

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

2023 Fall ADRC Meeting Richard J. Hodes, M.D. Director, National Institute on Aging

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Budget and Spending Updates

FY 2024 Appropriations Status

• House FY 2024 appropriations bill:

- On June 14, 2023, the House Labor-HHS spending bill advanced out of subcommittee. The bill must still be considered by the full committee and then passed by the House. If enacted:
 - \$43 billion for NIH, a decrease of \$3.8 billion from the FY 2023 enacted level.
 - \$4.41 billion for NIA essentially flat-funding relative to the FY 2023 enacted level.

• Senate FY 2024 appropriations bill:

- On July 27, 2023, the Senate Labor-HHS spending bill advanced out of the full Appropriations committee.
 The bill must still be passed by the Senate. If enacted:
 - \$47.8 billion for NIH, an increase of \$943 million in discretionary spending over FY 2023.
 - **\$4.51 billion for NIA**, an increase of more than \$100 million over the FY 2023 enacted level.
 - \$90 million increase for Alzheimer's and related dementias research.
 - \$12 million for palliative care research.
 - Overall, \$100 million in increased NIH funding for dementia research:
 - \$90 million to NIA (*referenced above*), plus \$10 million to NINDS.
- The federal government is currently funded through November 17th, 2023, via a Continuing Resolution.



Pay Line Updates

- Due to the Continuing Resolution, we are beginning FY 2024 with a very conservative pay line (including AD/ADRD grants). We will adjust accordingly once FY 2024 appropriations are enacted.
- We are, however, preparing for other options in case there is a substantial cut to the budget, including:
 - Use of multiple pay bands based on cost/budget amounts for AD/ADRD research.
 - Setting limits on Awaiting Receipt of Applications accepted for AD/ADRD topic preapprovals over \$500,000.
 - Reductions in competing awards and noncompeting awards.
- Please monitor the NIA pay line website for updates as they become available: <u>https://www.nia.nih.gov/research/grants-funding/funding-policies-and-pay-lines</u>
- For more information, please see NIA blog post: <u>https://www.nia.nih.gov/research/blog/2023/10/bracing-cloudy-nia-budget-forecast</u>





AD/ADRD Research Updates and Planning

Recent AD/ADRD Cleared Concepts From NACA Meetings

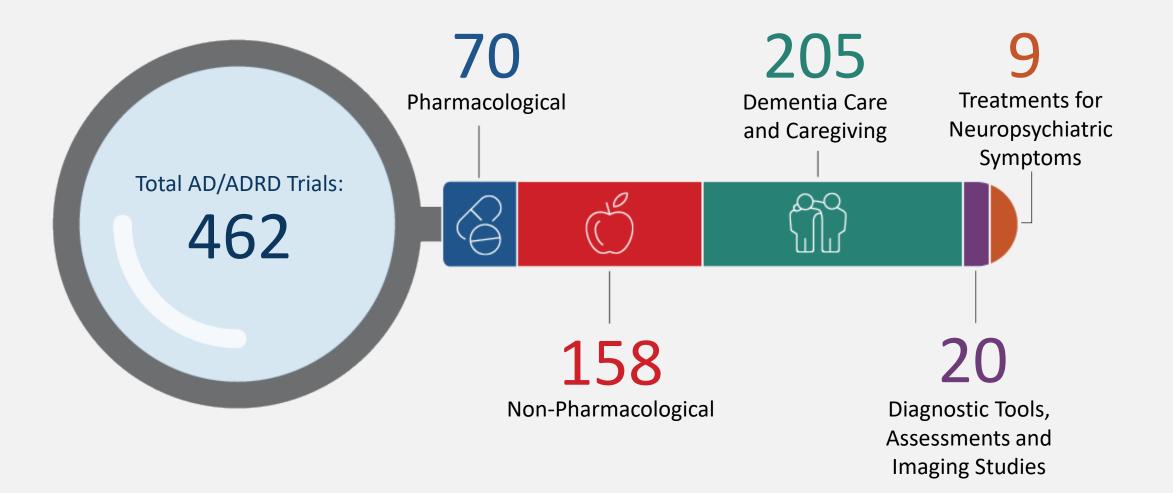
Approved concepts indicate areas of special interest for NIA and often evolve into funding opportunity announcements to spur activity in given areas of research.

