

NINDS Update: National Plan to Address Alzheimer's Disease ADRD Milestones

Roderick A. Corriveau, Ph.D.
Program Director and
AD/ADRD Program Planning Lead, NINDS



NINDS Complements the NIA's Lead Role at the NIH in Responding to the National Plan

Alzheimer's Disease-Related Dementias (ADRD)

Related dementias include frontotemporal dementia (FTD), Lewy body (LBD), mixed, and vascular dementias (VCID).

Goal 1: Prevent and Effectively Treat AD/ADRD by 2025

HHS will identify interim milestones and set ambitious deadlines for achieving these milestones in order to meet this goal.

Action 1.A.8

NINDS/NIH to regularly convene stakeholders for ADRD Summit to review research progress and refine and add new milestones as appropriate, based on recent scientific discoveries.



- NIA leads overall response to National Plan, as well as the priority setting AD Summits

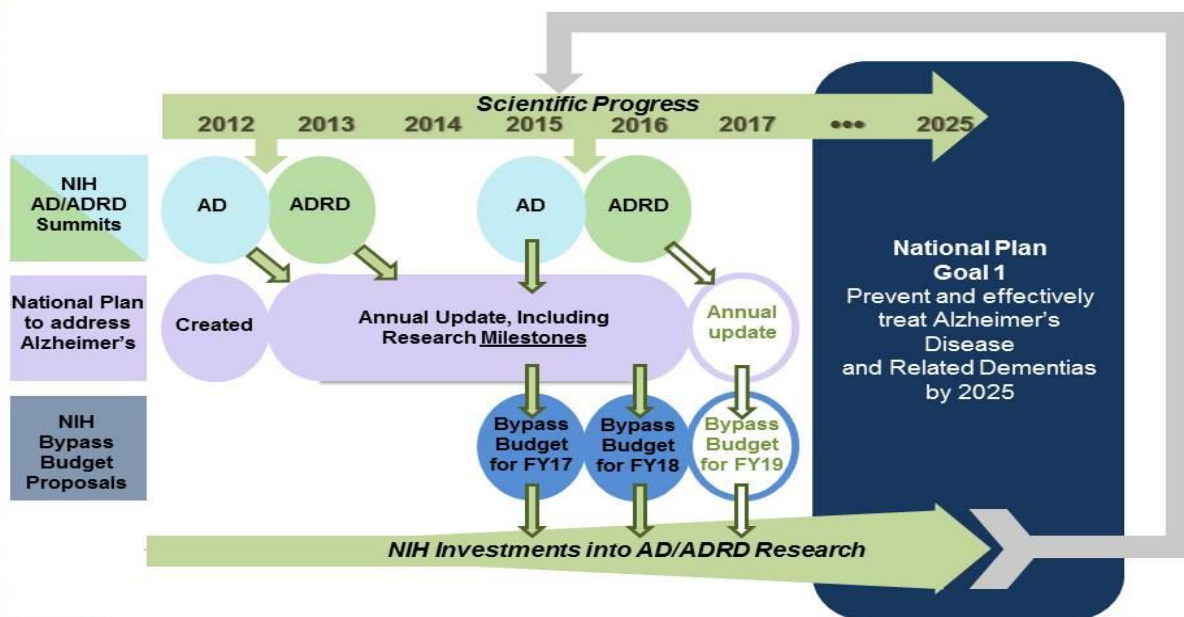


NINDS Complements the NIA's Lead Role at the NIH in Responding to the National Plan

- Interest across neurodegenerative disorders: potential for mechanistic, translational, and clinical synergy
- NINDS AD portfolio focuses on molecular mechanisms of disease pathophysiology: \$66.6M in FY15 (NIH \$589M)
- NINDS ADRD portfolio:
 - ❑ FTD: \$19M in FY15 (NIH \$36M)
 - ❑ LBD: \$7M in FY15 (NIH \$15M)
 - ❑ VCID: \$10M in FY15 (NIH \$72M)
- Lead for NAPA-Responsive ADRD Summits (2013, 2016)



NIH AD/ADRD Research Planning and Relationship to Funding





ADRD 2016 Summit

David M. Holtzman, MD
Washington University SOM
Scientific Chair

Roderick A. Corriveau, PhD
NINDS, Program Director
NIH Lead

- **Steering Committee**
 - Karen Chen, Tom Montine, Bruce Obviagele, Ron Petersen, Tony Phelps
- **Session Committees – 67 Leading Scientists & NGO members**
 - **Overarching: MED** (Chairs: D. Knopman, D. Bennett); **Health Disparities** (J. Manly); **NGO*** (*new in 2016; S. Dickinson, H. Fillit; A. Taylor [nomenclature])
 - **Disease-Specific: LBD** (K. Marder, D. Dickson); **FTD** (W. Seeley, M. Hutton); **VCID** (S. Greenberg, T. Carmichael)



