Alzheimer's Disease and Related Dementias Research Update

Advisory Council on Alzheimer's Research, Care, and Services Meeting

Richard J. Hodes, M.D.
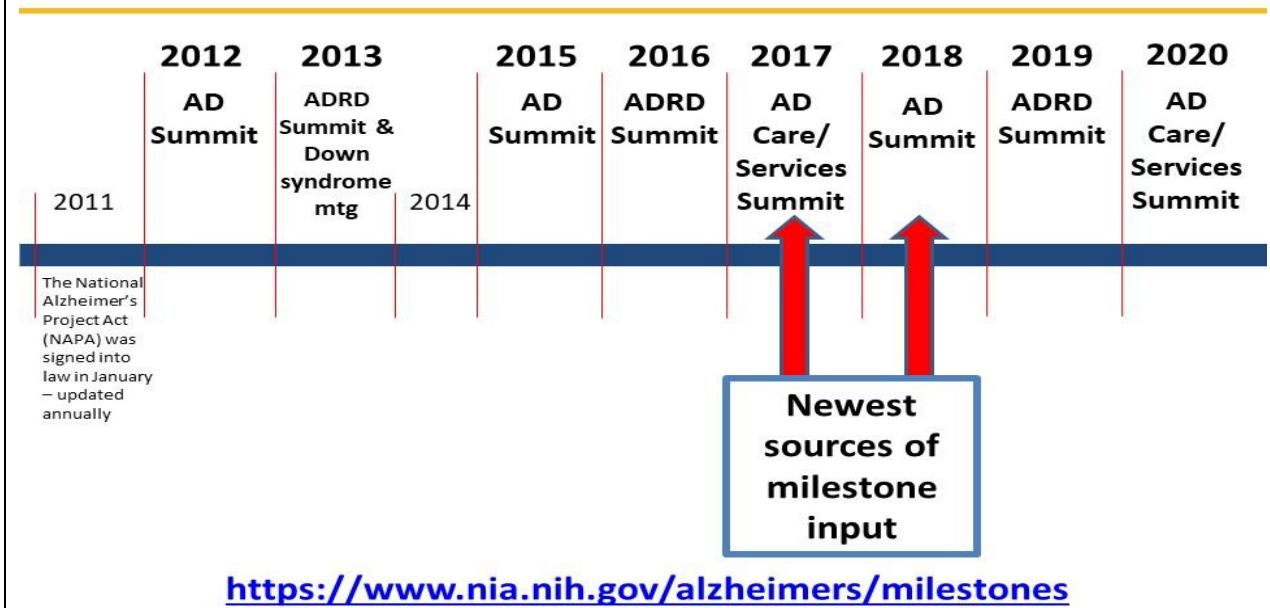Director, NIA
July 29, 2019

NIH National Institute on Aging

NIH Research Implementation Milestones are *Based on Broad Input*

2012	2013		2015	2016	2017	2018	2019	2020
AD Summit	ADRD Summit & Down syndrome mtg		AD Summit	ADRD Summit	AD Care/ Services Summit	AD Summit	ADRD Summit	AD Care/ Services Summit
2011		2014						

The National Alzheimer's Project Act (NAPA) was signed into law in January – updated annually

Newest sources of milestone input

https://www.nia.nih.gov/alzheimers/milestones

Combined External and Internal Input – FY21 AD/ADRD Bypass Budget

Input at 2012-2019 meetings:
- ❑ Academic research community
- ❑ Industry
- ❑ Non-governmental organizations

Other Input:
- ❑ 2017 Request for Information

Development of comprehensive milestones (NIH staff) – based on summit and other input

Trans-NIH (including NINDS) staff discussion; milestones edited to ensure comprehensive inclusion of priorities for FY21

NIH staff "price" the milestones

Final budget estimate for FY21

Bypass Budget Language

SEC. 230. Hereafter, for each fiscal year through fiscal year 2025, the Director of the National Institutes of Health shall **prepare and submit directly to the President for review and transmittal to Congress, after reasonable opportunity for comment, but without change, by the Secretary of Health and Human Services and the Advisory Council on Alzheimer's Research, Care, and Services, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institutes) for the initiatives of the National Institutes of Health pursuant to the National Alzheimer's Plan**, as required under section 2(d)(2) of Public Law 111–375.

Trans-NIH Input for FY21 ADBB

- 18 Institutes/Centers/Offices contributed to the development of this year's professional judgment budget:

  - NIA
  - NEI
  - NHLBI
  - NIAAA
  - NIAMS
  - NIBIB

  - NICHD
  - NIDA
  - NIDCD
  - NINR
  - NIDCR
  - NIDDK

  - NIEHS
  - NIMH
  - NIMHD
  - NINDS
  - FIC
  - NIH Office of AIDS Research

Using CADRO as a Framework

- The eight CADRO (Common Alzheimer's Disease Research Ontology) categories provide the overarching framework for the FY21 AD Bypass Budget and narrative.

