical School; and Ronald C. Petersen, MD, PhD, director of the Mayo Clinic Alzheimer's Disease Research Center and professor of neurology at Mayo Clinic College of Medicine and Science.

The ACTC will include a coordinating center at ATRI and 10 units staffed with teams to manage areas such as biomarkers, biostatistics, clinical operations, informatics, MR imaging, PET, and recruitment. As part of its recruitment unit, the ACTC is establishing a new Minority Outreach and Recruitment Team, which will use innovations in recruitment to support both central and local partnerships with diverse communities. "When we announced the funding opportunity for a new publicly supported clinical trials network, we envisioned a next-generation consortium, where shared expertise could enhance the ideas and approaches of individual investigators proposing and conducting trials," said Laurie Ryan, PhD, chief of the Dementias of Aging Branch in NIA's Division of Neuroscience. "I think we will have that now. I am particularly interested in how we can better engage diverse communities into research, so that trials can more effectively include and benefit everyone who is affected by Alzheimer's."

National Institutes of Health