National Institute of
Neurological Disorders
and Stroke



National Institute
on Aging



ADRD Summit 2016 TIMELINE



- **Steering committee formed September 2015**
- **Pre-conference work from October 2015 to March 2016**



- **Presented rationale for revisions to 2013 milestones**
- **Lively discussion among experts**
- **Feedback/opinions from audience; wide range of stakeholders**
 - **490 registrants, 325 in person, 300 online**
- **Closed session to plan post-conference work**
- **Post-conference work from April to August 2016**
- **Report presented to NINDS Council & approved, 9/2016**
- **Report & 37 milestones delivered to NAPA Council, 11/2017**
- **Publication under preparation**

IMPORTANT POINTS



- **Many more recommendations/milestones were suggested than made the final list**
 - Broad agreement that all items included are important research goals
- **Prioritization with Timelines**
 - Based on advancing scientific discovery needed to achieve the NAPA goal of prevention or effective intervention for ADRD by 2025
 - Each Topic Committee reached consensus on priority after long deliberation
- **Timelines are independent of priority**
- **Aspirational, Operational: both are needed**

AD/ADRD Research Increases at NIH



Courtesy of Robert Egge, Richard Hodes, Amy Adams

Orange: Added Funds



NIH Investment in ADRD Research (millions)

Fiscal Year:	2012	2013	2014	2015
Frontotemporal Dementia	\$26	\$32	\$37	\$36
Lewy Body Dementia	Not Determined	Not Determined	\$15	\$15
VCID	Not Determined	Not Determined	\$45	\$72
ADRD Total	Not Determined	Not Determined	Not Determined	\$120 (2016 Est*: \$161)

*unofficial



What Does this Mean for the NIH and NINDS in Moving Forward National Plan Goals?

- 1) Funds have been added for AD/ADRD research. For example, NIH, via NIA, during FY16 received a \$360 M increase in annual funding. During FY16 ADRD research had an estimated \$41 M increase in funding.
- 2) NIA and NINDS, as the leading NIH institutes in supporting AD/ADRD research, are working together to oversee expenditure of these additional funds.
- 3) Added funds shared by NIA with NINDS are used in 2 major ways:
 - i. Funding announcements for ADRD research, for example via the NINDS RFAs this Council round
 - ii. Investigator-initiated AD/ADRD research beyond the payline



FY16 NINDS ADRD Initiatives Responsive to National Plan

RFA-NS16-022: Biomarkers for the Lewy Body Dementias (U01)

- Milestones: LBD FA1-R2, FA2-R3, FA2-R4, FA3-R5, FA3-R6; 4 awards

RFA-NS16-023: Center without Walls for the Identification & Validation of Molecular Mechanisms Contributing to Tau Pathogenesis & Associated Neurodegeneration in Frontotemporal Degeneration (U54)

- Milestone: FTD FA1-R1; 2 awards

RFA-NS16-021: Mechanistic Basis of Diffuse White Matter Disease in Vascular Contributions to Cognitive Impairment & Dementia (VCID)(R01)

- Milestone: VCID FA1-R2; 3 awards

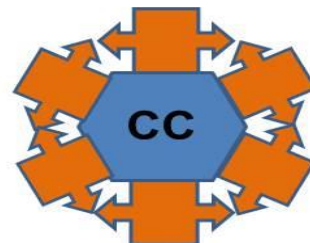
RFA-NS16-019, -020: Small Vessel Vascular Contributions to Cognitive Impairment & Dementia (VCID) Biomarkers Consortium: Coordinating Center (U24) and Biomarkers Development Projects (UH2/UH3)

