

# Alzheimer's and Related Dementias Research: Policy and Program Updates

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## 2018 Fall ADC Meeting

Richard Hodes, M.D.  
Director  
National Institute on Aging

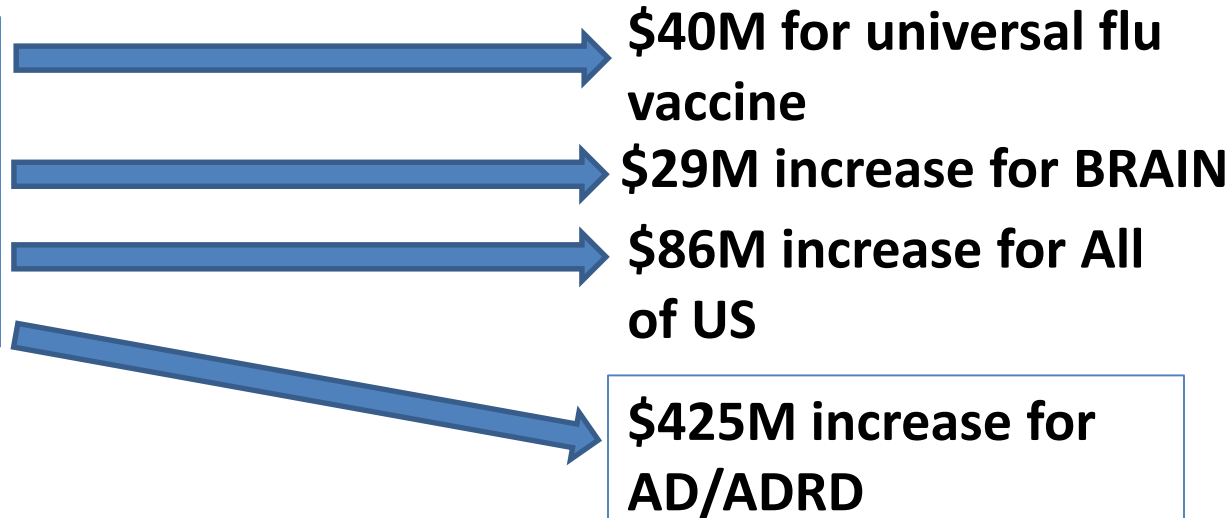
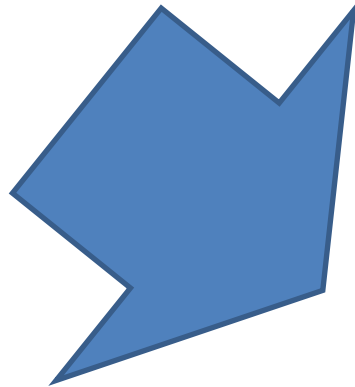
October 20, 2018



# FY19 Budget Status – Funding Increases Across the Board

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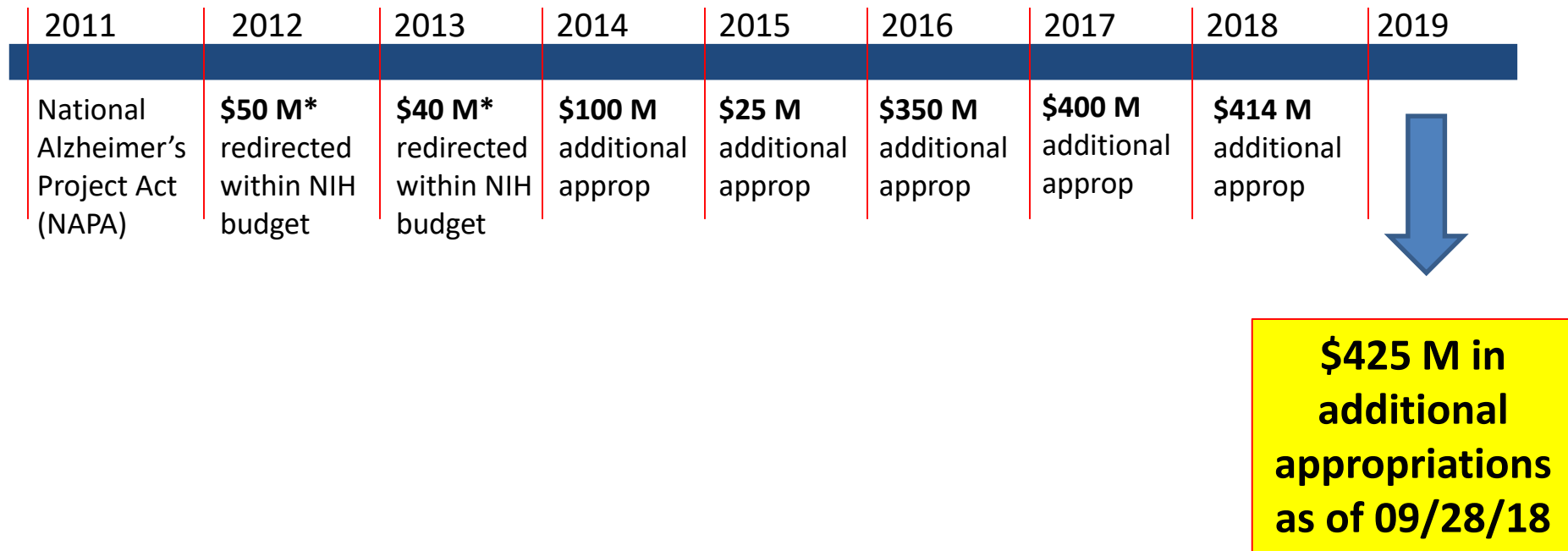
**\$39 Billion  
for the NIH**



- **\$3.1B for the NIA**
- \$84M increase for NIA research; percent increase comparable to other ICs
- **All divisions will benefit**
  - DBSR
  - DGCG
  - DAB
  - DN

