Methods

Knight ADRC and ADNI* studies for clinical disease progression in human AD patients

The recruitment, assessment, and exclusion criteria methods for the Knight ADRC study has been published previously[30,31]. In the case of the ADNI study, further information was previously described[32]. Knight ADRC individuals were evaluated by Clinical Core personnel at Washington University and in the case of ADNI, each local site was in charge for the evaluation of local participants[32,33]. Briefly, cases received a clinical diagnosis of AD in accordance with the standard criteria[34] and presence or absence of dementia. The severity of dementia was staged with the Clinical Dementia Rating (CDR) where 0 indicates cognitive normality, 0.5 is defined as very mild dementia, 1 is mild dementia, 2 is moderate dementia, and 3 is severe dementia[35]. The scores in each of the six cognitive and functional domains surveyed by the CDR are summed to yield a Sum of Box scores (CDR-SB) ranging from 0 (no impairment) to 18 (maximal impairment)[36]. Sample selection was done as follow: only participants that had an AD diagnosis at the last visit and had a CSF profile compatible with AD were included in our analyses. Non-AD dementia was excluded, as well as individuals in which the CDR at last assessment was equal to 0. Individuals with diagnoses of neurological diseases other than AD were excluded. Not informative longitudinally measured CDR-SB was removed for each participant. After removing the non-informative data points only individuals with at least 1.5 year of follow-up were included. A total of 592 participants were included in the analyses.

Statistical analysis was carried out using R statistical software and the packages nlme was used for linear mixed model. A linear mixed-model repeated measure framework was used to account for correlation between repeated measures in the same individual. Disease progression was modeled as follows:

$$(\mathbf{Y}) = \boldsymbol{\beta_1}[\mathbf{SNP} * \mathbf{Time}] + \boldsymbol{\beta_2} * \mathbf{CDR_{baseline}} + \boldsymbol{\beta_3}\mathbf{AGE_{baseline}} + \boldsymbol{\beta_4}\mathbf{Gender} + \boldsymbol{\beta_5}\mathbf{Educacion} + \boldsymbol{\beta_6}\mathbf{SNP} + \boldsymbol{\beta_7}\mathbf{Time} + \boldsymbol{\beta_8}\mathbf{PC1} + \boldsymbol{\beta_9}\mathbf{PC2}$$

Where: Y was CDR-SB, the change in CDR Sum of Boxes per year baseline CDR, baseline Age, Gender, follow-up time, level of education, and, to avoid the possibility of spurious association due to population substructure, the two first principal components scores were included as covariates.

A portion of the human AD data were obtained from the Alzheimer's Disease Neuroimaging Initiative database (http://adniloni.usc.edu). The ADNI was launched in 2003 as a public-private partnership, led by Principal Investigator Michael W. Weiner, MD. The primary goal of ADNI has been to test whether serial magnetic resonance imaging (MRI), biological markers, and clinical and neuropsychological assessment can be combined to measure the progression of mild cognitive impairment (MCI) and early AD. For up-to-date information, see www.adni-info.org.

Sample blinding and randomization for animal studies

Randomization

For biochemical assay and histological staining, the "RAND" function in EXCEL was applied to assign each sample a random number and sorted smallest to largest to generate random order. For gene expression assay, equal number of samples from each group were placed on each chip by complete randomization to avoid cross-chip variability.

Blinding

Quantification of brain volume, AT8 staining, p-tau patterns, and fluorescent staining were performed by individuals blinded to samples IDs. Microglial/astrocytic gene expression assays were performed by collaborators who were blinded to sample IDs. Cell culture images were taken and data quantified by individuals blinded to sample IDs.