- Milestone: VCID FA2-R1; 8 awards
- *MarkVCID Consortium Established*

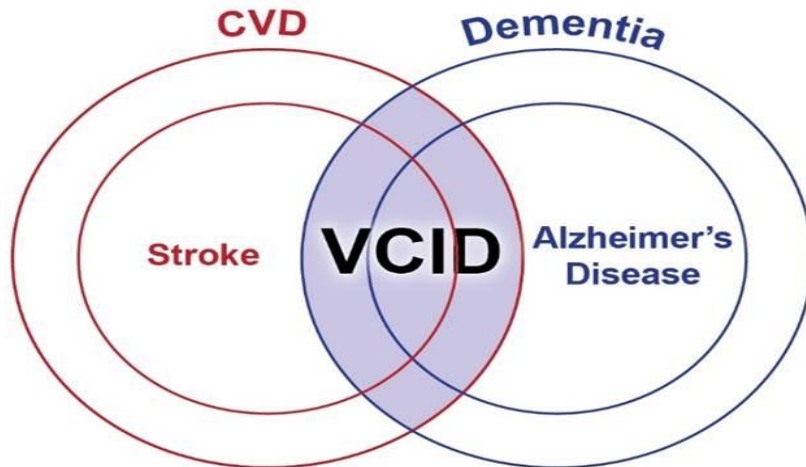


***MarkVCID*: National Consortium Moving VCID Biomarkers Toward the Clinic**

- **Why was MarkVCID established?** To meet large unmet need for clinical trial-ready VCID biomarkers with high potential for positive impact in public health.
- **Established via RFA-16-020, RFA-16-021**
 - 7 project sites across the United States: CA, IL, KY, MD, MA, NM
 - Coordinating Center PI: Dr. Steve Greenberg, MGH
- **External Advisory Committee:** Billy Dunn, Ron Petersen, Tom Montine, Geert Jan Biessels, Rebecca Gottesman
- **Consortium Kickoff Meeting** in February 2017

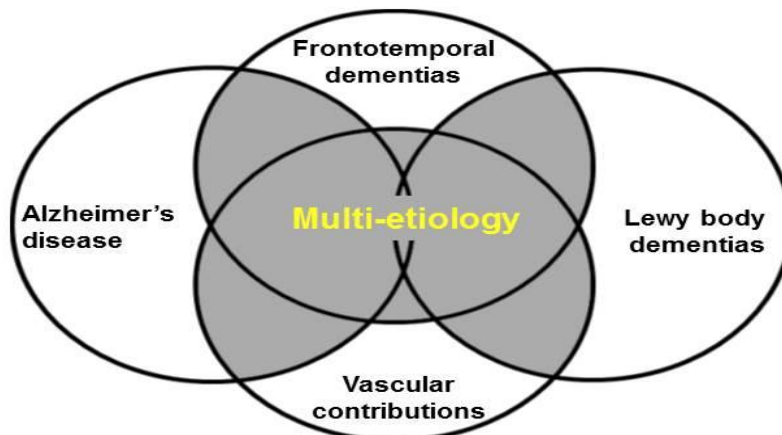


The Science of Vascular Contributions to Cognitive Impairment and Dementia (VCID)



Corriveau, Koroshetz et al., Cell Mol Neurobiol (2016) 36:281-288
Synder, Corriveau et al., Alzheimer's & Dementia (2014) 1-8

ADRD Initiatives that Address Mixed Etiologies



PAR-17-028: Common Mechanisms and Interactions Among Neurodegenerative Diseases (R01)

- Milestone: MED FA1-R2, MED FA2-R5

RFA-AG-15-010: Interdisciplinary Research to Understand the Vascular Contributions to Alzheimer's Disease (*M²OVE AD Consortium*)

- Milestone: VCID FA2-R2

FY17 NINDS ADRD Initiatives Responsive to National Plan

RFA-NS17-016: Leveraging Existing Resources for Research on Lewy Body Dementia (R03)

- Milestone: LBD FA3-R5, FA3-R6

RFA-NS17-017: Frontotemporal Degeneration (FTD) Sequencing Consortium: Discovery, Replication and Validation (UG3/UH3)

- Milestone: FTD FA2-R1

FY17 NINDS ADRD Concepts Responsive to National Plan

Detecting Cognitive Impairment, Including Dementia, in Primary Care and Other Everyday Clinical Settings for the General Public and in Health Disparities Populations

- Milestone: MED FA1-R1

Health Disparities NIA ADRD Initiative NINDS has Joined

PAR-15-349: Health Disparities & AD (R01)

- Milestone: FA1-R1



ALZHEIMER'S DISEASE-RELATED DEMENTIAS SUMMIT 2016

MARCH 29-30
2016



NGO Session: Catalyzing Research Through Unique Programs & Partnerships

Milestone 1. Establish more effective communication between NIH and the NGOs on activities and progress toward the ADRD goals in the off-years between the triennial ADRD Research Summits

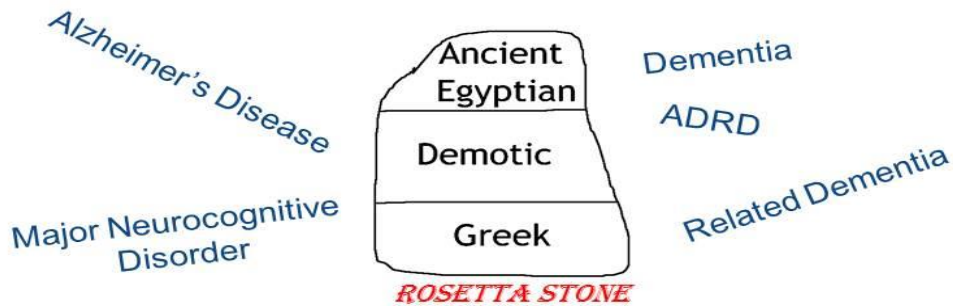
- Post all ADRD Summit 2016 milestones and success criteria publicly [complete]
- NINDS to present annually to NAPA Council on progress toward the ADRD goals/milestones from 2017 onwards [on-going]
- Convene annual meetings during which NINDS, NIA, and NGOs share activities, funding-related information, and progress relevant to the ADRD recommendations [on-going]





