

Alzheimer's Disease Centers meeting

San Diego, CA

October 14, 2017

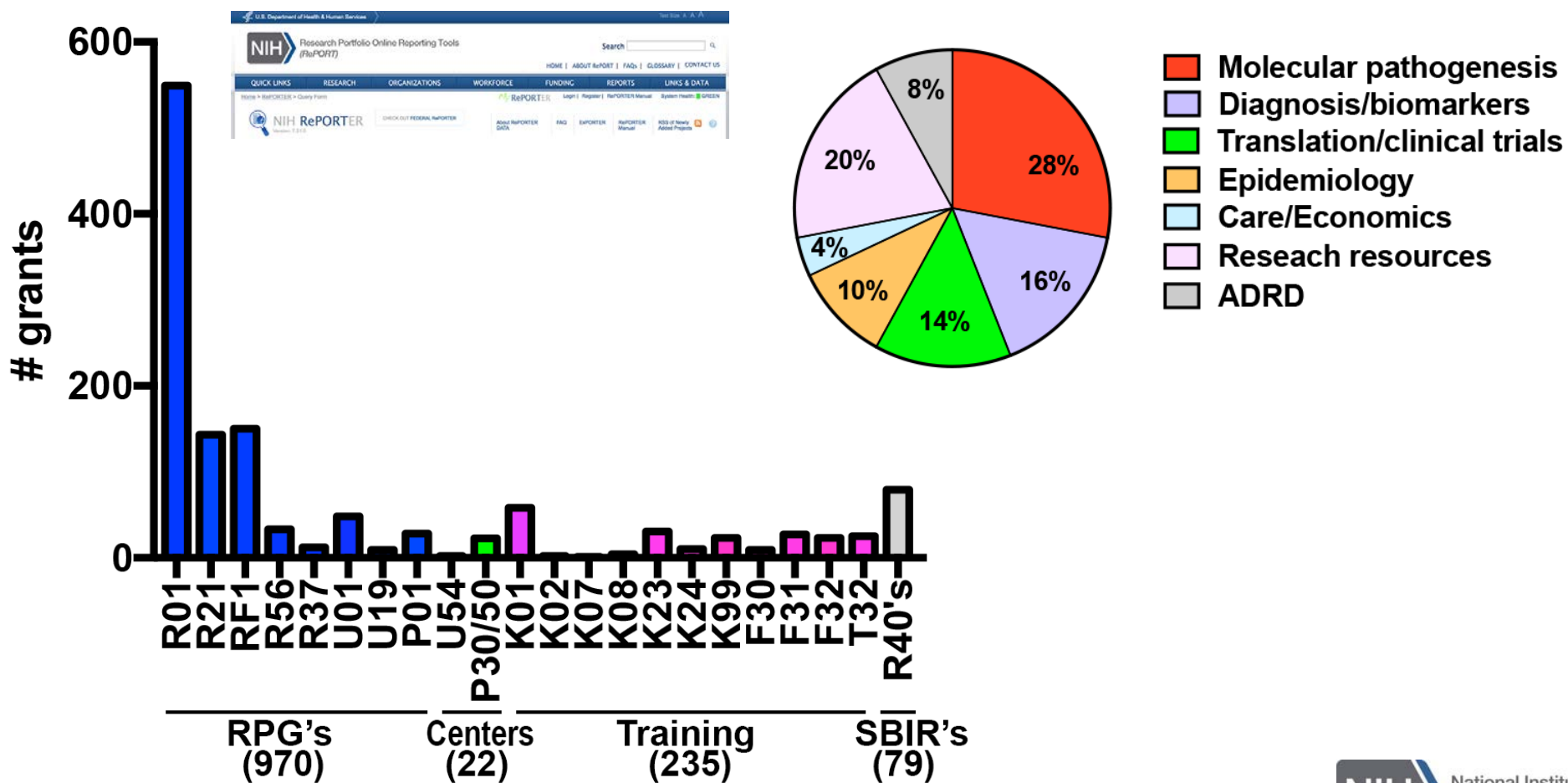
"NIA-Division of Neurosciences update"

Eliezer Masliah, M.D.