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Lilly and Company; EuroImmun; F. Hoffmann-La Roche Ltd and its affiliated company Genentech, Inc.; Fujirebio; GE Healthcare; IXICO Ltd.; Janssen Alzheimer Immunotherapy Research & Development, LLC.; Johnson & Johnson Pharmaceutical Research & Development LLC.; Lumosity; Lundbeck; Merck & Co., Inc.; Meso Scale Diagnostics, LLC.; NeuroRx Research; Neurotrack Technologies; Novartis Pharmaceuticals Corporation; Pfizer Inc.; Piramal Imaging; Servier; Takeda Pharmaceutical Company; and Transition Therapeutics. The Canadian Institutes of Health Research is providing funds to support ADNI clinical sites in Canada. Private sector contributions are facilitated by the Foundation for the National Institutes of Health (www.fnih.org). The grantee organization is the Northern California Institute for Research and Education, and the study is coordinated by the Alzheimer's Therapeutic Research Institute at the University of Southern California. ADNI data are disseminated by the Laboratory for Neuro Imaging at the University of Southern California.

ADNI Alzheimer's Disease Neuroimaging Initiative

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I. ADNI I, GO and II

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Principal Investigator

Michael W. Weiner, MD	UC San Francisco

ADCS PI and Director of Coordinating Center Clinical Core

Paul Aisen, MD	University of Southern California

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Michael Weiner, MD	UC San Francisco
Paul Aisen, MD	University of Southern California
Ronald Petersen, MD, PhD	Mayo Clinic, Rochester
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John Q. Trojanowki, MD, PhD	U Pennsylvania
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Clinical Informatics and Operations

Ronald G. Thomas, PhD	UC San Diego
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Sarah Walter, MSc	UC San Diego
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Tamie Sather, MA	UC San Diego
Gus Jiminez, MBS	UC San Diego
Archana B. Balasubramanian, PhD	UC San Diego
Jennifer Mason, MPH	UC San Diego
Iris Sim	UC San Diego

Biostatistics Core Leaders and Key Personnel

Laurel Beckett, PhD	UC Davis (Core PI)
Danielle Harvey, PhD	UC Davis
Michael Donohue, PhD	UC San Diego

MRI Core Leaders and Key Personnel

Clifford R. Jack, Jr., MD	Mayo Clinic, Rochester (Core PI)
Matthew Bernstein, PhD	Mayo Clinic, Rochester
Nick Fox, MD	University of London
Paul Thompson, PhD	UCLA School of Medicine
Norbert Schuff, PhD	UCSF MRI
Charles DeCArli, MD	UC Davis
Bret Borowski, RT	Mayo Clinic
Jeff Gunter, PhD	Mayo Clinic
Matt Senjem, MS	Mayo Clinic
Prashanthi Vemuri, PhD	Mayo Clinic
David Jones, MD	Mayo Clinic
Kejal Kantarci	Mayo Clinic
Chad Ward	Mayo Clinic

PET Core Leaders and Key Personnel

William Jagust, MD	UC Berkeley (Core PI)
Robert A. Koeppe, PhD	University of Michigan
Norm Foster, MD	University of Utah
Eric M. Reiman, MD	Banner Alzheimer's Institute
Kewei Chen, PhD	Banner Alzheimer's Institute
Chet Mathis, MD	University of Pittsburgh
Susan Landau, PhD	UC Berkeley

Neuropathology Core Leaders

John C. Morris, MD	Washington University St. Louis
Nigel J. Cairns, PhD, FRCPath	Washington University St. Louis
Erin Franklin, MS, CCRP	Washington University St. Louis
Lisa Taylor-Reinwald, BA, HTL (ASCP) – Past Investigator	Washington University St. Louis

Biomarkers Core Leaders and Key Personnel

Leslie M. Shaw, PhD	UPenn School of Medicine
John Q. Trojanowki, MD, PhD	UPenn School of Medicine
Virginia Lee, PhD, MBA	UPenn School of Medicine
Magdalena Korecka, PhD	UPenn School of Medicine
Michal Figurski, PhD	UPenn School of Medicine

Informatics Core Leaders and Key Personnel

Arthur W. Toga, PhD	USC (Core PI)
Karen Crawford	USC
Scott Neu, PhD	USC

Genetics Core Leaders and Key Personnel

Andrew J. Saykin, PsyD	Indiana University
Tatiana M. Foroud, PhD	Indiana University
Steven Potkin, MD UC	UC Irvine
Li Shen, PhD	Indiana University
Kelley Faber, MS, CCRC	Indiana University
Sungeun Kim, PhD	Indiana University
Kwangsik Nho, PhD	Indiana University

