Alzheimer's Disease and AD Related Dementias Research: Policy and Program Updates

2020 Fall ADRC Meeting

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October 2020

NIH/NIA Budget Update

FY 2021 Budget Status

➢ **Senate**
  - No draft bills released at this time
➢ **House**
  - The House bill includes an additional $5.5B for NIH above FY20 funding levels - $5B of which was designated for COVID-related emergency funding
    - ○ NIA FY20 Enacted: $3.543B
    - ○ NIA FY21 House Mark: $3.609B, 0.86% increase to the NIA base plus an additional $35M targeted for AD/ADRD research and $228M COVID-related emergency funding
➢ The Federal government is currently **funded through, December 11, 2020,** with a Continuing Resolution that maintains FY 20 funding levels

Growth of AD and ADRD Research Spending at NIH

NIH Funding for AD/ADRD Research – *in millions*
From NIH's Research, Condition, and Disease Categories (RCDC) System

Research/Disease Areas (Dollars in millions and rounded)	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	Difference – FY15 to FY19
AD/ADRD	$631	$986	$1,423	$1,911	$2,398	3.8-fold increase
Alzheimer's Disease	$589	$929	$1,361	$1,789	$2,240	3.8-fold increase
Alzheimer's Disease Related Dementias[1]	$120	$175	$249	$387	$515	4.3-fold increase
Lewy Body Dementia	$15	$22	$31	$38	$66	4.4-fold increase
Frontotemporal Dementia	$36	$65	$91	$94	$158	4.4-fold increase
Vascular Cognitive Impairment/Dementia	$72	$89	$130	$259	$299	4.2-fold increase

[1] The ADRD row reflects the sum of the three existing RCDC categories: Frontotemporal Dementia, Lewy Body Dementia, and Vascular Cognitive Impairment/Dementia—where duplicates are removed.
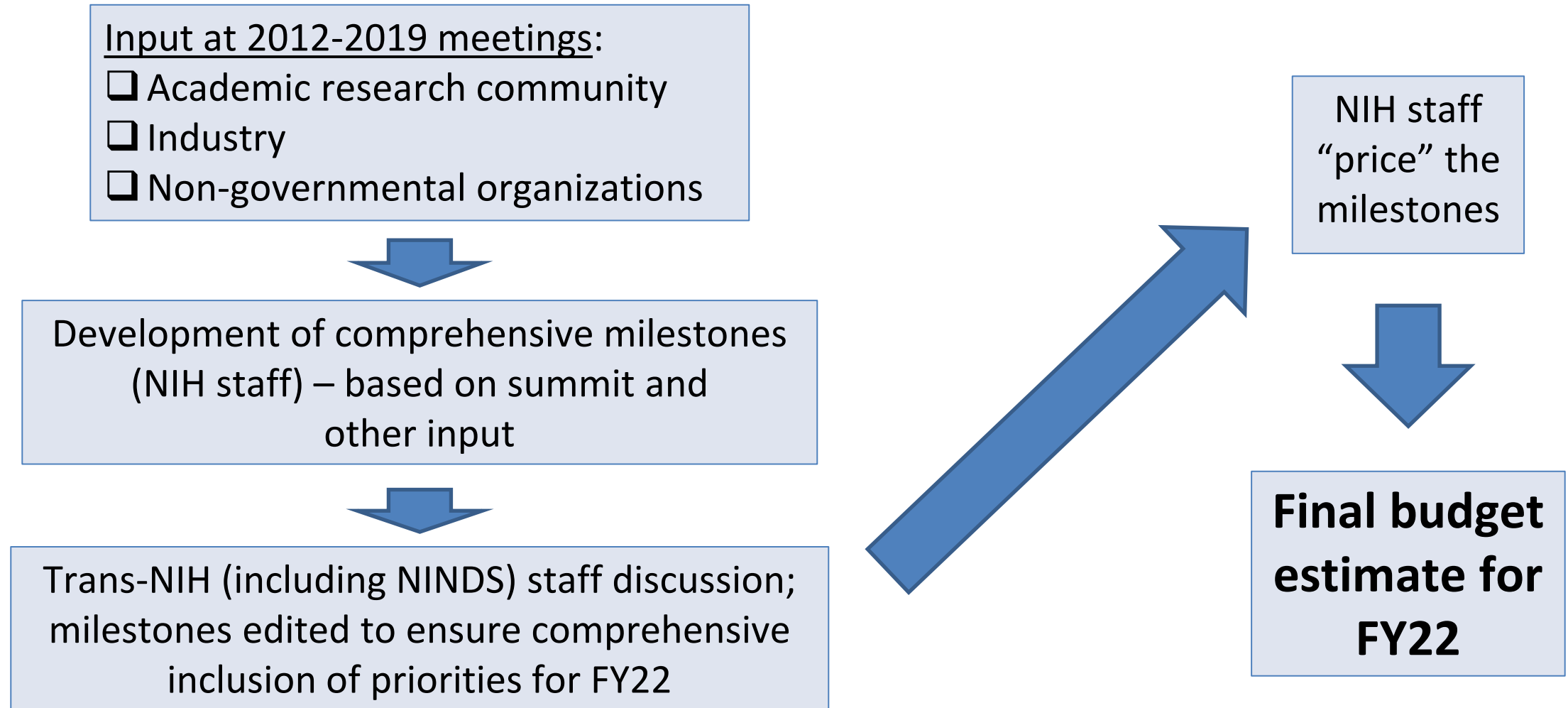
https://report.nih.gov/categorical_spending.aspx

FY2022 Alzheimer's Disease Bypass Budget

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.