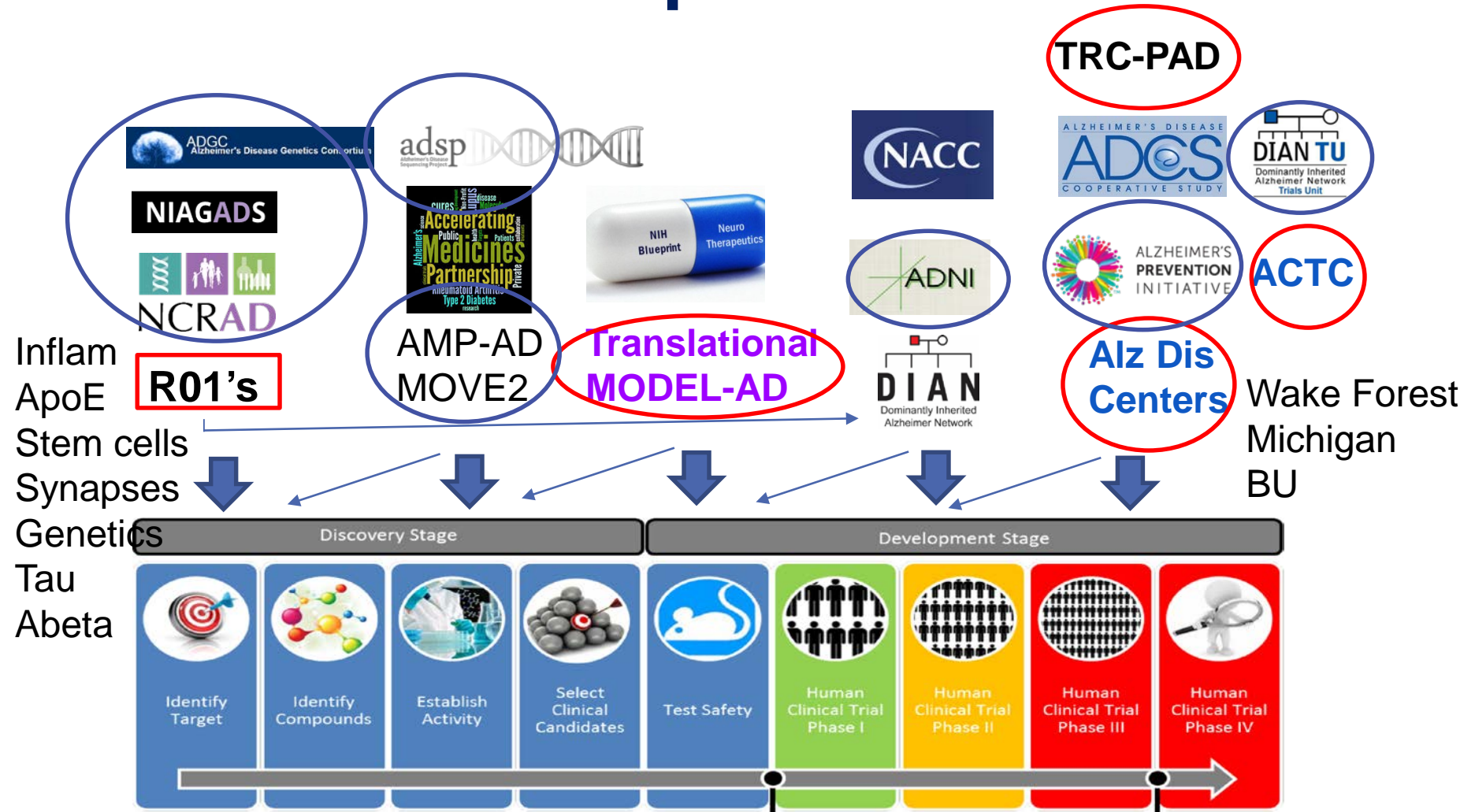
**Director, Division of Neuroscience,
National Institute on Aging, NIH**