Initial Concept Planning & Development

Michael W. Weiner, MD	UC San Francisco
Lean Thal, MD	UC San Diego
Zaven Khachaturian, PhD	Prevent Alzheimer's Disease 2020

Early Project Proposal Development

Leon Thal, MD	UC San Diego
Neil Buckholtz	National Institute on Aging
Michael W. Weiner, MD	UC San Francisco
Peter J. Snyder, PhD	Brown University
William Potter, MD	National Institute of Mental Health
Steven Paul, MD	Cornell University
Marilyn Albert, PhD	Johns Hopkins University
Richard Frank, MD, PhD	Richard Frank Consulting
Zaven Khachaturian, PhD	Prevent Alzheimer's Disease 2020

NIA

John Hsiao, MD	National Institute on Aging

Part B: Investigators By Site

Oregon Health & Science University:
Jeffrey Kaye, MD
Joseph Quinn, MD
Lisa Silbert, MD
Betty Lind, BS
Raina Carter, BA – Past Investigator
Sara Dolen, BS – Past Investigator

University of Southern California:
Lon S. Schneider, MD
Sonia Pawluczyk, MD
Mauricio Becerra, BS
Liberty Teodoro, RN
Bryan M. Spann, DO, PhD – Past Investigator

University of California – San Diego:
James Brewer, MD, PhD
Helen Vanderswag, RN
Adam Fleisher, MD – Past Investigator

University of Michigan:
Judith L. Heidebrink, MD, MS
Joanne L. Lord, LPN, BA, CCRC – Past Investigator

Mayo Clinic, Rochester:
Ronald Petersen, MD, PhD
Sara S. Mason, RN
Colleen S. Albers, RN
David Knopman, MD
Kris Johnson, RN – Past Investigator

Baylor College of Medicine:
Rachelle S. Doody, MD, PhD
Javier Villanueva-Meyer, MD
Valory Pavlik, PhD
Victoria Shibley, MS
Munir Chowdhury, MBBS, MS – Past Investigator
Susan Rountree, MD – Past Investigator
Mimi Dang, MD – Past Investigator

Columbia University Medical Center:
Yaakov Stern, PhD
Lawrence S. Honig, MD, PhD
Karen L. Bell, MD

Washington University, St. Louis:
Beau Ances, MD
John C. Morris, MD
Maria Carroll, RN, MSN
Mary L. Creech, RN, MSW
Erin Franklin, MS, CCRP
Mark A. Mintun, MD – Past Investigator
Stacy Schneider, APRN, BC, GNP – Past Investigator
Angela Oliver, RN, BSN, MSG – Past Investigator

University of Alabama - Birmingham:
Daniel Marson, JD, PhD
David Geldmacher, MD
Marissa Natelson Love, MD
Randall Griffith, PhD, ABPP – Past Investigator
David Clark, MD – Past Investigator
John Brockington, MD – Past Investigator
Erik Roberson, MD – Past Investigator

Mount Sinai School of Medicine:
Hillel Grossman, MD
Effie Mitsis, PhD

Rush University Medical Center:
Raj C. Shah, MD
Leyla deToledo-Morrell, PhD – Past Investigator

Wien Center:
Ranjan Duara, MD
Maria T. Greig-Custo, MD
Warren Barker, MA, MS

Johns Hopkins University:
Marilyn Albert, PhD
Chiadi Onyike, MD
Daniel D'Agostino II, BS
Stephanie Kielb, BS – Past Investigator

New York University:
Martin Sadowski, MD, PhD
Mohammed O. Sheikh, MD
Anaztasia Ulysse
Mrunalini Gaikwad

Duke University Medical Center:
P. Murali Doraiswamy, MBBS, FRCP
Jeffrey R. Petrella, MD

Salvador Borges-Neto, MD
Terence Z. Wong, MD – Past Investigator
Edward Coleman – Past Investigator

University of Pennsylvania:
Steven E. Arnold, MD
Jason H. Karlawish, MD
David A. Wolk, MD
Christopher M. Clark, MD