# AD/ADRD Targeted Increases

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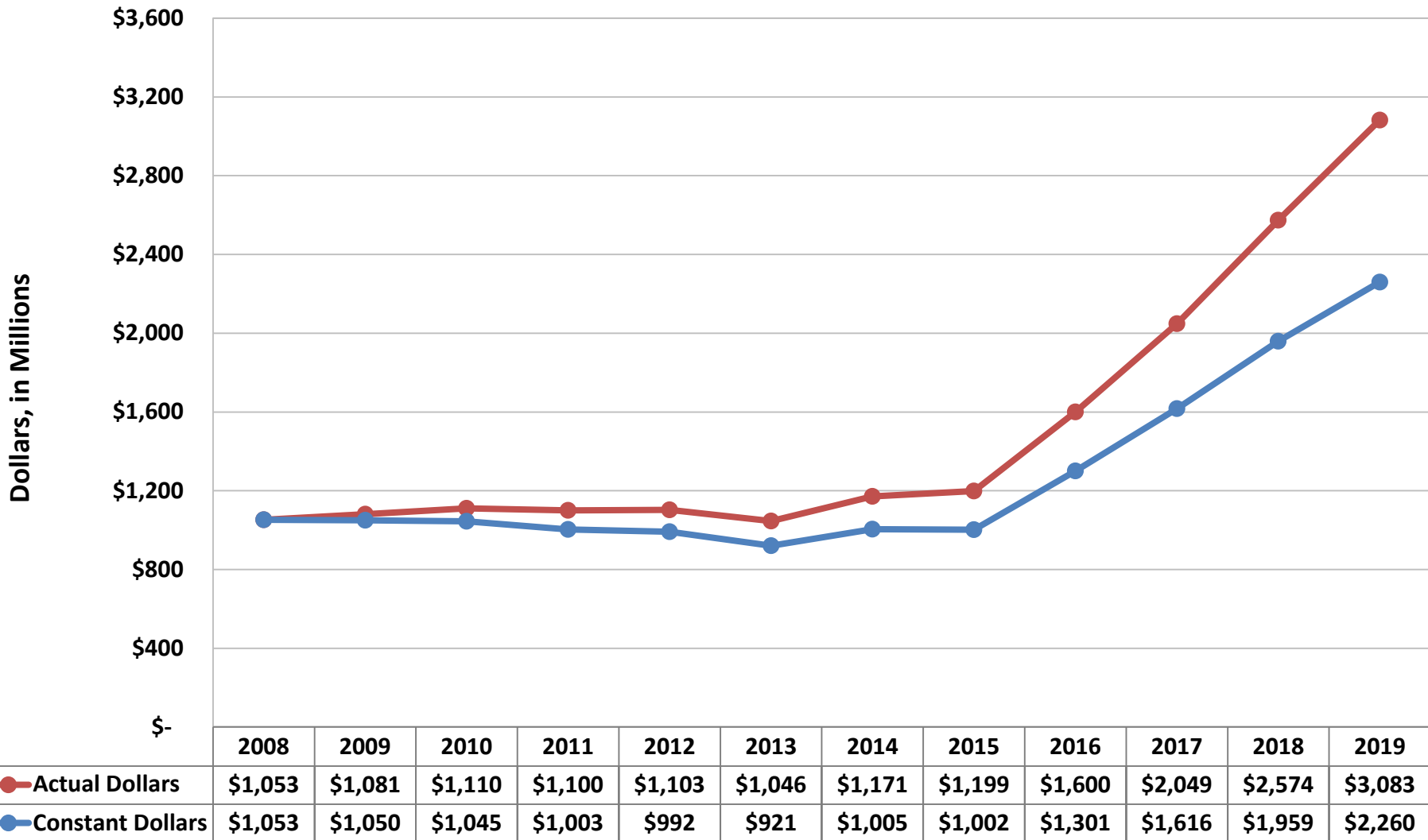


\*one-year money

Years displayed are Fiscal Years

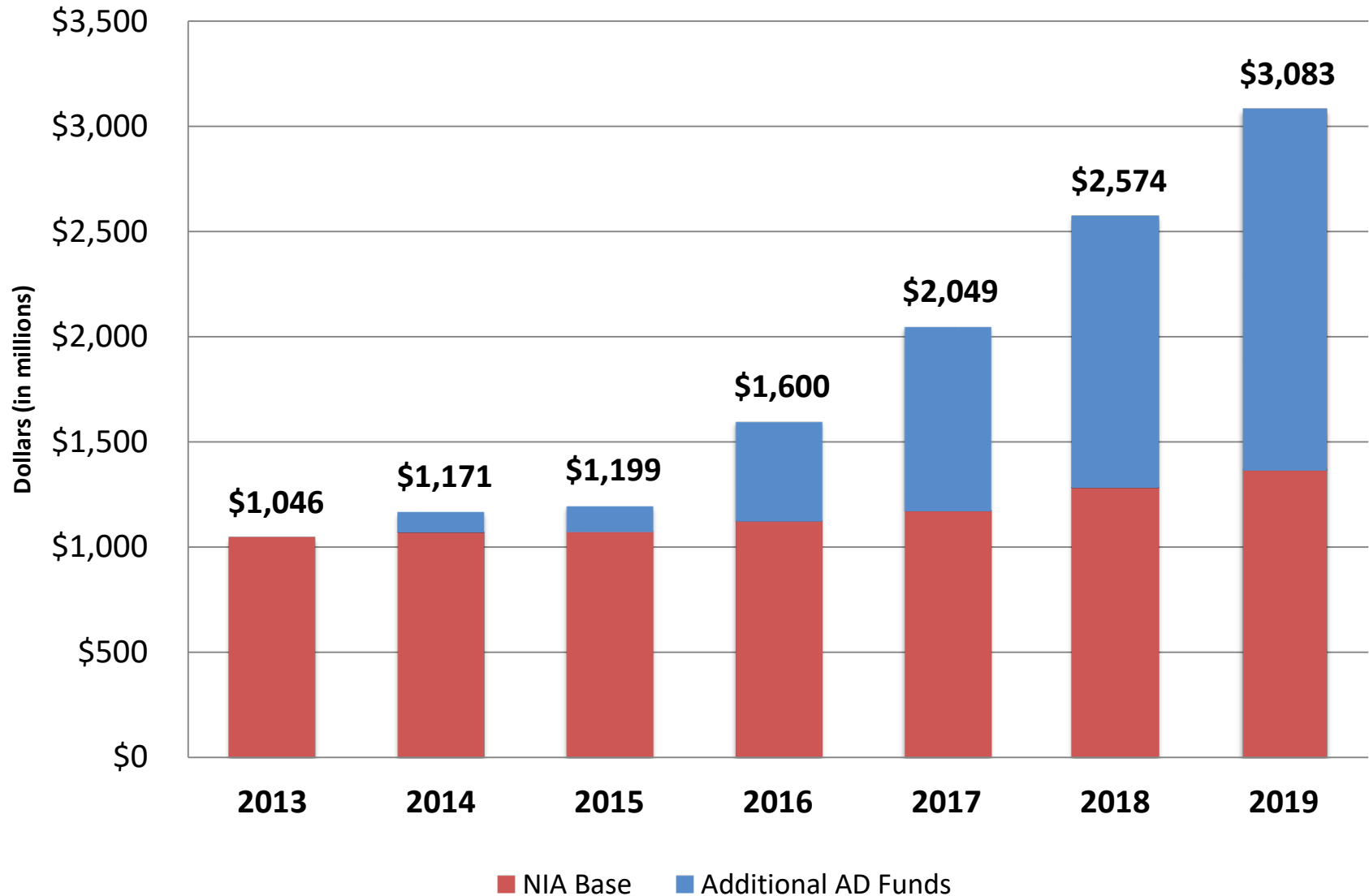
# NIA Appropriations

## *Fiscal Years 2008-2019*



# NIA Appropriations

*Fiscal Years 2013-2019*



# Allocations for Competing Research Grant Awards, FY 2018

CSR-reviewed Research Applications				
	General Pay line, <\$500k	General Pay line, =>\$500k	AD/ADRD pay line, <\$500k	AD/ADRD pay line, =>\$500k
All applications except as noted below	23	20	28	25
N.I. R01s	26	23	31	28
E.S.I. R01s	29	26	33	30

*New investigator: An applicant who has not received a prior R01 award or its equivalent.*