Select Concepts:

- Technology to Facilitate Characterization of the Exposome in Under-Resourced Populations for AD/ADRD Studies
- Consortium for Palliative Care Research Across the Lifespan
- Exploring Proteogenomic Approaches to Unravel the Mechanisms of Mis-folded Protein Accumulation in Tauopathies
- Multi-Scale Models Bridging Levels Of Analysis In Aging and AD/ADRD
- Open Measurement Coordinating Network for Non-Pharmacological AD/ADRD Primary Prevention Trials
- Quantitative Systems Pharmacology Approach to Develop Predictive Models of Differential Responsiveness to Treatment
- Research Collaboration Network In Structural Racism Measurement And Modeling
- Small Research Grant Program for the Next Generation of Researchers in Low- And Middle-Income Countries for Aging and AD/ADRD Research
- Translational Bioinformatics and Experimental Approaches to Advance Drug Repositioning and Combination Therapy Development for AD/ADRD

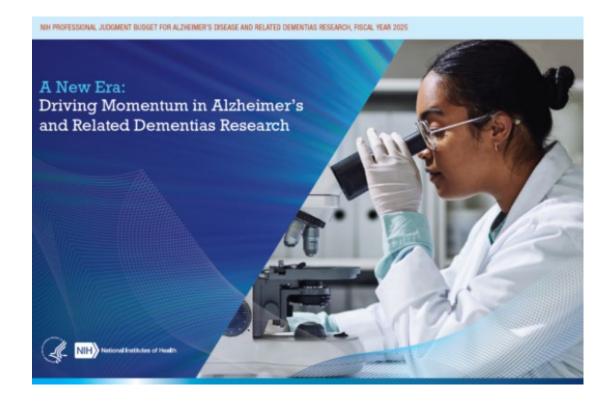


Total Active NIA AD/ADRD Clinical Trials



FY 2025 Alzheimer's and Related Dementias Professional Judgment Budget

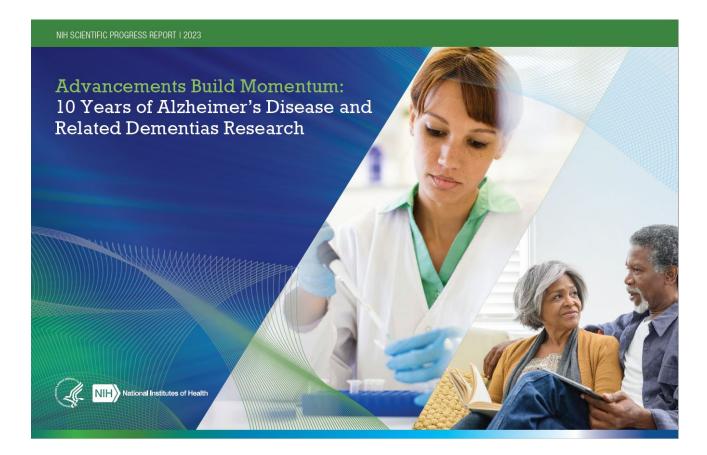
- Outlines an estimate of the additional funding needed in FY 2025 to advance NIH-supported research toward achieving the goals outlined by the National Plan to Address Alzheimer's Disease.
- Describes examples of potential future research opportunities that could be pursued with additional funding.





Alzheimer's and Related Dementias Progress Report

Summarizes significant
 NIH-funded dementia
 research advances
 from the last ten years.