Special Joint Session

Milestone: Develop Consistent Nomenclature in Dementia Research & Care



- **Organize a working group of dementia stakeholders**, including founding partnerships with health disparities communities, **to review the current nomenclature** used in public awareness, clinical care services and research and to propose strategies to help advance early differential diagnosis and the understanding of dementia and its underlying causes



NAPA Council's 2016 Recommendation #4:

Emphasis should be given to the standardization of terminology in dealing with cognitive and dementing disorders.

1. An integrated conference should be convened to develop consistent language for cognitive disorders among the scientists, care providers and the public.
2. Engage all of the stakeholders around these issues to reach a consensus for the benefit of persons with dementia, their family members and caregivers, and the scientific and service communities.



Upcoming Summits

- **Dementia Care and Services Research Summit**
- October 16-17, 2017
- **The 3rd Alzheimer's Disease (AD) Summit**
- March 2018
- **The 3rd Alzheimer's Disease-Related Dementias (ADRD) Summit**
- March 2019



U.S. Department of Health & Human Services

NIH MindYourRisks

Know Manage About Resources Partners Healthcare Professionals Research

HIGH BLOOD PRESSURE IS EVEN RISKIER

Stroke and dementia are more likely to affect people with high blood pressure. Understand the links and learn what you can do to minimize your risk.



Thank You NIH Leadership & Colleagues

- Walter Koroshetz
- Richard Hodes
- Robert Finkelstein
- David Owens
- Marian Emr
- Paul Scott
- Ernie Lyons
- Tony Phelps
- Amelie Gubitza
- Beth-Anne Sieber
- Birgit Neuhuber
- Carole Jelsema
- Christine Swanson
- Christine Torborg
- Claudia Moy
- Debra Babcock
- Joel Saydoff
- Jordan Gladman
- Linda MacArthur
- Linda McGavern
- Marg Sutherland
- Monica Flemming
- Natalia Strunnikova
- Nena Wells
- Nina Silverberg
- Salina Waddy
- Patricia Walicke
- Sophia Jeon
- Susan Fowler
- Tracey David
- Jonathan Sabbagh



**Thank you to our
ADRD Summit 2016
partners:**



February 3, 2017 -- Advisory Council Meeting #23

The meeting was held on Friday, February 3, 2017, in Washington, DC. The theme of this Advisory Council meeting was clinical trials for Alzheimer's disease and related dementias and recruitment challenges. Additional afternoon presentations included updates on progress towards a Care and Services Summit, federal workgroup updates, and preparation for the Advisory Council's 2017 Recommendations, due in April 2017. Material available from this meeting is listed below and is also available at <https://aspe.hhs.gov/advisory-council-alzheimers-research-care-and-services-meetings#Feb2017>.

Comments and questions, or alerts to broken links, should be sent to napa@hhs.gov.

General Information

Agenda	[HTML Version] [PDF Version]
Meeting Announcement	[HTML Version] [PDF Version]
Meeting Summary	[HTML Version] [PDF Version]
Public Comments	[HTML Version]

Handouts

Panelist Bios	[HTML Version] [PDF Version]
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Presentation Slides

2017 Recommendations	[HTML Version] [PDF Version]
Alzheimer's Association TrialMatch	[HTML Version] [PDF Version]
Clinical Services Subcommittee Federal Update	[HTML Version] [PDF Version]
Clinical Studies Recruitment Strategy	[HTML Version] [PDF Version]
Development and Use of Registries to Accelerate Enrollment into Alzheimer's Trials	[HTML Version] [PDF Version]
Long-Term Services and Supports Committee Update	[HTML Version] [PDF Version]
National Recruitment Strategy	[HTML Version] [PDF Version]

NINDS Update	[HTML Version] [PDF Version]
Randomized Controlled Trials for Alzheimer's Disease	[HTML Version] [PDF Version]
Strategies to Facilitate Recruitment and Screening for Alzheimer's Clinical Trials	[HTML Version] [PDF Version]
Transforming AD Therapy Development	[HTML Version] [PDF Version]
Update National Research Summit on Care, Services and Supports for Persons with Dementia and Their Caregivers	[HTML Version] [PDF Version]

Videos

Welcome thru Perspectives	[Video]
Rachel, Jessica, George Presentations	[Video]
Keith Presentation and Panel Discussion	[Video]
Public Comments	[Video]
Care Summit and Milestones	[Video]
Federal Workgroups and Adjourn	[Video]

Last Updated: 06/29/2018