*Early-Stage Investigator: A new investigator who is within 10 years of finishing research training.*

*First-time renewing; A former new or early-stage investigator's first renewal application when the investigator has no other NIH grant support.*

*ADRD: Research on Alzheimer's disease and on Alzheimer's-related Dementias*

# FY 2018 Pay Lines

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NIA-reviewed Applications		
	General pay line	AD/ADRD pay line
Program projects (PO1)	33	38
Other NIA-reviewed research	33	38

# FY 2018 Pay Lines

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Training-related Applications		
	General pay line	AD/ADRD pay line
Training grants (T32, T35)	21	35
Career awards	21	28
Fellowships	28	32



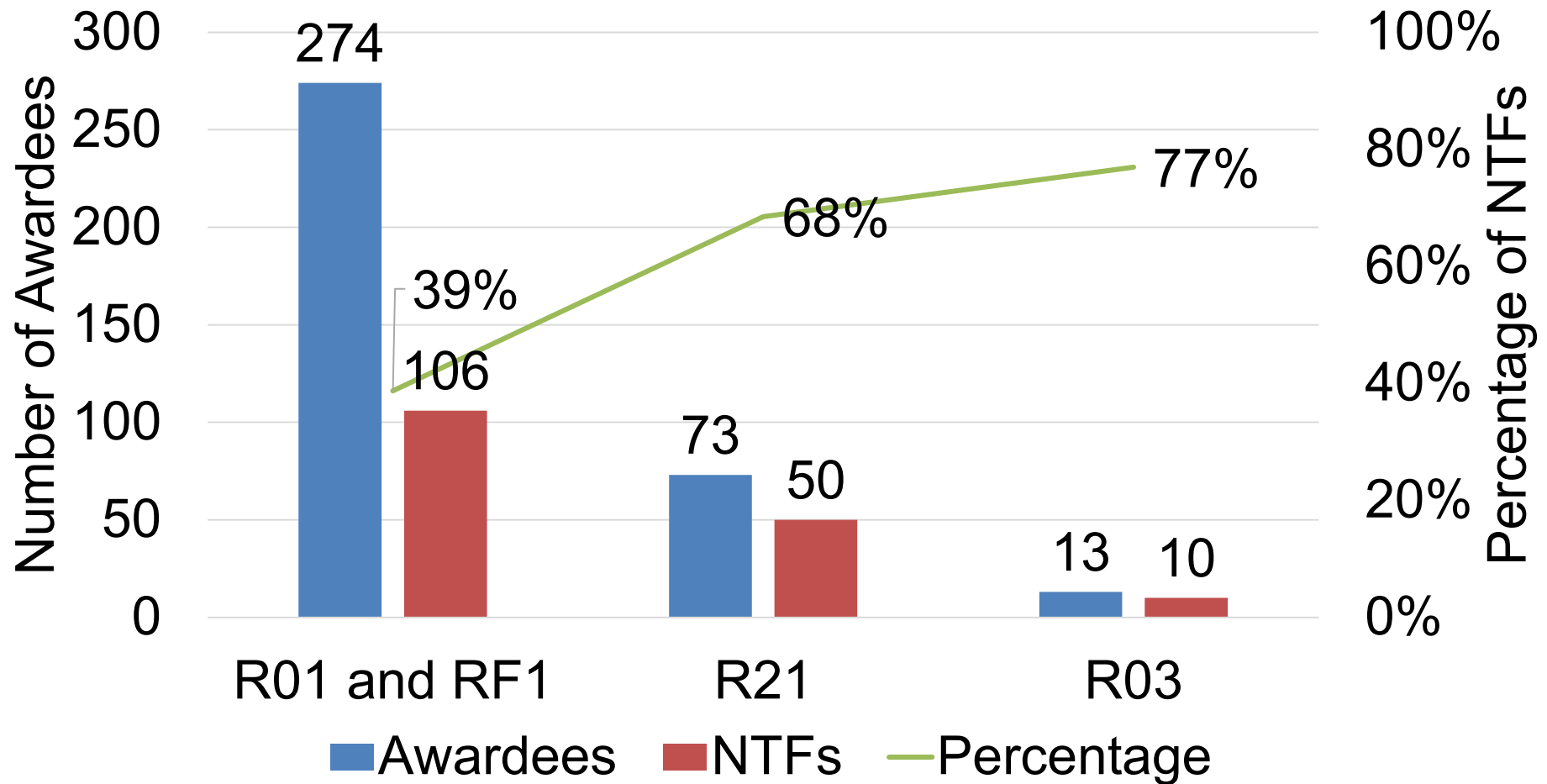
# Recruitment to a growing AD/ADRD workforce

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**Over 1/4** of NIA's Alzheimer's and related dementias awardees from Fiscal Year 2015-2018 were either new or early stage investigators