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



NIA/NIH Updates

Limbic-predominant Age-related TDP-43 Encephalopathy (LATE)

ALZHEIMER'S DISEASE AND RELATED DEMENTIAS RELATED DEMENTIAS What Is Limbic-Predominant Age-**Related TDP-43 Encephalopathy** (LATE)?

https://www.nia.nih.gov/health/what-limbic-predominant-agerelated-tdp-43-encephalopathy-late



https://www.ninds.nih.gov/about-ninds/strategic-plans-evaluations/strategicplans/alzheimers-disease-related-dementias-summits

NIH held a workshop in May 25, 2023 to explore gaps and opportunities related to clinical detection of LATE

https://www.nia.nih.gov/research/dn/workshop-gaps-and-opportunities-related-clinicaldetection-limbic-predominant-age



EUREKA Challenge for Early Prediction of AD/ADRD

- A challenge prize competition to discover the best data, methods, and strategies for the early prediction of Alzheimer's and related dementias launched last month (September 2023).
- The challenge includes an emphasis on **building diverse teams and** solutions that generalize to groups that historically have been excluded from participation in AD/ADRD research.
- Phase 1 Find IT!: Data for Early Prediction
 - Phase 1 is focused on identifying, accessing and/or building representative, inclusive, open, shareable datasets that can be used for early prediction of AD/ADRD.
 - Deadline to Submit: 01/31/24
- <u>https://www.challenge.gov/?challenge=prepare-challenge</u>



PREPARE: Pioneering Research for Early Prediction of Alzheimer's and Related Dementias EUREKA Challenge



The challenge intends to offer **cash awards totaling \$650,000**.



NIA's AD/ADRD Clinical Trial Recruitment Tool: OutreachPro

OutreachPro is an online tool that helps researchers and grantees create outreach materials, designed for and tested with specific audiences.

OutreachPro and its materials were systematically created through literature reviews, listening sessions with stakeholders, focus groups, surveys, and user feedback testing.

Over 200 unique materials that can be developed from a combination of designs, health statuses, race/ethnicities, and languages.

https://outreachpro.nia.nih.gov/



available during the breaks.

NASEM Study on Research Priorities for Preventing and Treating AD/ADRD

- Task order established: March 27, 2023
- Committee

 establishment:
 September 19, 2023
- **First committee meeting:** October 2, 2023
- Final report anticipated: Jan - March 2025

In response to a congressional mandate, an ad hoc committee of NASEM will conduct a study and recommend research priorities to advance the prevention and treatment of AD/ADRD. In conducting its study, the committee will:

- Examine and assess the current state of biomedical research aimed at preventing and effectively treating AD/ADRD, along the R&D pipeline from basic to translational to clinical research;
- 2) Assess the evidence on nonpharmacological interventions aimed at preventing and treating AD/ADRD;
- 3) Identify key barriers to advancing AD/ADRD prevention and treatment (e.g., infrastructure challenges that impede large scale precision medicine approaches, inadequate biomarkers for assessing response to treatment, lack of diversity in biobanks and clinical trials), and opportunities to address these key barriers and catalyze advances across the field;
- 4) Explore the most promising areas of research into preventing and treating AD/ADRD.



https://www.nationalacademies.org/our-work/research-priorities-for-preventing-and-treating-alzheimers-disease-and-related-dementias

Upcoming Summits and Meetings



Save the Date: 2024 NIH Alzheimer's Disease Research Summit



National Institute on Aging 2024 NIH Alzheimer's Disease Research Summit: Path to Precision Medicine for Treatment and Prevention

September 23-25, 2024

NIH National Institute on Aging



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Biden Nominates Dr. Monica Bertagnolli as Next NIH Director

- On May 15th, President Biden announced his intent to nominate National Cancer Institute (NCI) Director Dr. Monica Bertagnolli as director of NIH.
- Dr. Bertagnolli is a world-renowned surgical oncologist, cancer researcher, educator, and physician-leader.
- She became the first woman to serve as director of NCI in October 2022.
- Appointment to the position of NIH director requires confirmation by the U.S. Senate. Dr. Bertagnolli's confirmation hearing occurred yesterday, 10/18.





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