Combined External and Internal Input –
FY22 AD/ADRD Bypass Budget

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

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 FY22

NIH staff "price" the milestones

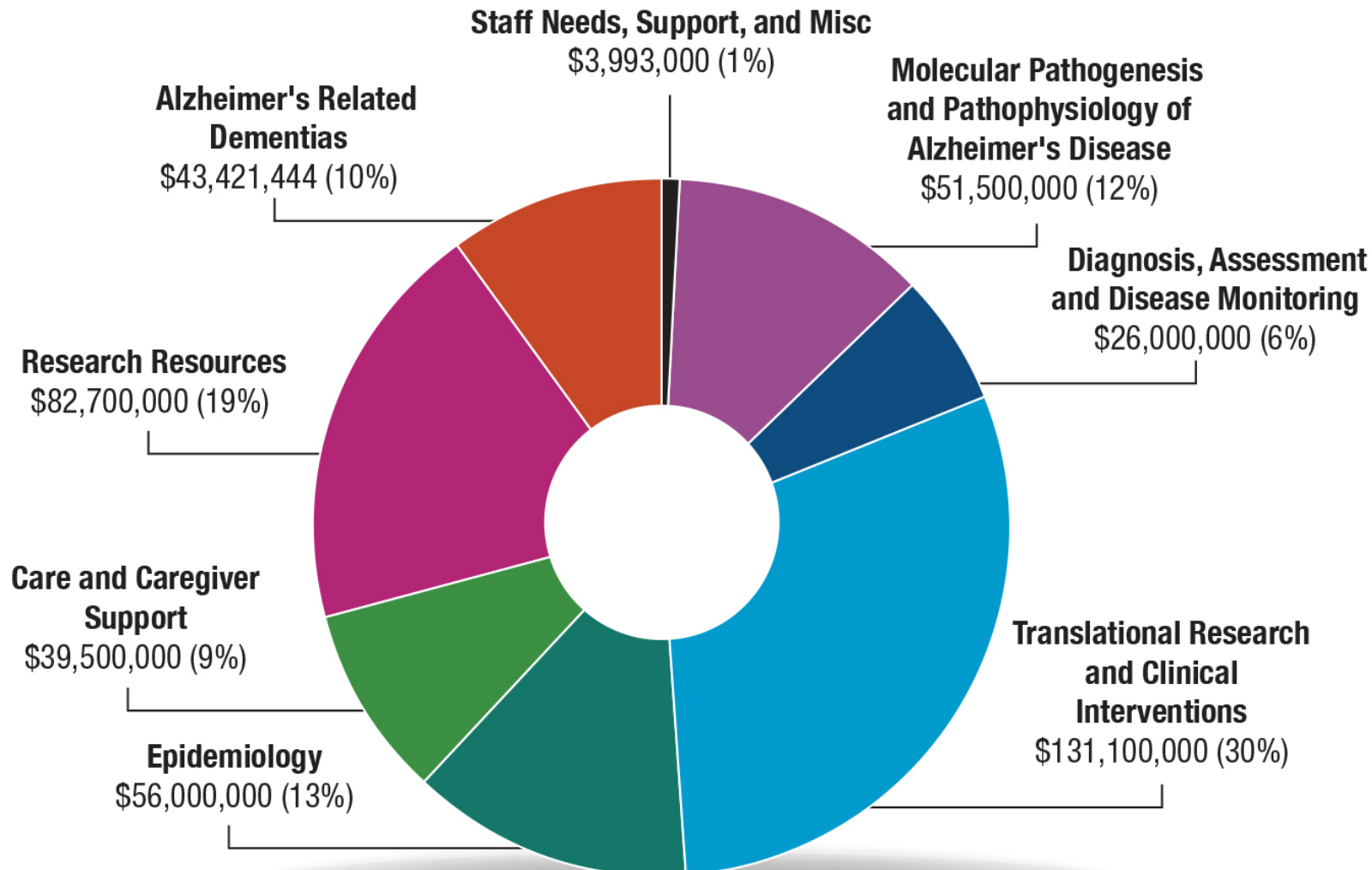**Final budget estimate for FY22**

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Using CADRO as a Framework

- The eight CADRO (Common Alzheimer's and Related Dementias Research Ontology) categories provide the overarching framework for the FY22 AD Bypass Budget and narrative.