**Over 1/3** of NIA's Alzheimer's and related dementias awardees were new to the field

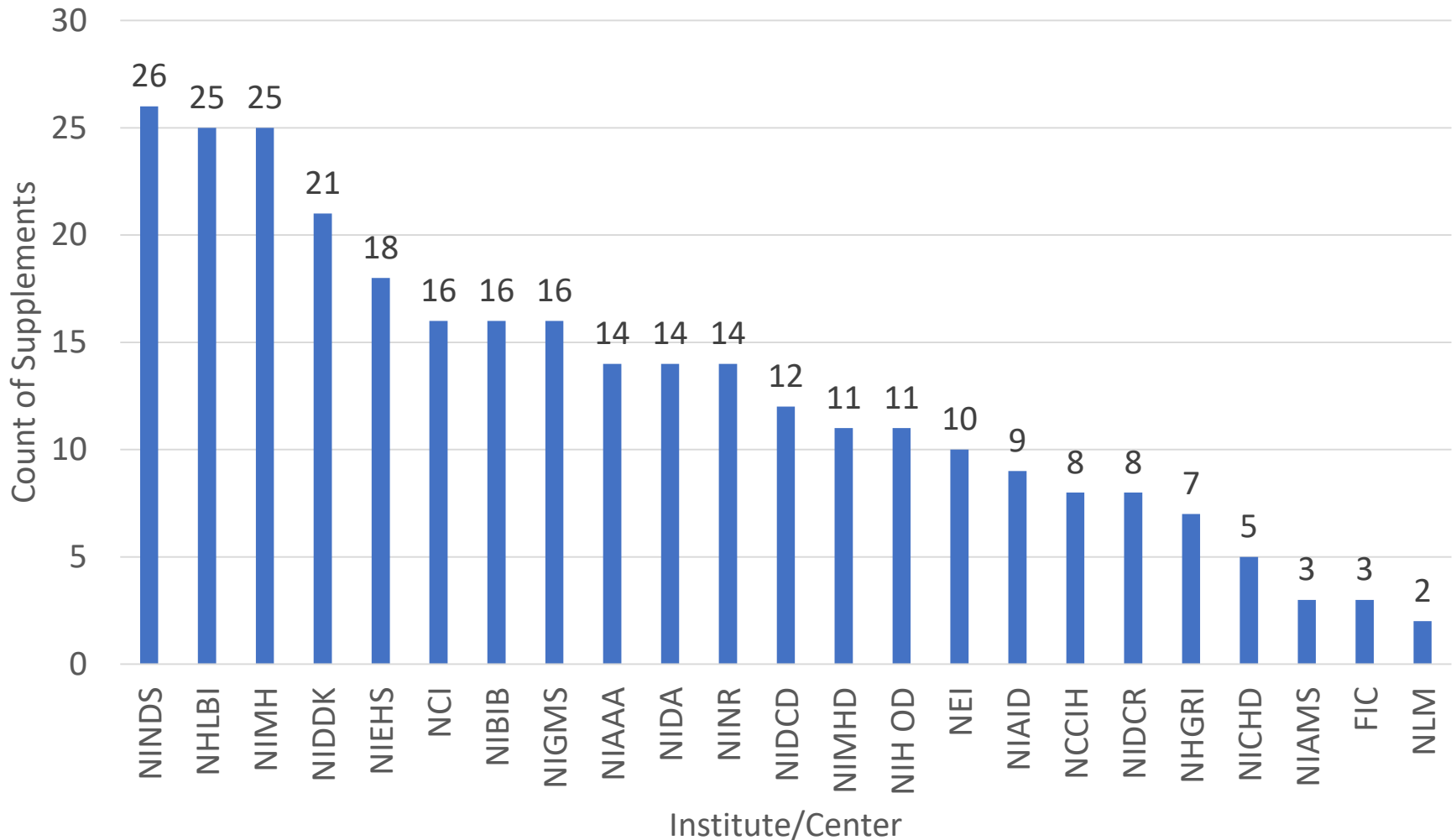
# AD/ADRD Awardees/ NTF FY2017



New to AD/ADRD Field (NTF): Investigator who never had any prior NIH AD/ADRD award/ application

# Supplements by Institute/Center

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# Opportunities for Small Business

## – AD/ADRD specific

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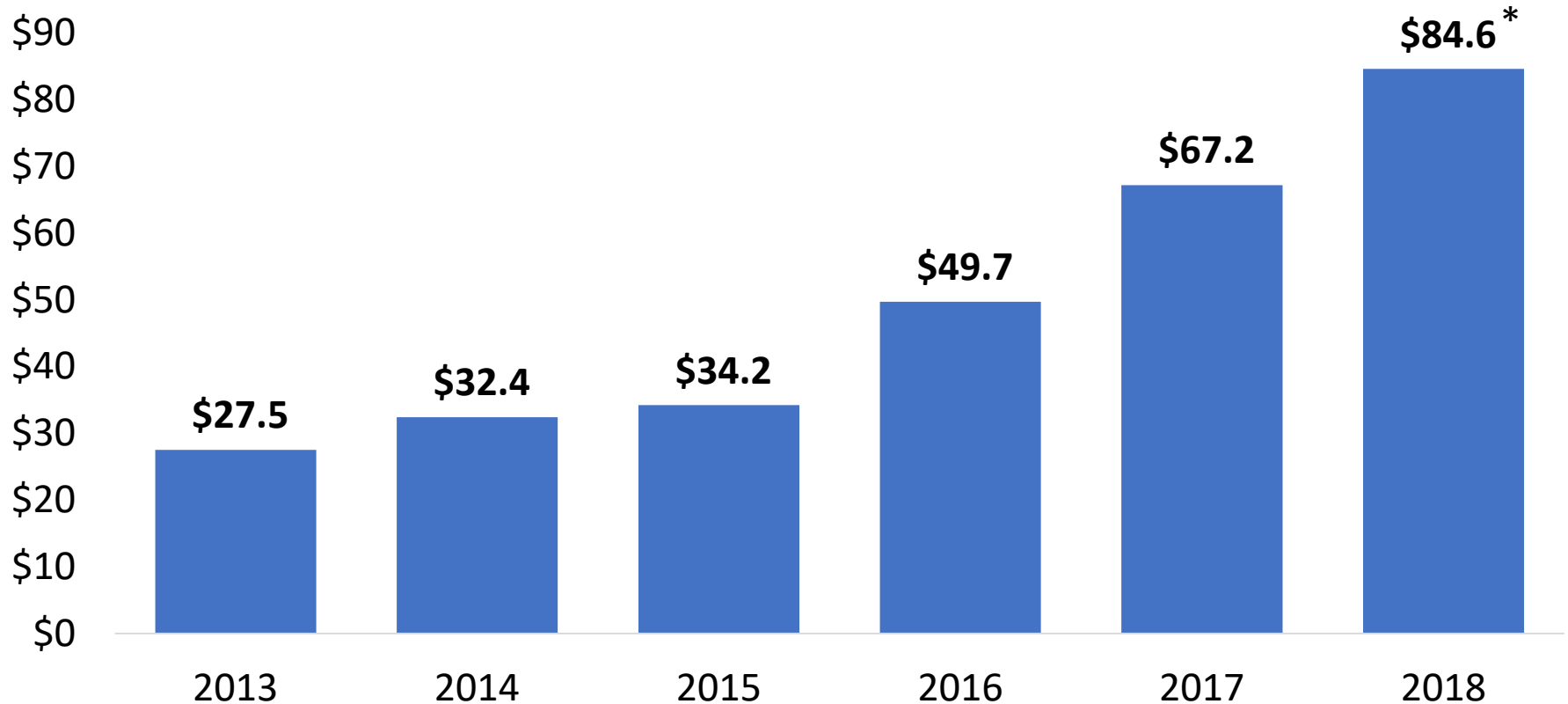
- **Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R41/R42/R43/R44)**
- **Tools for Clinical Care and Management of Alzheimer's Disease (AD) and its Comorbidities (R41/R42/R43/R44)**
- **Development of Socially-Assistive Robots (SARs) to Engage Persons with Alzheimer's Disease (AD) and AD-Related Dementias (ADRD), and their Caregivers (R41/R42/R43/R44)**

**<https://www.nia.nih.gov/research/grants-funding/small-business-innovation-research-and-technology-transfer-programs>**

# NIA SBIR/STTR Obligations

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Dollars in Millions



\*estimate

# Tracking Funding Opportunities

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## **Concept Approvals:**

<https://www.nia.nih.gov/approved-concepts>

## **General FOAs:**

<https://www.nia.nih.gov/research/funding>

## **Alzheimer's Disease and Related Dementias FOAs:**

<http://www.nia.nih.gov/AD-FOAs>

## **Follow our “Inside NIA” blog:**

<https://www.nia.nih.gov/research/blog>

# Neurodegenerative Disorders Biorepositories at Indiana University

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Number of aliquots of...	NCRAD
DNA	143,509
Plasma	85,222
Serum	91,869
RNA	3,092
Whole Blood	5,593
PBMC	20,156
Fibroblast	0
CSF	11,260
Urine	0
Tissue	350



Study	Population	# Plasma Aliquots
GEMS*	Elderly nondemented	43,915
ARTFL/LEFFTDS /4RTNI-2	FTD	30,173
NiAD/ADDS	Down Syndrome	5,198
ADNI-Depression	Cognitive decline in late life depression	5,088
SALAD	Mild/Moderate AD (clinical trial)	827
LEADS	Early onset AD	21