University of Kentucky:
Charles D. Smith, MD
Greg Jicha, MD
Peter Hardy, PhD
Partha Sinha, PhD
Elizabeth Oates, MD
Gary Conrad, MD

University of Pittsburgh:
Oscar L. Lopez, MD
MaryAnn Oakley, MA
Donna M. Simpson, CRNP, MPH

University of Rochester Medical Center:
Anton P. Porsteinsson, MD
Bonnie S. Goldstein, MS, NP
Kim Martin, RN
Kelly M. Makino, BS – Past Investigator
M. Saleem Ismail, MD – Past Investigator
Connie Brand, RN – Past Investigator

University of California, Irvine:
Steven G. Potkin, MD
Adrian Preda, MD
Dana Nguyen, PhD

University of Texas Southwestern Medical School:
Kyle Womack, MD
Dana Mathews, MD, PhD
Mary Quiceno, MD

Emory University:
Allan I. Levey, MD, PhD
James J. Lah, MD, PhD
Janet S. Cellar, DNP, PMHCNS-BC

University of Kansas, Medical Center:
Jeffrey M. Burns, MD
Russell H. Swerdlow, MD
William M. Brooks, PhD

University of California, Los Angeles:
Liana Apostolova, MD
Kathleen Tingus, PhD
Ellen Woo, PhD
Daniel H.S. Silverman, MD, PhD
Po H. Lu, PsyD – Past Investigator
George Bartzokis, MD – Past Investigator

Mayo Clinic, Jacksonville:
Neill R Graff-Radford, MBBCH, FRCP (London)
Francine Parfitt, MSH, CCRC
Kim Poki-Walker, BA

Indiana University:
Martin R. Farlow, MD
Ann Marie Hake, MD
Brandy R. Matthews, MD – Past Investigator
Jared R. Brosch, MD
Scott Herring, RN, CCRC

Yale University School of Medicine:
Christopher H. van Dyck, MD
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McGill Univ., Montreal-Jewish General Hospital:
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Sunnybrook Health Sciences, Ontario:
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Bojana Stefanovic, PhD
Curtis Caldwell, PhD

U.B.C. Clinic for AD & Related Disorders:
Ging-Yuek Robin Hsiung, MD, MHSc, FRCPC
Benita Mudge, BS
Vesna Sossi, PhD
Howard Feldman, MD, FRCPC – Past Investigator
Michele Assaly, MA – Past Investigator

Cognitive Neurology - St. Joseph's, Ontario:
Elizabeth Finger, MD
Stephen Pasternack, MD, PhD
Irina Rachisky, MD
Dick Trost, PhD – Past Investigator

Andrew Kertesz, MD – Past Investigator

Cleveland Clinic Lou Ruvo Center for Brain Health:
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Sandra Weintraub, PhD
Borna Bonakdarpour, MD
Diana Kerwin, MD – Past Investigator
Chuang-Kuo Wu, MD, PhD – Past Investigator
Nancy Johnson, PhD – Past Investigator

Premiere Research Inst (Palm Beach Neurology):
Carl Sadowsky, MD
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Georgetown University Medical Center:
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Kathleen Johnson, NP
Brigid Reynolds, NP

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Gad Marshall, MD

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Allyson Rosen, PhD – Past Investigator
Jared Tinklenberg, MD – Past Investigator

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Marwan N. Sabbagh, MD
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Sandra A. Jacobson, MD
Sherye A. Sirrel, CCRC

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Patricia Lynn Johnson, BA – Past Investigator

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Parianne Fatica, BA, CCRC

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John Olichney, MD
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Owen Carmichael, PhD – Past Investigator

Neurological Care of CNY:
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Adrian Preda, MD
Dana Nguyen, PhD

Banner Alzheimer's Institute:
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Anna Burke, MD
Ann Marie Milliken, NMD
Nadira Trncic, MD, PhD, CCRC – Past Investigator
Adam Fleisher, MD – Past Investigator
Stephanie Reeder, BA – Past Investigator

Dent Neurologic Institute:
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Michelle Rainka, PharmD, CCRP