AD grants funded for FY17 (estimate)

NIH RePORTER FY17 (as of 10-6-17)



NIA-AD accomplishments FY16-17



Renewed FY16 and 17
 New program






New AD Epidemiological studies FY16-17

Selected Themes in the Dementia Epidemiology Portfolio – FY16 & FY17 (N=50 grants) [Dallas Anderson]

Vascular etiology (n= 24)	Diet (n= 6)	Air pollution (n= 4)
Resilience in the presence of AD/ADRD pathology (n= 2)	Combinations of existing cohorts to better understand risk patterns for AD/ADRD (n= 11)	Development of novel statistical methods for a variety of purposes related to AD/ADRD (n= 7)
Sex and APOE4 effects; reproductive risk factors for AD (n= 4)	Mechanisms for race/ethnic disparities in AD/ADRD (n= 20)	Neuropathologic mechanisms underlying clinical manifestations of AD/ADRD (n= 22)

Examples of new epidemiological studies FY17

Examples of Dementia Epidemiology Projects First Funded in FY2017

	Title	PI	Institution	Cohort(s)
	Brain atrophy, cognitive impairment and Alzheimer's in a low CVD-risk population (1RF1AG054442)	Kaplan, Hillard S	Chapman University	N= 1,310 Tsimane adults, an indigenous Native American population in Bolivia
	Diet patterns and Alzheimer disease and other dementias (1R01AG054476)	Morris, Martha Clare	Rush University Medical Center	N= 600 autopsied brains, along with associated clinical and neuropathological data, from the Rush Memory and Aging Project (MAP)
	COSMIC: An international consortium to identify risk and protective factors and biomarkers of cognitive ageing and dementia in diverse ethno-racial groups and geographical settings (1RF1AG057531)	Sachdev, Perminder S	University of New South Wales	N= >70,000 from 26 studies from 16 countries in five continents
	Exceptional aging: Identifying modifiers of Alzheimer's disease trajectories (1R01AG056366)	Vemuri, Prashanthi	Mayo Clinic Rochester	N= 800 from the Mayo Clinic Study of Aging (MCSA) and the Rochester Epidemiology Project (REP)
	Gender and APOE4 effects on brain morphometry, cognition, and clinical progression to Alzheimer's Disease (1RF1AG054617)	Pa, Judy	University of Southern California	N= 2,739 from four cohorts: National Alzheimer's Coordinating Centers (NACC), Alzheimer's Disease Neuroimaging Initiative (ADNI), Australian Imaging Biomarkers and Lifestyle study (AIBL), and Banner Alzheimer Institute APOE4/4 study (BAI/Mayo)

NIA contact: Dallas Anderson

ApoE, Sex and risk for AD

Research

JAMA Neurology | Original Investigation

Apolipoprotein E Genotype and Sex Risk Factors for Alzheimer Disease A Meta-analysis