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

Distribution of FY 2022 Projected Costs Across Research Areas

Staff Needs, Support, and Misc
$3,993,000 (1%)

Alzheimer's Related Dementias
$43,421,444 (10%)

Molecular Pathogenesis and Pathophysiology of Alzheimer's Disease
$51,500,000 (12%)

Diagnosis, Assessment and Disease Monitoring
$26,000,000 (6%)

Research Resources
$82,700,000 (19%)

Care and Caregiver Support
$39,500,000 (9%)

Epidemiology
$56,000,000 (13%)

Translational Research and Clinical Interventions
$131,100,000 (30%)

Total Projected Costs:
$434,214,444*

Additional Resources Needed for New Research:
$289,214,444

*In FY 2022, 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 $434 million. This estimate will be reduced by $145 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 2022 budget is $289 million.

Total Resource Needs, FY 2022

Factor	Amount
FY 2021 President's Budget Request for AD/ADRD Research (Baseline estimate)	$2,564,000,000

- We start with the prior year's President's Budget request as the base

Total Resource Needs, FY 2022

Factor	Amount
FY 2021 President's Budget Request for AD/ADRD Research (Baseline estimate)	$2,564,000,000
Difference between the FY 2021 President's Budget Request and FY 2020 Appropriation for AD/ADRD Research[3]	+ $254,000,000

- Since the FY2021 President's Budget request included less than the FY2020 enacted budget did for AD/ADRD, we calculate the difference, and add that back in
- This brings us up to a flat level

Total Resource Needs, FY 2022

Factor	Amount
FY 2021 President's Budget Request for AD/ADRD Research (Baseline estimate)	$2,564,000,000
Difference between the FY 2021 President's Budget Request and FY 2020 Appropriation for AD/ADRD Research[3]	+ $254,000,000
ADDITIONAL FY 2022 Resources Needed for New AD/ADRD Research	+ $289,214,444

- Next, we add the "new" FY 2022 funding that could be utilized for AD/ADRD research

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Total Resource Needs, FY 2022

Factor	Amount
FY 2021 President's Budget Request for AD/ADRD Research (Baseline estimate)	$2,564,000,000
Difference between the FY 2021 President's Budget Request and FY 2020 Appropriation for AD/ADRD Research[3]	+ $254,000,000
ADDITIONAL FY 2022 Resources Needed for New AD/ADRD Research	+ $289,214,444
TOTAL FY 2022 Resources Needed for AD/ADRD Research	= $3,107,214,444

- This yields a total needed for FY 2022 AD/ADRD research funding

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

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

https://www.nia.nih.gov/about/bypass-budget-proposal-archive
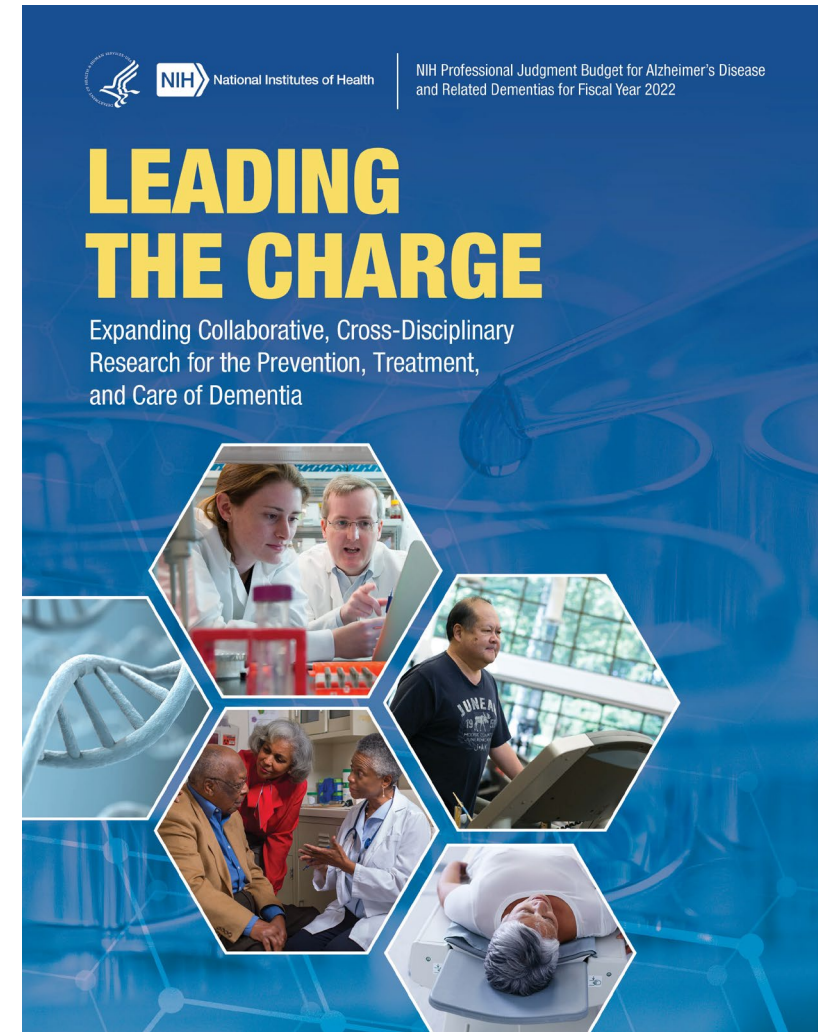
Implementation Tracking