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Brendan Kelley, MD

Albany Medical College:
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Dzintra Celmins, MD
Alice D. Brown, FNP

Hartford Hospital, Olin Neuropsychiatry Research Center:
Godfrey D. Pearlson, MD
Karen Blank, MD
Karen Anderson, RN

Dartmouth-Hitchcock Medical Center:
Laura A. Flashman, PhD
Marc Seltzer, MD
Mary L. Hynes, RN, MPH
Robert B. Santulli, MD – Past Investigator

Wake Forest University Health Sciences:
Kaycee M. Sink, MD, MAS
Leslie Gordineer
Jeff D. Williamson, MD, MHS – Past Investigator
Pradeep Garg, PhD – Past Investigator
Franklin Watkins, MD – Past Investigator

Rhode Island Hospital:
Brian R. Ott, MD
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Butler Hospital:
Stephen Salloway, MD, MS
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Irina Rachinsky, MD
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Dick Drost, MD – Past Investigator

Nathan Kline Institute
Nunzio Pomara, MD
Raymundo Hernando, MD
Antero Sarrael, MD

University of Iowa College of Medicine
Susan K. Schultz, MD
Karen Ekstam Smith, RN
Hristina Koleva, MD
Ki Won Nam, MD
Hyungsub Shim, MD– Past Investigator

Cornell University
Norman Relkin, MD, PhD
Gloria Chiang, MD
Michael Lin, MD
Lisa Ravdin, PhD

University of South Florida: USF Health Byrd Alzheimer's Institute
Amanda Smith, MD
Balebail Ashok Raj, MD
Kristin Fargher, MD– Past Investigator

DOD ADNI

Part A: Leadership and Infrastructure

Principal Investigator

Michael W. Weiner, MD	University of California, San Francisco

ADCS PI and Director of Coordinating Center Clinical Core

Paul Aisen, MD	University of Southern California

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Michael Weiner, MD	UC San Francisco
Paul Aisen, MD	University of Southern California
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Clifford R. Jack, Jr., MD	Mayo Clinic, Rochester
William Jagust, MD	UC Berkeley
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Leslie M. Shaw, PhD	Perelman School of Medicine, UPenn
Arthur W. Toga, PhD	USC
John Q. Trojanowki, MD, PhD	Perelman School of Medicine, University of Pennsylvania

Psychological Evaluation/PTSD Core

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Traumatic Brain Injury/TBI Core

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Robert C. Green, MD, MPH	BWH/HMS (Chair)

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Clinical Core Leaders

Michael Weiner MD	Core PI
Ronald Petersen, MD, PhD	Mayo Clinic, Rochester (Core PI)
Paul Aisen, MD	University of Southern California

Clinical Informatics and Operations

Ronald G. Thomas, PhD	UC San Diego
Michael Donohue, PhD	UC San Diego
Devon Gessert	UC San Diego
Tamie Sather, MA	UC San Diego
Melissa Davis	UC San Diego
Rosemary Morrison, MPH	UC San Diego
Gus Jiminez, MBS	UC San Diego

San Francisco Veterans Affairs Medical Center

Thomas Neylan, MD	UC San Francisco
Jacqueline Hayes	UC San Francisco
Shannon Finley	UC San Francisco

Biostatistics Core Leaders and Key Personnel

Danielle Harvey, PhD	UC Davis (Core PI)
Michael Donohue, PhD	UC San Diego

MRI Core Leaders and Key Personnel

Clifford R. Jack, Jr., MD	Mayo Clinic, Rochester (Core PI)
Matthew Bernstein, PhD	Mayo Clinic, Rochester
Bret Borowski, RT	Mayo Clinic
Jeff Gunter, PhD	Mayo Clinic
Matt Senjem, MS	Mayo Clinic
Kejal Kantarci	Mayo Clinic
Chad Ward	Mayo Clinic

PET Core Leaders and Key Personnel

William Jagust, MD	UC Berkeley (Core PI)
Robert A. Koeppe, PhD	University of Michigan
Norm Foster, MD	University of Utah
Eric M. Reiman, MD	Banner Alzheimer's Institute
Kewei Chen, PhD	Banner Alzheimer's Institute
Susan Landau, PhD	UC Berkeley