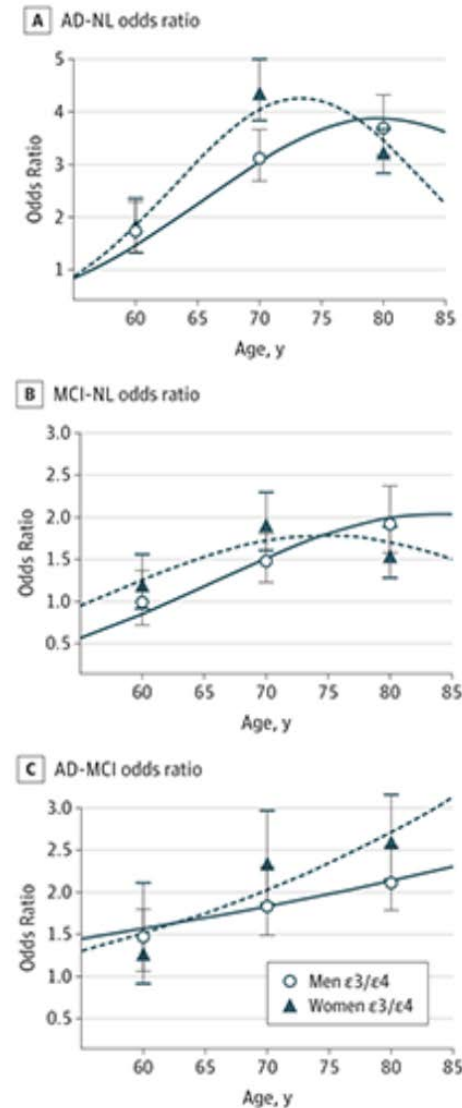
Scott C. Neu, PhD; Judy Pa, PhD; Walter Kukull, PhD; Duane Beekly, BS; Amanda Kuzma, MS; Prabhakaran Gangadharan, MS; Li-San Wang, PhD; Klaus Romero, MD; Stephen P. Arneric, PhD; Alberto Redolfi, PhD; Daniele Orlandi, MsC; Giovanni B. Frisoni, MD; Rhoda Au, PhD; Sherral Devine, PhD; Sanford Auerbach, MD; Ana Espinosa, PhD; Mercè Boada, MD, PhD; Agustín Ruiz, MD, PhD; Sterling C. Johnson, PhD; Rebecca Kosciak, PhD; Jiun-Jie Wang, PhD; Wen-Chuin Hsu, MD; Yao-Liang Chen, MD; Arthur W. Toga, PhD

IMPORTANCE It is unclear whether female carriers of the apolipoprotein E (APOE) $\epsilon 4$ allele are at greater risk of developing Alzheimer disease (AD) than men, and the sex-dependent association of mild cognitive impairment (MCI) and APOE has not been established.

- ↑ Editorial
- + Author Audio Interview
- + Supplemental content

CONCLUSIONS AND RELEVANCE Contrary to long-standing views, men and women with the APOE $\epsilon 3/\epsilon 4$ genotype have nearly the same odds of developing AD from age 55 to 85 years, but women have an increased risk at younger ages.

JAMA Neurol. doi:10.1001/jamaneurol.2017.2188
Published online August 28, 2017.



AD grants **CLINICAL TRIALS** FY16-17 (Total= 59)

NIA contact: Laurie Ryan and Kristina McLinden

Early-stage Clinical Drug Development (Phase I and Phase II Clinical Trials) (23 total)

- Amyloid (8)
- Neurotransmitter receptors (2)
- Metabolism and Bioenergetics (3)
- Vasculature (2)
- Growth Factors and Hormones (1)
- Multi-target (4)
- Oxidative stress (1)
- “other” (2)

Late-stage Clinical Drug Development (Phase III Clinical Trials) (5 total)

- Amyloid (3)
- Vasculature (2)

Non-pharm (23 total)

- Exercise (5)
- Combination therapy (5)
- Cognitive training (5)
- Diet (2)
- Other (6)

Clinical Therapy Development for the Neuropsychiatric Symptoms of AD (8 total)

- Pharmacological (5)
- Non-pharmacological (5)

NIH new clinical trials definition and efforts to enhance recruitment

A research study in which one or more human subjects are prospectively assigned to one or more interventions for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints, to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

- **Increase transparency**
- **Increase data sharing**
- **Increase reporting of results**
- **(even if negative)**

- With Alzheimer's Association implemented a working group to establish a **National strategy to enhance recruitment for clinical trials**
- F2F meeting April 28, 2017; met at AAIC 2017; National strategy by the fall

Please cite this article in press as: Roskies, New NIH Regulations Say Most Basic Human Brain Research Is a Clinical Trial, *Neuron* (2017), <http://dx.doi.org/10.1016/j.neuron.2017.09.001>