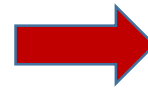
***Limited high quality plasma  
for AD, MCI, HC***

\* GEMS (2000-2008) – older collection protocol

# Neurodegenerative Disorders Biorepositories at Indiana University

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Number of aliquots of...	NCRAD
DNA	143,509
Plasma	86,412
Serum	91,709
RNA	3,092
Whole Blood	5,593
PBMC	20,156
Fibroblast	0
CSF	11,260
Urine	0
Tissue	350



Study	Population	# Serum Aliquots
GEMS*	Elderly nondemented	74,404
ARTFL/LEFFTDS/ 4RTNI-2	FTD	7,529
ADNI-Depression	Cognitive decline in late life depression	4,958
NiAD/ADDS	Down Syndrome	4,374
SALAD	Mild/Moderate AD (clinical trial)	426
LEADS	Early onset AD	18

***Limited high quality serum  
for AD, MCI, HC***

\* GEMS (2000-2008) – older collection protocol



# Neurodegenerative Disorders Biorepositories at Indiana University

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Number of aliquots of...	NCRAD
DNA	143,509
Plasma	86,412
Serum	91,869
RNA	3,092
Whole Blood	5,593
PBMC	20,156
Fibroblast	0
CSF	11,260
Urine	0
Tissue	350

*Limited high quality CSF for  
AD, MCI, HC*



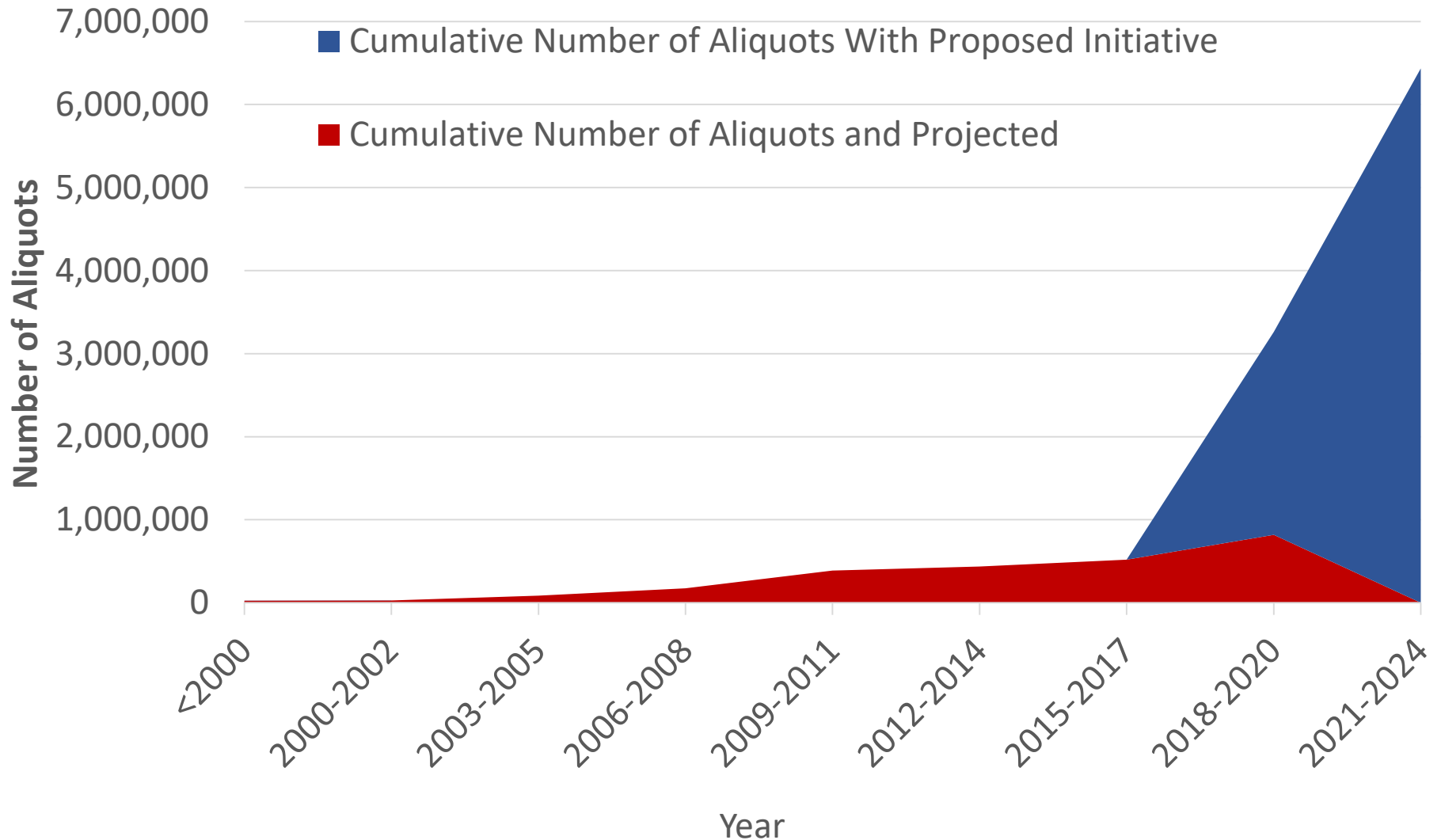
Study	Population	# CSF Aliquots
ARTFL/LEFFTDS/ 4RTNI-2	FTD	10,449
SALAD	Mild/Moderate AD (clinical trial)	777
LEADS	Early onset AD	34