- CADRO provides the framework for IADRP (the International Alzheimer's Disease Research Portfolio) and will allow tracking of implementation in the budget areas in future years.

Professional Judgment Budget FY 2021, Projected Costs and Additional Resources Needed
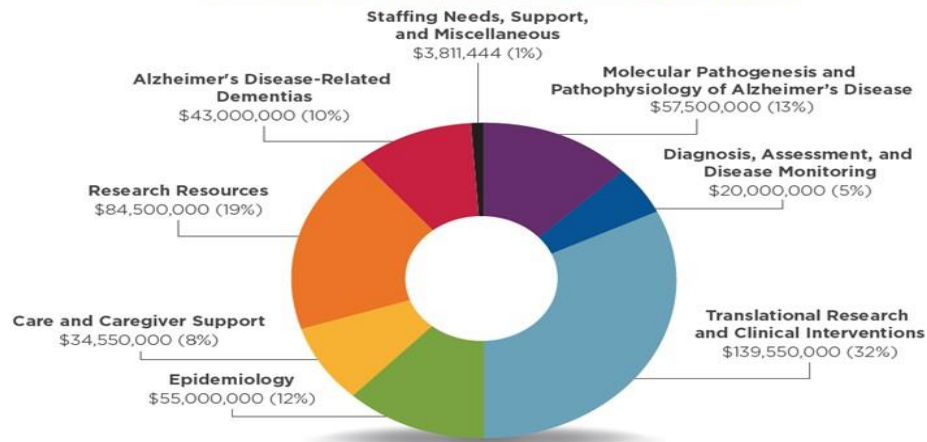
Molecular Pathogenesis and Pathophysiology of Alzheimer's Disease	$57,500,000
Diagnosis, Assessment, and Disease Monitoring	$20,000,000
Translational Research and Clinical Interventions	$139,550,000
Epidemiology	$55,000,000
Care and Caregiver Support	$34,550,000
Research Resources	$84,500,000
Alzheimer's Disease-Related Dementias	$43,000,000
Staffing Needs, Support, and Miscellaneous	$3,811,444
Projected Costs for New AD/ADRD Research	$437,911,444
Less Funding from Prior Appropriations that is Available for New AD/ADRD Research	($84,000,000)
Additional FY 2021 Resources Needed for New AD/ADRD Research	$353,911,444

Distribution of FY 2021 Projected Costs Across Research Areas

Distribution of FY 2021 Projected Costs Across Research Areas

Total Projected Costs: $437,911,444*

Additional Resources Needed for New Research: $353,911,444

Staffing Needs, Support, and Miscellaneous
$3,811,444 (1%)

Alzheimer's Disease-Related Dementias
$43,000,000 (10%)

Research Resources
$84,500,000 (19%)

Care and Caregiver Support
$34,550,000 (8%)

Epidemiology
$55,000,000 (12%)

Molecular Pathogenesis and Pathophysiology of Alzheimer's Disease
$57,500,000 (13%)

Diagnosis, Assessment, and Disease Monitoring
$20,000,000 (5%)

Translational Research and Clinical Interventions
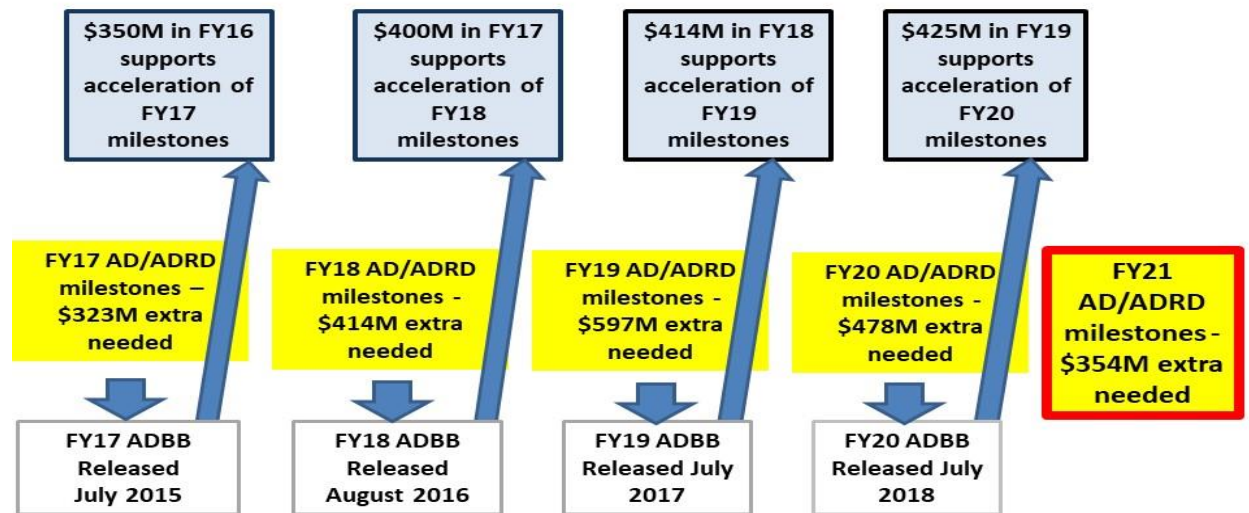$139,550,000 (32%)