Neuron
NeuroView

CellPress

New NIH Regulations Say Most Basic Human Brain Research Is a Clinical Trial

Adina L. Roskies^{1,*}

¹Department of Philosophy, Dartmouth College, Hanover, NH 03755, USA

*Correspondence: adina.roskies@dartmouth.edu

<http://dx.doi.org/10.1016/j.neuron.2017.09.001>

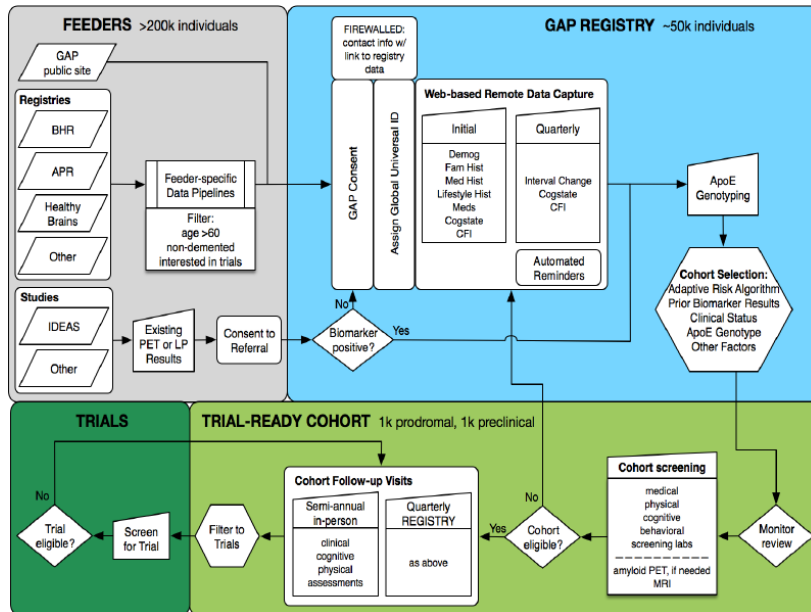
New NIH definitions classify virtually all human brain and behavioral research as clinical trials. The new definitions will change regulatory, reporting, and funding schemes for noninvasive studies such as neuroimaging. Resulting burdens threaten the viability of basic biobehavioral science research.

Global Alzheimer's Platform: TRC-PAD

NIA contact: Laurie Ryan

Trial-Ready Cohort for Preclinical/Prodromal Alzheimer's Disease

- Academic PIs: *Paul Aisen, Reisa Sperling, Jeff Cummings*
- The GAP Foundation: *George Vradenburg, John Dwyer, Debra Lappin, Richard Mohs, Luc Truyen, Jason Bork et al*



- Accelerate drug development for AD and establish an infrastructure to ensure timely recruitment
- TRC-PAD will establish a trial-ready, biomarker-positive cohort (initial n=2000) at ~60 sites across North America, to facilitate recruitment into preclinical and prodromal AD trials.

Continued and NEW Funding Opportunities for FY18

- *Commonalities and Interactions Between Neurodegenerative Diseases (J. Hsiao)*
- *Understanding the Impact of Sex Differences (S. Petanceska)*
- *Biogenesis of Exosomes in Alzheimer's Disease (A. Yang)*
- *Mechanisms of Selective Neuronal Vulnerability in Alzheimer's Disease (B. Wise)*
- *Human Cell biology of genetic variants in Alzheimer's Disease (B. Wise)*
- *Complex biology of resilience in Alzheimer's Disease (S. Petanceska)*
- *Pragmatic Trials for Dementia Care in Long Term Services (P. Bhattachayya/N. Silverberg)*
- *Leveraging Existing Cohort Studies to Clarify Risk and Protective Factors (D. Anderson)*
- *Understanding the Effects of APOE2 (S. Petanceska)*
- *Health disparities in Alzheimer's Disease (C. Elliot)*
- *Relationship between Delirium and Alzheimer's Disease (L. Roberts)*

- Network to establish **definition for cognitive resilience** (M. Wagster)
- **Sensory/motor system impact** on Alzheimer's Disease (C. St Hillaire-Clarke)
- **Misfolded protein polymorphism** in Alzheimer's Disease (A. Yang)
- **Sleep and circadian disorders** in Alzheimer's Disease (M. Mackiewicz)
- **NOI to publish FOA for AD Centers (P30)** (N. Silverberg)

https://www.nia.nih.gov/research/grants-funding

U.S. Department of Health & Human Services

NIH National Institute on Aging

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Office of Extramural Research