# Proposal: Planning Ahead

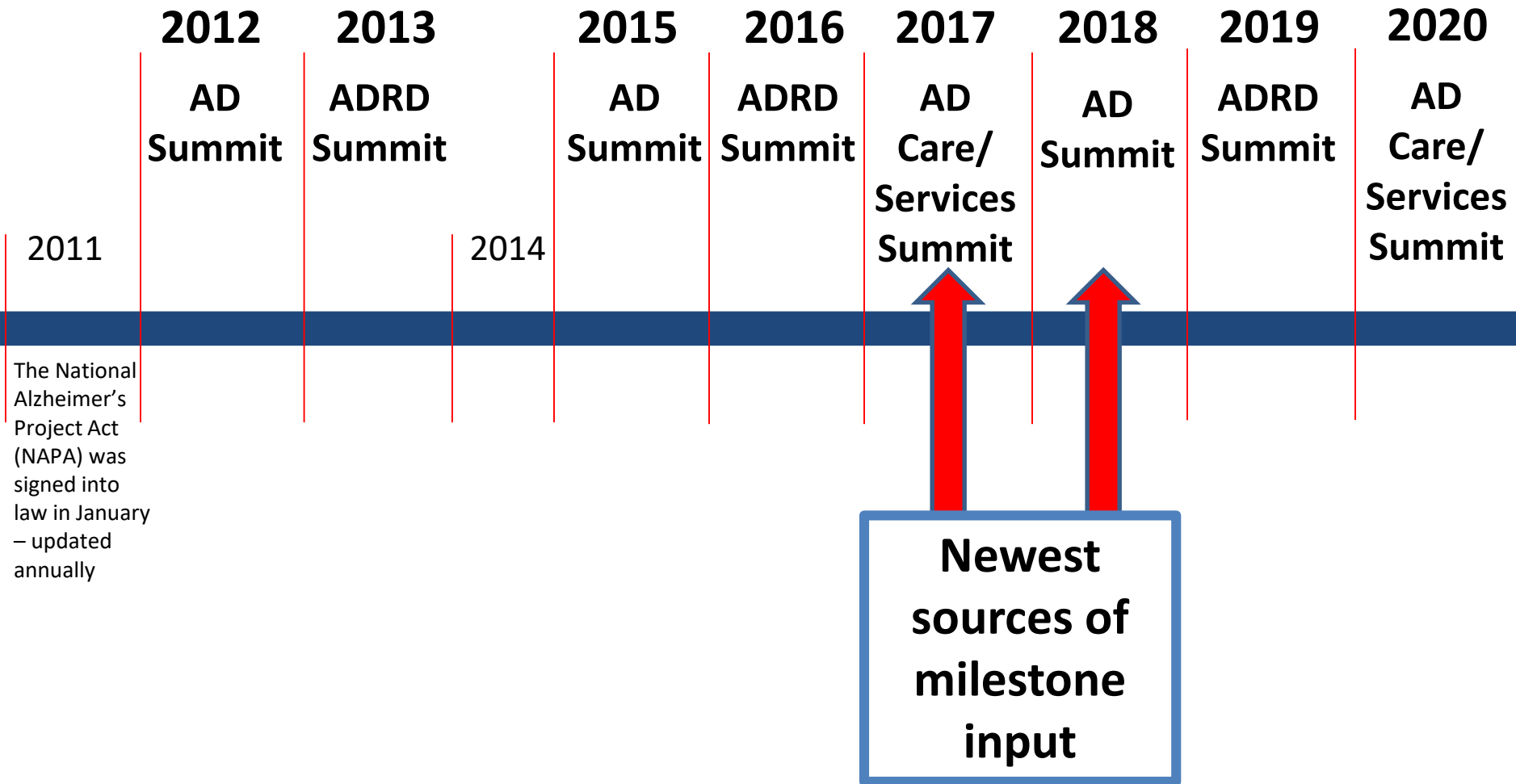


	Pilot N=3,000	Full Program (All ADCs) N=10,000 blood/yr; 5,000 CSF/year				
	2019	2020	2021	2022	2023	2024
Plasma						
DNA						
Serum						
PBMCs						
RNA						
CSF						

# Projected Increase in Centrally Banked Aliquots



# NIH Research Implementation Milestones are *Based on Broad Input*



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

# Combined External and Internal Input – FY20 AD/ADRD Bypass Budget

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Input at 2012-2018 meetings:

- ☐ Academic research community
- ☐ Industry
- ☐ Non-governmental organizations

Other Input:

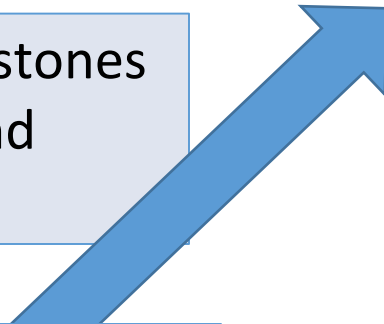
- ☐ 2017 Request for Information



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 FY20



NIH staff  
“price” the  
milestones



**Final budget  
estimate for  
FY20**

# Bypass Budget Language

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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 FY20 ADBB

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- Thirteen Institutes and Centers provided feedback that contributed to the development of this year's professional judgment budget:

- |         |         |
|---------|---------|
| ■ NIA   | ■ NIEHS |
| ■ NINDS | ■ NIGMS |
| ■ NHLBI | ■ NIMH  |
| ■ NIAAA | ■ NINR  |
| ■ NICHD | ■ NCATS |
| ■ NIDCR | ■ FIC   |
| ■ NIDDK |         |

# Using CADRO as a Framework

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- The eight CADRO (Common Alzheimer's Disease Research Ontology) categories provide the overarching framework for the FY20 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.



# FY20 Professional Judgment Budget – Additional Funding Needs

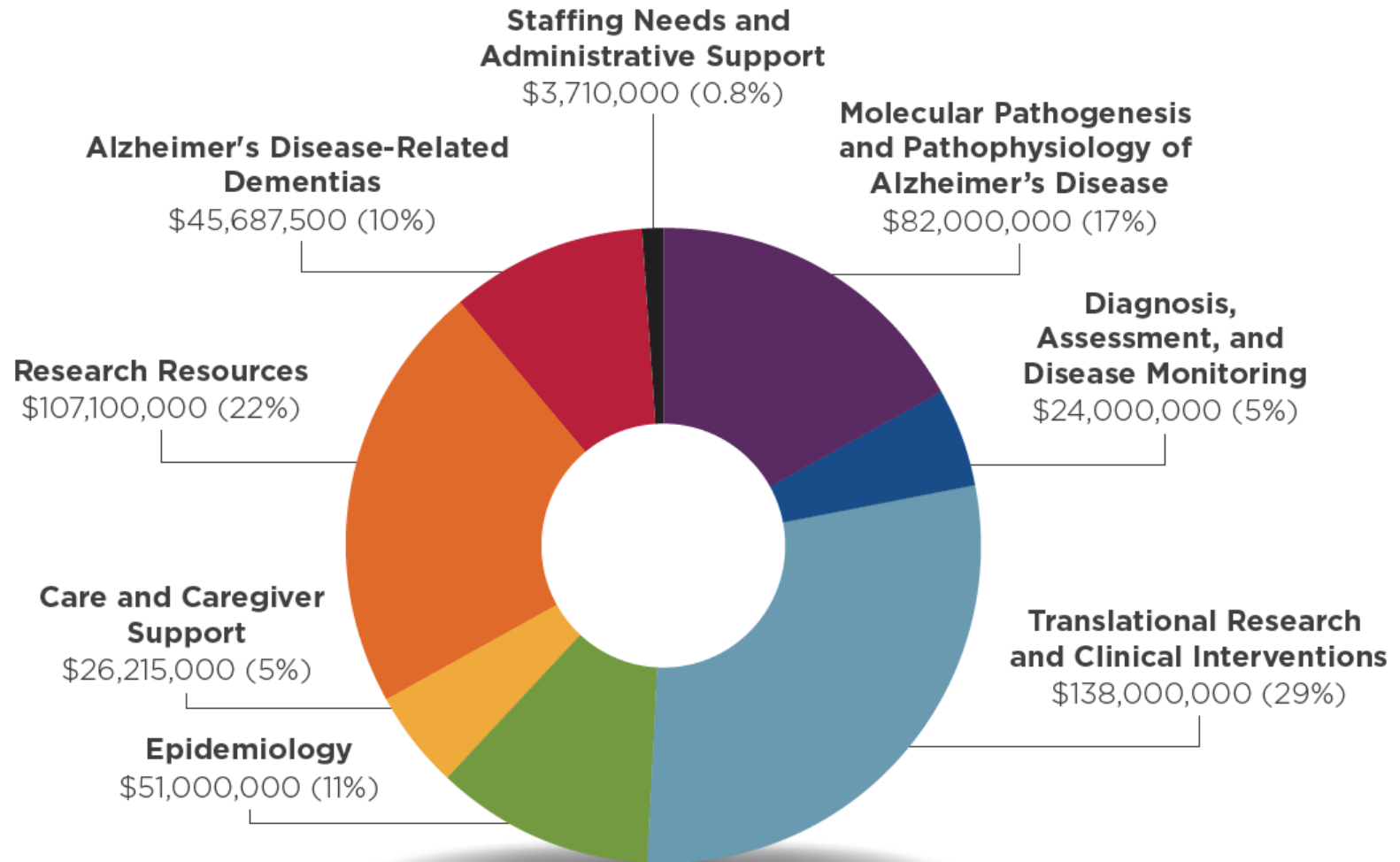
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Molecular Pathogenesis and Pathophysiology of Alzheimer's Disease	\$82,000,000
Diagnosis, Assessment, and Disease Monitoring	\$24,000,000
Translational Research and Clinical Interventions	\$138,000,000
Epidemiology	\$51,000,000
Care and Caregiver Support	\$26,215,000
Research Resources	\$107,100,000
Alzheimer's Disease-Related Dementias	\$45,687,500
Staffing Needs and Administrative Support	\$3,710,000
<b>ADDITIONAL FY20 Resources Needed for New AD/ADRD Research</b>	<b>\$477,712,500</b>