- **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**

  ➢ <u>*Newly revised*</u>

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

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COVID-19 Updates

NIH's Response to the COVID-19 Crisis: Funding Opportunities

- Across NIH, special funding announcements known as **Notices of Special Interest (NOSIs)** have been generated in response to the COVID-19 crisis.

- Goal is to expedite review of applications and distribution of funds to assist in COVID-19 research.

- Full NIH list available here: https://grants.nih.gov/policy/natural-disasters/corona-virus.htm.

- NIA's NOSI and other COVID-19-related funding opportunities and resources available here: https://www.nia.nih.gov/research/grants-funding/nia-covid-19-response

NIA COVID-19-Related Clinical Trial FOA

[PAR-20-234](#) / NIA Multi-Site COVID-19-Related Clinical Trial Implementation Grant on Aging-Related Topics in At-Risk Older Adult Populations (R01 Clinical Trial Required)

https://grants.nih.gov/grants/guide/pa-files/PAR-20-234.html

Funding Opportunity Title	NIA Multi-site COVID-19 Related Clinical Trial Implementation Grant on Aging-Related Topics in at-risk Older Adult Populations (R01 Clinical Trial Required)
Activity Code	R01 Research Project Grant
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	PAR-20-234

Rapid Acceleration of Diagnostics (RADx)

- Seeks to accelerate the innovation, development, and commercialization of COVID-19 testing technologies.

- Sponsored by a $1.5 billion investment from federal stimulus funding.

- Encompasses RADx-Tech, RADx-UP, RADx-Rad, and RADx-ATP.

NIH Rapid Acceleration of Diagnostics (RADx) Initiative for COVID-19

| NATIONAL CALL FOR INNOVATIVE TECHNOLOGIES | PHASE 0: "Shark Tank"–Like Rapid Selection Process | PHASE 1: Validation and Risk Review | PHASE 2: Clinical Tests, Regulatory Approval, and Scaling Up | END OF SUMMER/ FALL 2020 |

Rolling Submissions and Selections Begin April 29, 2020

FAST TRACK FOR ADVANCED DIAGNOSTIC TECHNOLOGIES

DEPLOY MILLIONS of tests per week

https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics

Overview of RADx Projects

RADx Tech ($500M): Highly competitive, three-phase challenge to identify, at an accelerated pace, the best candidates for at-home or point-of-care tests for COVID-19

RADx Underserved Populations (RADx-UP; $500M): Community-engaged projects focused on implementation strategies to enable and enhance COVID-19 testing in underserved and vulnerable populations

RADx-Radical (RADx-Rad; $200M): Develop and advance novel, non-traditional testing approaches or new applications of existing approaches

RADx Advanced Technology Platforms (RADx-ATP; $230M): Rapid scale-up of advanced technologies to increase testing pace and enhance/validate throughput; create ultra-high throughput machines and facilities

Data Management Support ($70M): Build an infrastructure to support coordination of the various data management needs of COVID-19 efforts.

RADx Underserved Populations (RADx-UP) FOAs

- **NOT-OD-20-119** / Emergency Competitive Revisions for Social, Ethical, and Behavioral Implications (SEBI) Research on COVID-19 Testing among Underserved and/or Vulnerable Populations

- **NOT-OD-20-120** / Emergency Competitive Revisions for Community-Engaged Research on COVID-19 Testing among Underserved and/or Vulnerable Populations

- **NOT-OD-20-121** / Limited Competition for Emergency Competitive Revisions for Community-Engaged Research on COVID-19 Testing among Underserved and/or Vulnerable Populations

- **RFA-OD-20-013** / RADx-UP Coordination and Data Collection Center (CDCC) (U24 Clinical Trial Optional)

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RADx-UP Awards

- On Wednesday, September 30, NIH announced nearly $234 million in awards to improve COVID-19 testing for underserved and vulnerable populations as part of RADx-UP

- The program will support 32 institutions across the United States and will focus on populations disproportionately affected by the pandemic

- These groups include African Americans, American Indians/Alaskan Natives, Latinos/Latinas, Native Hawaiians, older adults, pregnant women and those who are homeless or incarcerated

  https://www.nih.gov/research-training/medical-research-initiatives/radx

Increasing Diversity in AD/ADRD Recruitment and Training

NIA efforts to support inclusion of diverse participants

- PAR-18-749 **"Examining Diversity, Recruitment and Retention in Aging Research"** was launched to encourage, collaborative teams to target gaps in recruitment and retention methods and outcomes, as well as to establish the community infrastructure needed to accelerate recruitment