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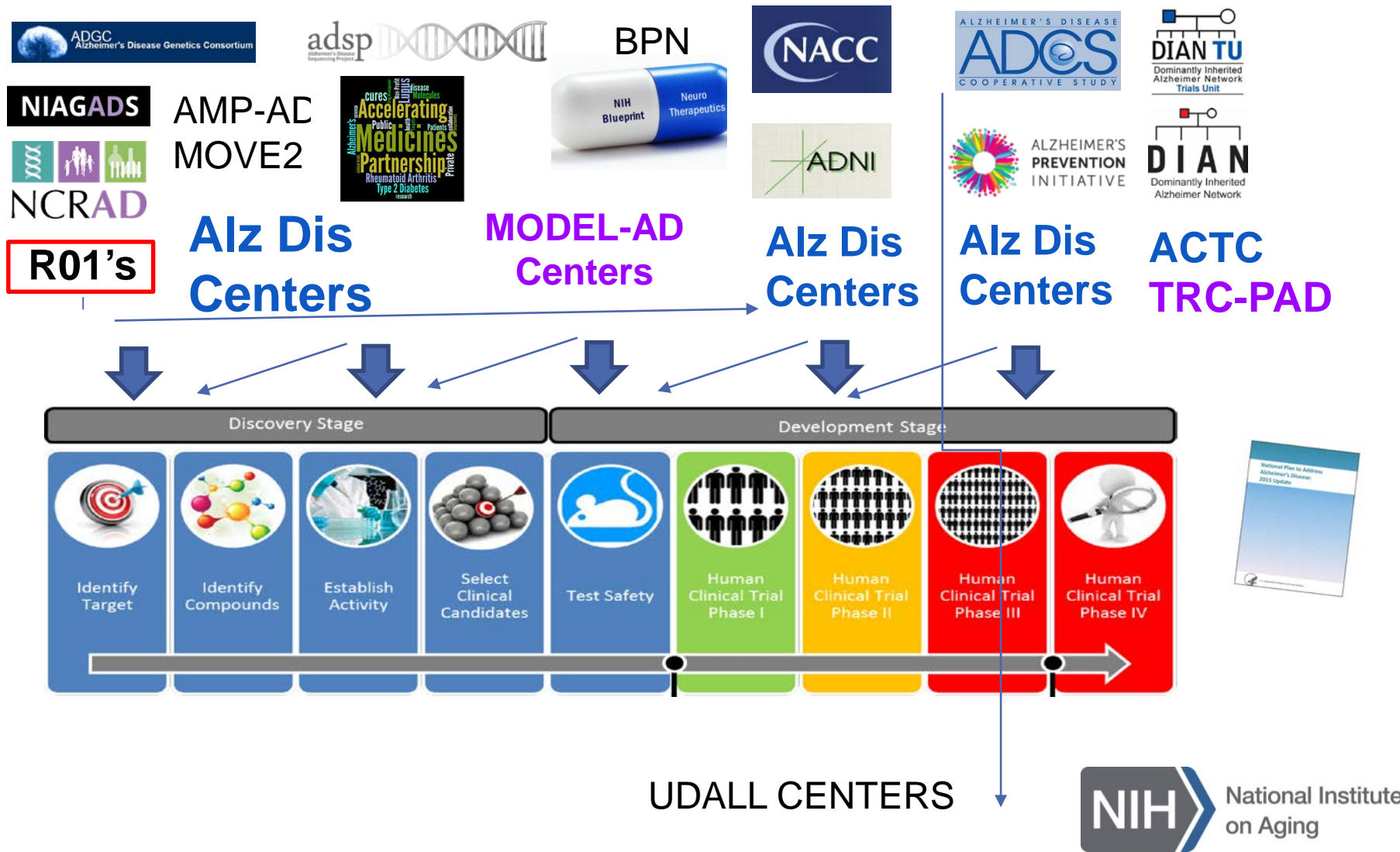
Active Funding Opportunities (RFAs & PAs) For Issuing Organization: NIA