# Distribution of *Additional* Budget Funding Request Across Research Areas, FY20

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TOTAL: \$477,712,500



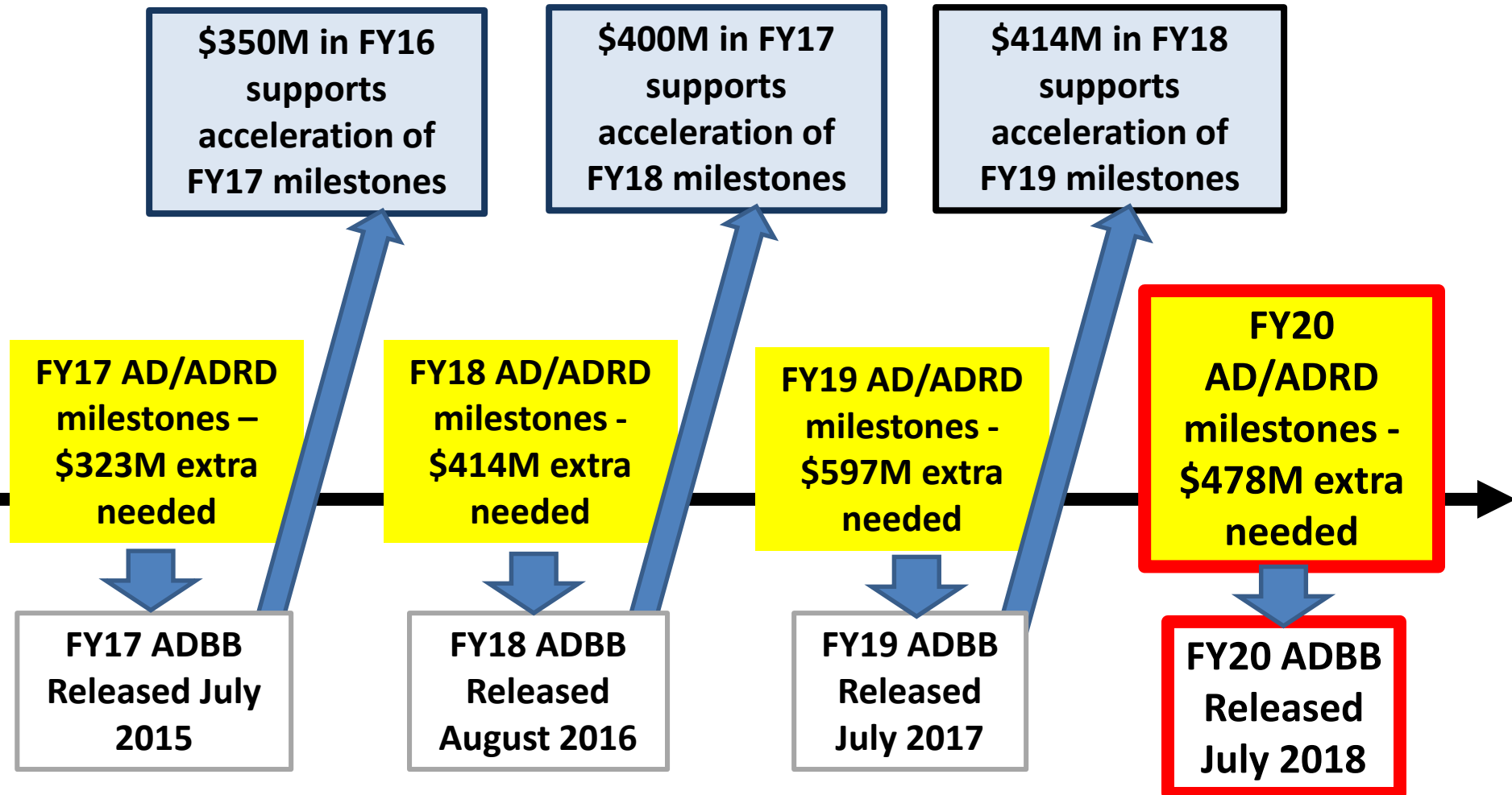
## FY20 Professional Judgment Budget – Total Funding Needs

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FY19 President's Budget Request for AD/ADRD Research (Baseline estimate)	\$1,516,000,000
Difference between the FY19 President's Budget Request and FY18 Omnibus Appropriation for AD/ADRD Research	\$399,000,000
<b><i>Subtotal (FY18 Omnibus – AD/ADRD Research)</i></b>	<b><i>1,915,000,000</i></b>
ADDITIONAL FY20 Resources Needed for New AD/ADRD Research	\$477,712,500
<b>TOTAL FY20 Resources Needed for AD/ADRD Research</b>	<b>\$2,392,712,500</b>