- NOT-AG-18-047 **"Health Disparities and Alzheimer's Disease"** encourages applications that examine mediators of disparities in Alzheimer's disease, using diverse cohorts of subjects with a focus on strategies for recruitment and retention in clinical trials

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NIA efforts to support inclusion of diverse participants

- In October 2018, NIA released a national strategy focused on increasing diversity and participation in clinical studies

- In 2019, NIA launched the Alzheimer's and Dementia Outreach, Recruitment, and Engagement (ADORE) Resources. This repository offers resources to support recruitment and retention https://www.nia.nih.gov/research/adore
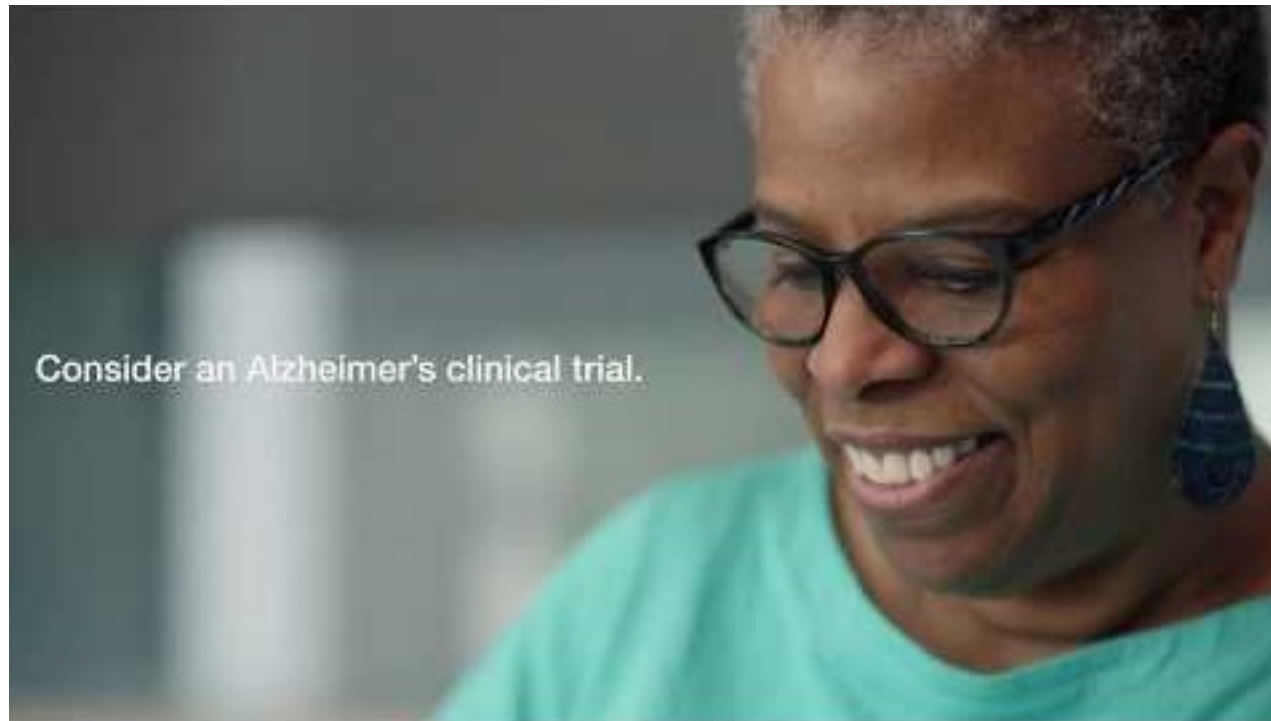
Consider an Alzheimer's clinical trial.

Resource Centers for Minority Aging Research (RCMARs)

Eleven centers designed to:

1) enhance the diversity of the aging research workforce
2) develop infrastructure to promote advances in areas of social, behavioral, and economic research on aging
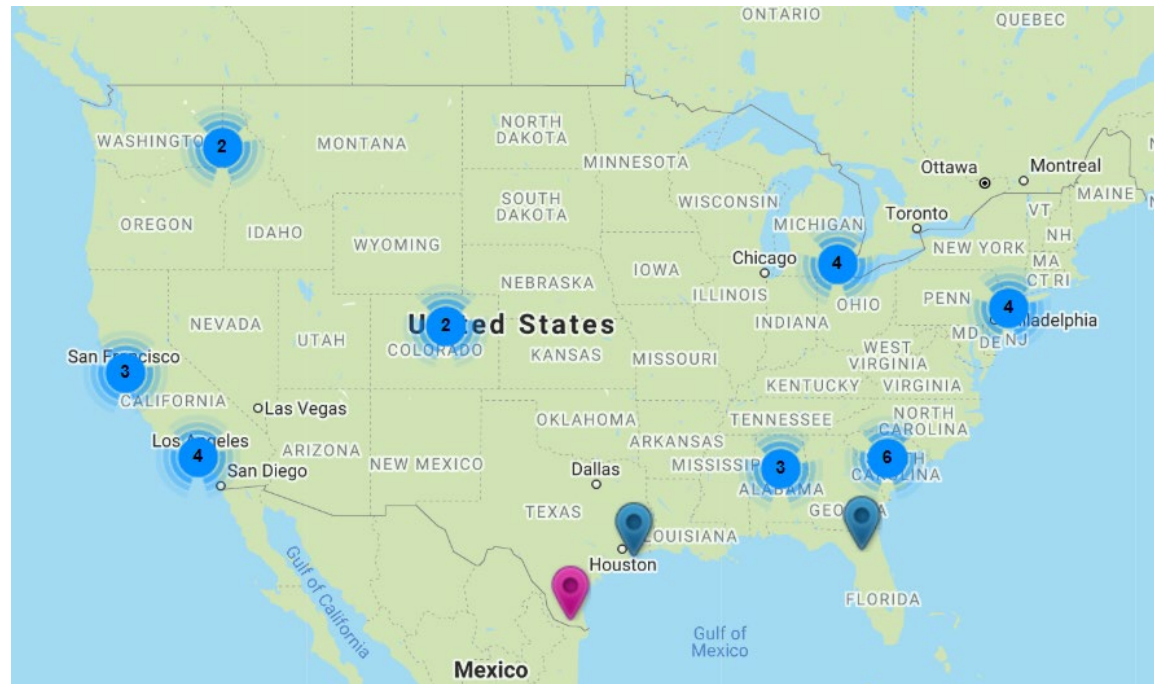
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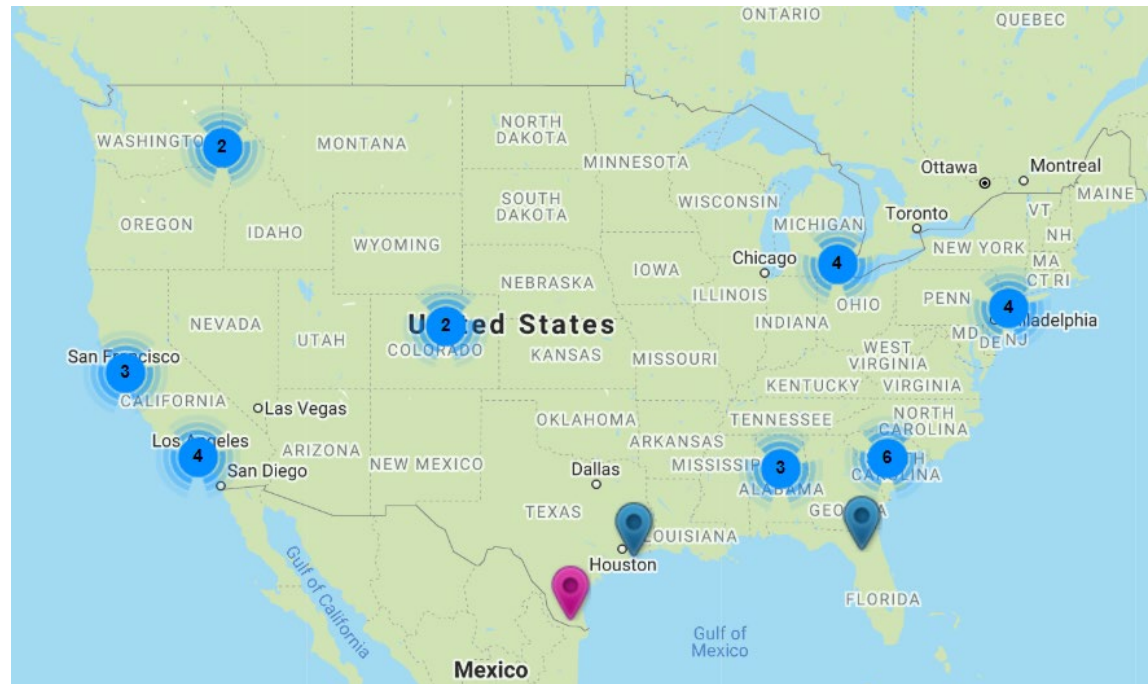
In 2018, the NIA expanded the RCMAR network to include **eight new centers** focused on priority areas of social and behavioral science related to **Alzheimer's disease**.