Neuropathology Core Leaders

John C. Morris, MD	Washington University St. Louis
Nigel J. Cairns, PhD, FRCPath	Washington University St. Louis
Erin Householder, MS	Washington University St. Louis

Biomarkers Core Leaders and Key Personnel

Leslie M. Shaw, PhD	Perelman School of Medicine, UPenn
John Q. Trojanowki, MD, PhD	Perelman School of Medicine, UPenn
Virginia Lee, PhD, MBA	Perelman School of Medicine, UPenn
Magdalena Korecka, PhD	Perelman School of Medicine, UPenn
Michal Figurski, PhD	Perelman School of Medicine, UPenn

Informatics Core Leaders and Key Personnel

Arthur W. Toga, PhD	USC (Core PI)
Karen Crawford	USC
Scott Neu, PhD	USC

Genetics Core Leaders and Key Personnel

Andrew J. Saykin, PsyD	Indiana University
Tatiana M. Foroud, PhD	Indiana University
Steven Potkin, MD UC	UC Irvine
Li Shen, PhD	Indiana University
Kelley Faber, MS, CCRC	Indiana University
Sungeun Kim, PhD	Indiana University

Kwangsik Nho, PhD Indiana University

Initial Concept Planning & Development

Michael W. Weiner, MD	UC San Francisco
Karl Friedl	Department of Defense (retired)

Part B: Investigators By Site

University of Southern California:
Lon S. Schneider, MD, MS
Sonia Pawluczyk, MD
Mauricio Becerra

University of California, San Diego:
James Brewer, MD, PhD
Helen Vanderswag, RN

Columbia University Medical Center:
Yaakov Stern, PhD
Lawrence S. Honig, MD, PhD
Karen L. Bell, MD

Rush University Medical Center:
Debra Fleischman, Ph.D.
Konstantinos Arfanakis, Ph.D.
Raj C. Shah, M.D.

Wien Center:
Dr. Ranjan Duara MD PI
Dr. Daniel Varon MD Co-PI
Maria T Greig HP Coordinator

Duke University Medical Center:
P. Murali Doraiswamy, MBBS
Jeffrey R. Petrella, MD
Olga James, MD

University of Rochester Medical Center:
Anton P. Porsteinsson, MD (director)
Bonnie Goldstein, MS, NP (coordinator)
Kimberly S. Martin, RN

University of California, Irvine:
Steven G. Potkin, MD
Adrian Preda, MD
Dana Nguyen, PhD

Medical University South Carolina:
Jacobo Mintzer, MD, MBA
Dino Massoglia, MD, PhD
Olga Brawman-Mintzer, MD

Premiere Research Inst (Palm Beach Neurology):
Carl Sadowsky, MD
Walter Martinez, MD
Teresa Villena, MD

University of California, San Francisco:
William Jagust MD
Susan Landau PhD
Howard Rosen, MD
David Perry

Georgetown University Medical Center:
Raymond Scott Turner, MD, PhD
Kelly Behan
Brigid Reynolds, NP

Brigham and Women's Hospital:
Reisa A. Sperling, MD
Keith A. Johnson, MD
Gad Marshall, MD

Banner Sun Health Research Institute:
Marwan N. Sabbagh, MD
Sandra A. Jacobson, MD
Sherye A. Sirrel, MS, CCRC

Howard University:
Thomas O. Obisesan, MD, MPH
Saba Wolday, MSc
Joanne Allard, PhD

University of Wisconsin:
Sterling C. Johnson, Ph.D.
J. Jay Fruehling, M.A.
Sandra Harding, M.S.

University of Washington:
Elaine R. Peskind, MD
Eric C. Petrie, MD, MS
Gail Li, MD, PhD

Stanford University:
Jerome A. Yesavage, MD
Joy L. Taylor, PhD
Ansgar J. Furst, PhD
Steven Chao, M.D.

Cornell University:
Norman Relkin, MD, PhD
Gloria Chiang, MD

Lisa Ravdin, PhD