*In FY 2021, the projected costs of resources needed for new research to enhance investigator-initiated research grants and initiatives to meet the 2025 treatment/prevention goal is $438 million. This estimate will be reduced by $84 million in funding that is projected to become available after completion of previously funded AD/ADRD research initiatives. As a result, the additional resources needed for new research in the FY 2021 budget is $354 million.
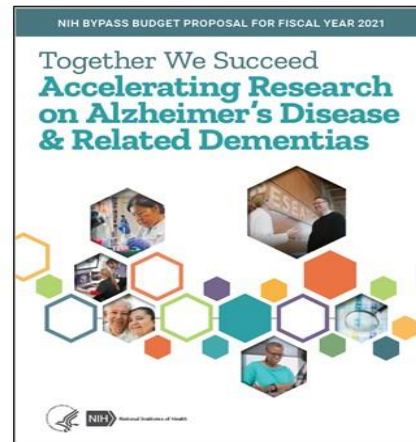
Total Resource Needs, FY21

FY 2020 President's Budget Request for AD/ADRD Research (baseline estimate)	$2,142,000,000
Difference Between FY 2020 President's Budget Request and FY 2019 Appropriation for AD/ADRD Research	$326,000,000
Additional FY 2021 Resources Needed for New AD/ADRD Research	$353,911,444
TOTAL FY 2021 Resources Needed for AD/ADRD Research	$2,821,911,444

Timing of ADBB Releases and AD/ADRD Appropriations

$350M in FY16 supports acceleration of FY17 milestones	$400M in FY17 supports acceleration of FY18 milestones	$414M in FY18 supports acceleration of FY19 milestones	$425M in FY19 supports acceleration of FY20 milestones	
FY17 AD/ADRD milestones – $323M extra needed	FY18 AD/ADRD milestones - $414M extra needed	FY19 AD/ADRD milestones - $597M extra needed	FY20 AD/ADRD milestones - $478M extra needed	FY21 AD/ADRD milestones - $354M extra needed
FY17 ADBB Released July 2015	FY18 ADBB Released August 2016	FY19 ADBB Released July 2017	FY20 ADBB Released July 2018	

AD/ADRD Progress Report – An important part of the ADBB

The AD/ADRD Bypass Budget *narrative* includes many examples of recent **science advances across multiple research topics** – basic to clinical, care/caregiving, etc.

NIH BYPASS BUDGET PROPOSAL FOR FISCAL YEAR 2021

Together We Succeed
Accelerating Research on Alzheimer's Disease & Related Dementias

NIH National Institutes of Health

https://www.nia.nih.gov/about/together-we-succeed-accelerating-research-on-alzheimers-disease-and-related-dementias

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Implementation Tracking

- **IADRP: http://iadrp.nia.nih.gov/**

  ➢*Will continue to offer detailed tracking of awards under the CADRO categories*

- **Web-based tool for tracking funding initiatives and activities: https://www.nia.nih.gov/research/milestones**

  ➢*Newly revised*

  ➢*Aimed at addressing the research milestones associated with NAPA*

Complex Considerations for this and Future Bypass Budgets

- Past/current appropriations, including funds that have allowed us to address milestones "in advance"

- Progress on milestones — what have we accomplished? what new milestones are emerging?

- Funds that are becoming available each year as prior awards end

- Incorporating new milestones, including focus on care/services, target identification and drug development

- Emerging investments by other groups — what gaps are best filled by the NIA/NIH?

- Successes in recruiting new and established researchers to AD/ADRD research and capacity of the field

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Save the Date!

**RESEARCH SUMMIT ON
DEMENTIA CARE**
Building Evidence for Services and Supports

The 2020 National Research Summit on
Care, Services, and Supports for
Persons with Dementia and Their Caregivers

March 24-25, 2020
Natcher Conference Center
NIH Main Campus, Bethesda, MD

NIH National Institute on Aging

Current List of Steering Committee Members

- Jennifer Wolff, Johns Hopkins University, Steering Committee Co-chair
- David Reuben, UCLA, Steering Committee Co-chair
- Susan Beane, Healthfirst
- Malaz Boustani, Indiana University School of Medicine
- Chris Callahan, Indiana University School of Medicine
- Elena Fazio, NIA
- Jason Karlawish, University of Pennsylvania
- Ian Kremer, LEAD Coalition
- Helen Lamont, HHS ASPE
- Katie Maslow, GSA
- Michael Monson, Centene Corporation
- Vincent Mor, Brown University
- Joanne Pike, Alzheimer's Association
- Robyn Stone, LeadingAge
- Sheryl Zimmerman, University of North Carolina
- Pending invitations remain, including:
    - Person Living with Dementia
    - Caregiver to a Person Living with Dementia

RESEARCH SUMMIT ON
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NIH National Institute on Aging