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Clinical Research Operations Management System (CROMS)

CROMS Purpose:

- Support the unique data and clinical research process needs identified by NIA's ERP leadership, staff, and grantees

- Provide institute-wide informatics capability to track, report, and manage NIA's clinical research data, activities, and grant portfolio in near real-time
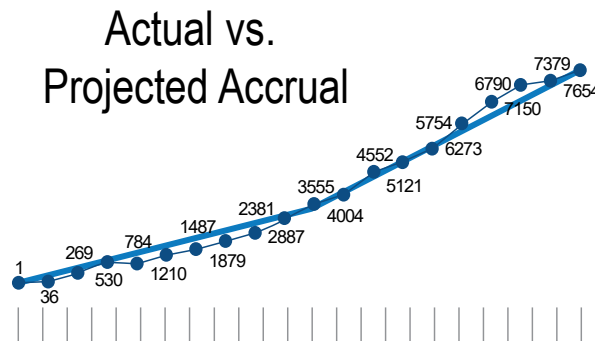
Clinical Research Operations Management System (CROMS)
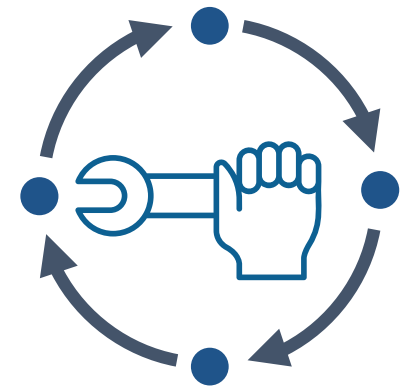
Operational Portfolio Management
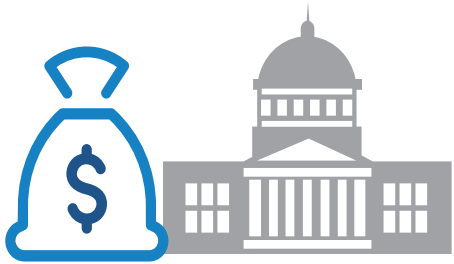
Institutional Accountability for Research

Actual vs. Projected Accrual
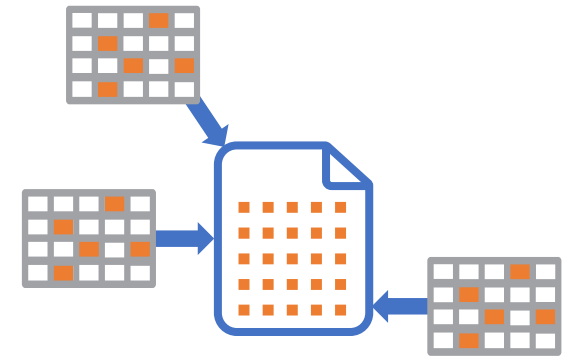
Data Needs

CROMS Components and Features

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Clinical Research Operations & Management System (NIA CROMS)

Logout
Welcome Jane Smith
Last successful Login: 02-Jun-2020 10:00 AM
No. of unsuccessful login attempts: 0

- Grant & Study Manager
- Data & Safety Monitoring
- Study Master File
- Master Contact
- Analytics & Visualization
- Grantee Portal
- Safety Reports Tracker
- API & Data Exchange

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NIA Updates

Alzheimers.gov Redesign

Coming in early 2021, the new website will:

- Provide information on Alzheimer's disease and related dementias care, research, and support

- Link people with dementia, caregivers, health care professionals, and others to resources from across the federal government

- Communicate the government's commitment to addressing Alzheimer's and related dementias