# Timing of ADBB Releases and AD/ADRD Appropriations

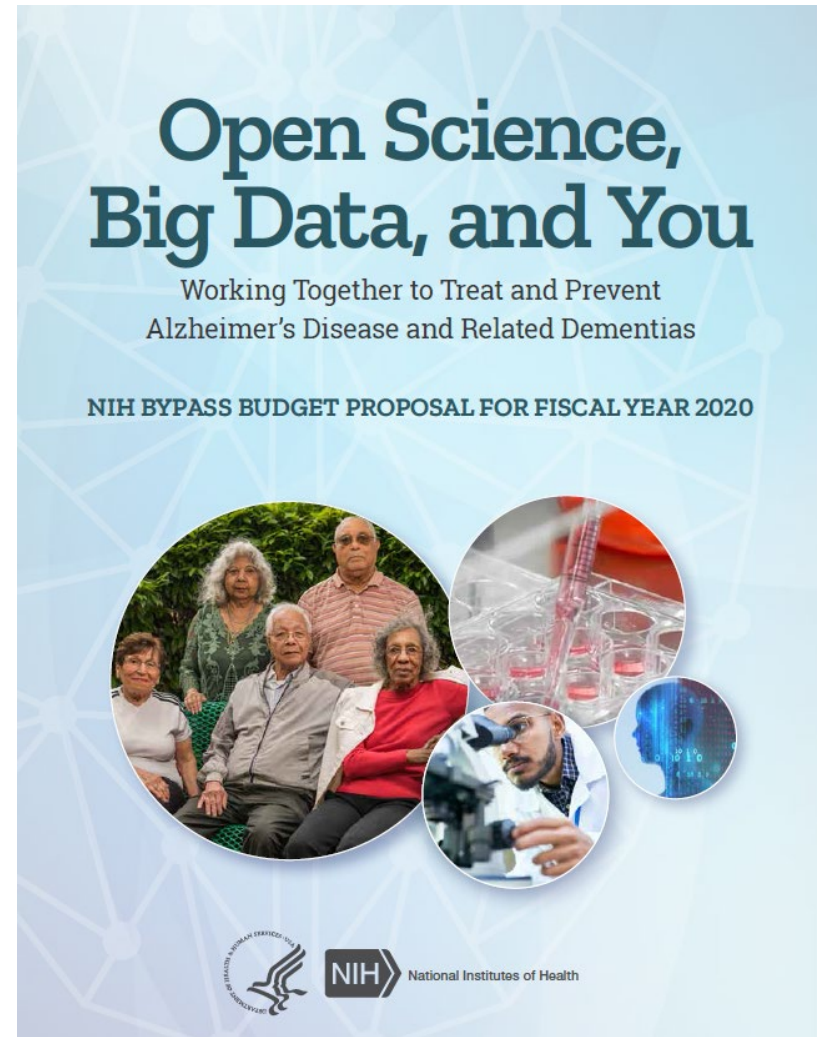
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# AD/ADRD Progress Report – An important part of the ADBB

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



# Care and Caregiving Actions

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- National Research Summit on Dementia Care & Services - October 2017
- Planned Evidence Review: Care Interventions for Individuals with Dementia and Their Caregivers
- Improving Care for People with AD/ADRD Using Technology (iCare-AD/ADRD) Challenge
  - NIH's first Eureka Prize Competition

# National Research Summit on Dementia Care & Services – Next Steps

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- Summit milestones have been incorporated into overarching AD/ADRD research implementation milestones
  - *Informed the FY2020 AD/ADRD Bypass Budget*
- Initiatives released
- *Preliminary* planning for next care/services summit underway

# Release of Initiatives

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- Disparities in Quality and Access to Dementia Care ([PAR-18-596](#))
- Improving the Lives of Persons with Dementia (PWD): Impacts on PWD, Families and Communities ([PAR-18-596](#))
- Dementia Care and Caregiver Support Interventions ([RFA-AG-18-030](#))
- NIA AD/ADRD Health Care Systems Research Collaboratory ([RFA-AG-19-009](#))
- Pragmatic Trials for Dementia Care in Long-term Services and Support (LTSS) Settings ([PAR-18-585](#))
- High Priority Behavioral and Social Research Networks in AD/ADRD ([RFA-AG-19-016](#))



# Save the Date

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**AD/ADRD Care/Services Summit (II)**

**March 24-25, 2020**

**Natcher Conference Center**

**Bethesda, MD**



# Planned Evidence Review: *Care Interventions for Individuals with Dementia and Their Caregivers*

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- **Two parts:**
  - ❑ **National Academies of Sciences, Engineering, and Medicine:**  
*Expert panel input on questions and study design*  
[www.nationalacademies.org/dementiacare](http://www.nationalacademies.org/dementiacare)
  - ❑ **Agency for Healthcare Research & Quality:** *Evidence review*
- **Status:**
  - ❑ **AHRQ Evidence-Based Practice Center award – Made to the Minnesota EPC – Drs. Mary Butler and Joseph Gaugler are leading the study**
  - ❑ **NASEM Committee list – posted to**  
<https://www8.nationalacademies.org/pa/projectview.aspx?key=HMD-HSP-18-04>

# NASEM Committee Members

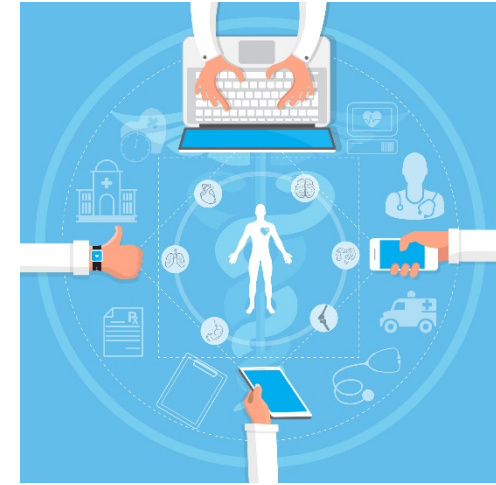
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- Eric B. Larson, MD, MPH (Chair)
- Marilyn Albert, PhD
- María P. Aranda, PhD, MSW, MPA, LCS
- Marilyn Blum, BA
- Christopher M. Callahan, MD
- Eileen M. Crimmins, PhD
- Peggye Dilworth-Anderson, PhD
- XinQi Dong, MD, MPH
- Miguel Hernán, MD, DrPH
- Ronald Hickman, Jr., PhD, RN, ACNP-BC, FNAP, FAAN
- Rebecca A. Hubbard, PhD
- Jason Karlawish, MD
- Robyn I. Stone, DrPH
- Jennifer L. Wolff, PhD

# iCare-AD/ADRD Challenge

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## Improving Care for People with AD/ADRD Using Technology Challenge



- Seeks to spur the development of technology applications to improve dementia care coordination and/or care navigation
- Up to **\$400,000 in cash prizes** may be awarded to teams or individuals that participate in the competition
- Submissions accepted from October 1, 2018 through June 30, 2019
- NIA challenge managers held a **webinar on October 17, 2018** to introduce attendees to the Challenge and cover participation requirements
- See <https://nia.nih.gov/challenge-prize> for full prize details



**SAVE THE DATE**

MARCH 14-15

2019

# ALZHEIMER'S DISEASE-RELATED DEMENTIAS SUMMIT 2019:

RESEARCH CHALLENGES AND OPPORTUNITIES

Register online at:

<https://meetings.ninds.nih.gov/?ID=21149>

**Scholarship Program: Deadline, Dec. 12**

**MARCH 14-15, 2019**  
**NATCHER AUDITORIUM, NIH CAMPUS,**  
**BETHESDA MD**

Julie Schneider, MD  
Rush University Medical Center  
*Scientific Chair*

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

## Sessions on:

- Multiple Etiology Dementias
- Health Disparities
- Emerging Topics
- Nomenclature
- Frontotemporal Degeneration
- Lewy Body Dementias
- Vascular Contributions to Cognitive Impairment and Dementia



**NIH** National Institute of  
Neurological Disorders  
and Stroke

Register now: [\*\*https://meetings.ninds.nih.gov/?ID=21149\*\*](https://meetings.ninds.nih.gov/?ID=21149)