Search within All Matching Records: Search

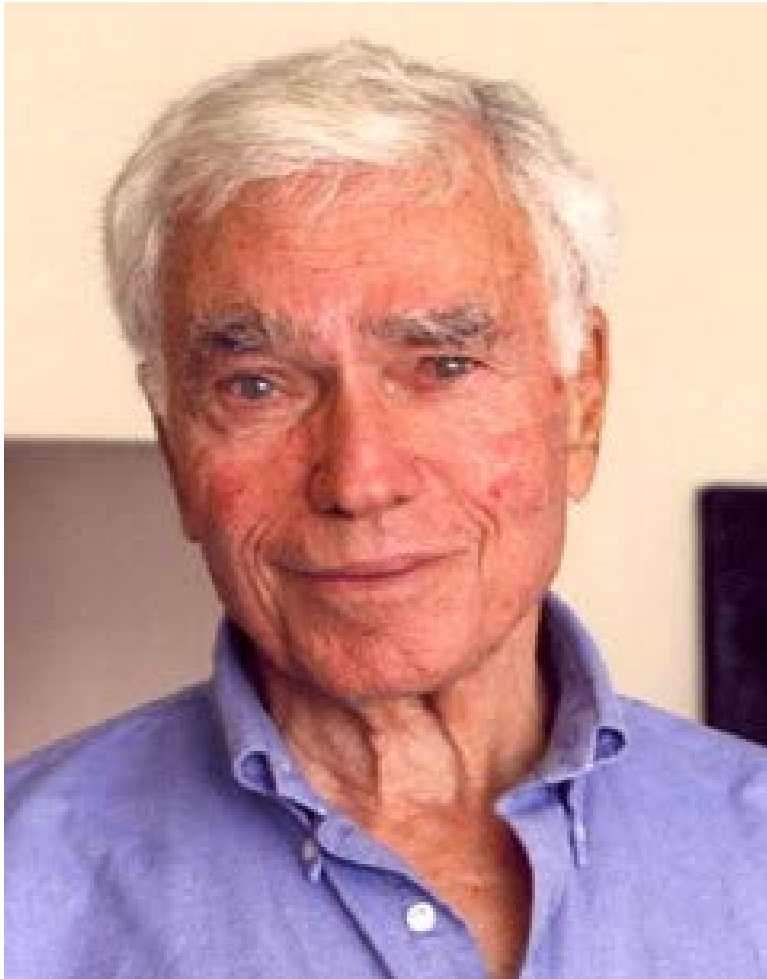
Matching Records: 92 Sorted by: Release Date (Desc) then Announcement Number

Announcement Number	Related Announc.	Issuing Organization	Release Date	Opening Date (SF424 Only) ?	Expiration Date	Activity Code(s)	Title
RFA-AG-18-014	See Related	NIA	09/27/2017	01/20/2018	02/21/2018	U24	Limited Competition: Data Coordinating Center for the Accelerating Medicines Partnership Target Discovery and Preclinical Validation Consortium AMP-AD DCC (U24 Clinical Trial Not Allowed)
RFA-AG-18-013	See Related	NIA	09/27/2017	01/20/2018	02/21/2018	U01	Continuation of the AMP-AD Target Discovery and Preclinical Validation Consortium (U01 Clinical Trial Optional)

Program integration toward achieving the 2025 goal of NAPA (from discovery to the clinic)



Robert D. Terry (1924-2017)



- Hartford Connecticut, January 13, 1924
- San Diego, May 20, 2017
- WWII Veteran, 82nd airborne
- Battle of Bulge, 1943
- Trained many generations of neuropathologists
- Founder of modern neuropathology of neurodegenerative disorders
- Chair of Pathology, 1969
- Fine structure of tangles and plaques, 1960
- First NIA grant for AD research, 1961
- Founder of first AD Research Center, UCSD 1985
- First winner Potamkin prize, 1988
- Met Life Foundation Award, 1990

THANKS