- Highlight clinical trials education and how to participate
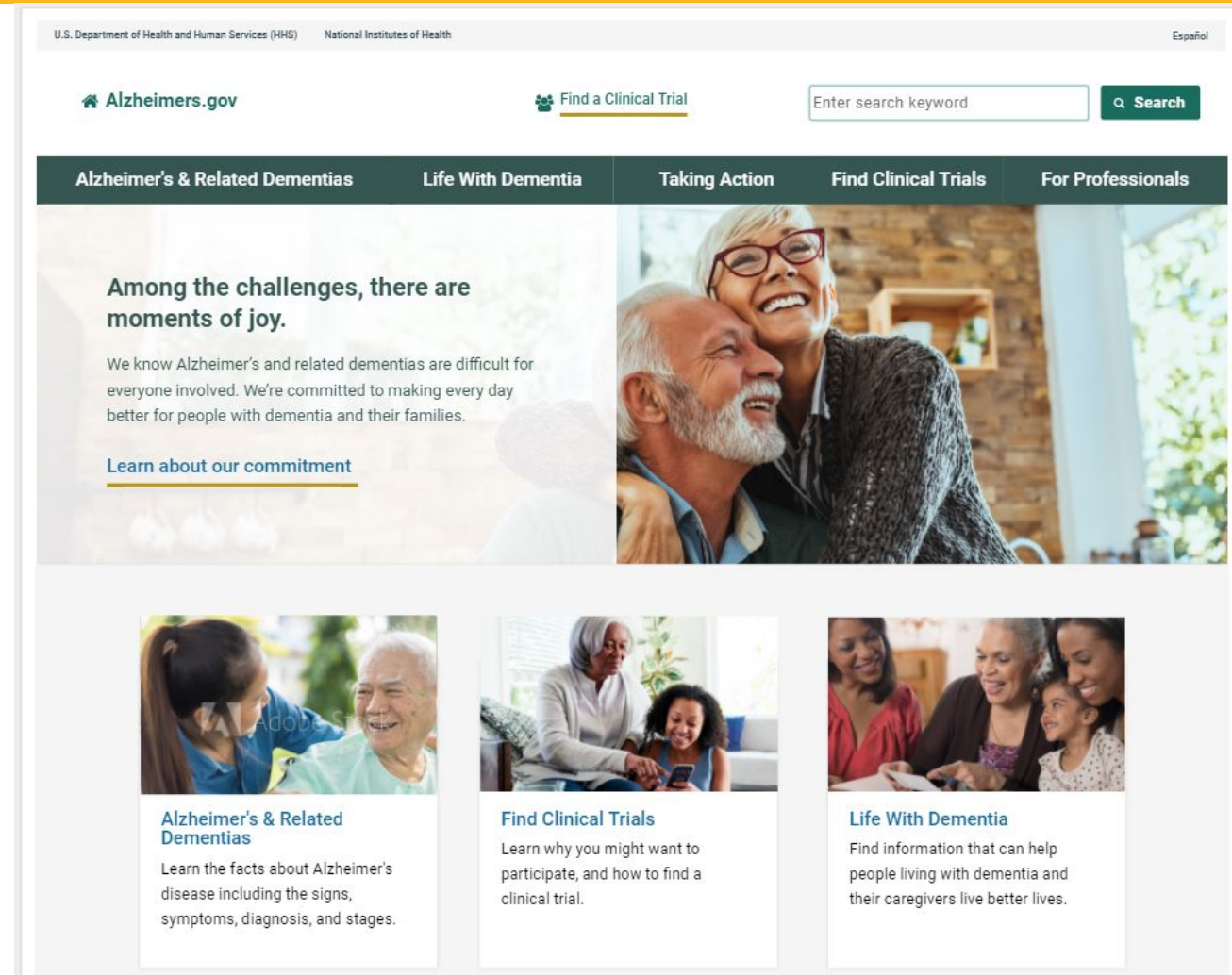
2021 Alzheimer's Disease Research Summit

Mark your calendars to join us <u>virtually</u> on:
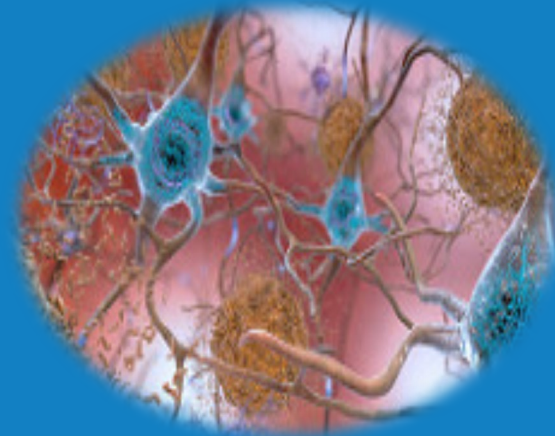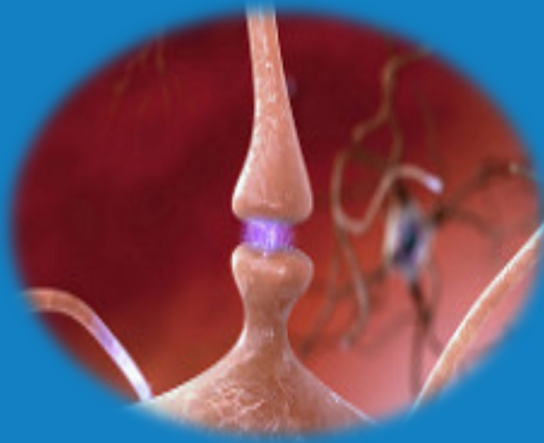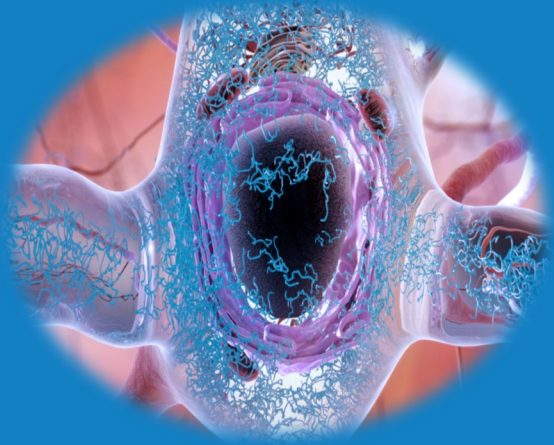**April 19th-20th, 2021**

Ways to Stay Informed and Connected

Search all active NIA funding opportunities:
https://www.nia.nih.gov/research/funding

Review the latest approved concepts:
https://www.nia.nih.gov/approved-concepts

Subscribe to our blog and stay up to date on the latest NIA news: **https://www.nia.nih.gov/research/blog**

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