Alzheimer's Disease and Related Dementias Research Update

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

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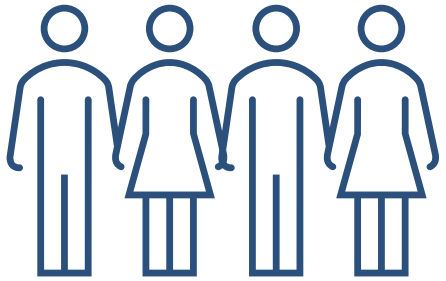
National Institutes of Health
Turning Discovery Into Health

February 9, 2026

The Societal Impact of Dementia



- In 2025, there were **7.1 million people** living with Alzheimer's in the U.S.; this number is projected to nearly double to **13.9 million by 2060**, with many others living with related forms of dementia.

Rajan, KB., et al. (2021). *Alzheimers Dement.* 17(12):1966-1975.

- A recent report estimates the total economic burden of dementia will reach **$781 billion** this year in the U.S.
- The impact goes beyond medical costs and includes hours of unpaid care by family and friends, earnings losses, and declines in quality of life.

https://schaeffer.usc.edu/research/the-cost-of-dementia-in-2025/

Overview of the National Institutes of Health (NIH)

NIH is the primary U.S. government agency responsible for biomedical and public health research.

It is comprised of 27 institutes and centers with specific areas of expertise.

Two of these institutes, the National Institute on Aging (NIA) and the National Institute of Neurological Disorders and Stroke (NINDS), collaborate closely to drive progress on the research goals of NAPA.

- NIA leads research on Alzheimer's disease
- NINDS leads research on the Alzheimer's related dementias

NIH Engagement with NAPA

Participation in the Advisory Council on Alzheimer's Research, Care, and Services

- The NIA Director serves as the NIH representative on the Council (in close collaboration with NINDS).
  - NIH provides federal updates at quarterly Council meetings.

Participation on Council Subcommittees

- Delegates from NIA and NINDS participate in Council subcommittee meetings.
- NIH subcommittee members provide technical assistance on annual recommendations developed by the subcommittees to advance the goals of NAPA.

Advancing Progress Towards Goals

- As the largest funder of biomedical research in the US, NIH plays a central role in advancing the goals of NAPA.

NIH Research Efforts to Advance the Goals of NAPA

Progressing through Research

Research efforts across NIH are aimed at:

- Identifying the disease mechanisms,
- Improving diagnosis, assessment, and monitoring,
- Delaying and stopping disease progression,
- Reducing dementia risk and preventing disease, and
- Improving clinical care

Tracking Progress

NIH has established a robust system for tracking, analyzing, and reporting on progress and activities related to NAPA – the **AD/ADRD Research Implementation Milestones.**

NIH Tracks Progress through AD/ADRD Research Implementation Milestones

- NIH research implementation milestones are generated with **input from a multistakeholder community** including leading experts working on AD/ADRD and other chronic diseases, public advocates, and others.
- These milestones represent a **research framework detailing specific steps and success criteria** towards achieving National Plan goals.
- This research framework **directly informs NIH funding priorities.**

Research Implementation Milestones
https://www.nia.nih.gov/research/milestones

- Epidemiology/Population Studies
- Disease Mechanisms
- Diagnosis, Assessment, & Disease Monitoring
- Translational Research and Clinical Interventions
- Dementia Care and Impact of Disease
- Research Resources
- AD Related Dementias Focus

Research Priorities are Identified through the Annual Dementia Research Summits

2025	2026	2027
Alzheimer's Disease-Related Dementias Research Summit	**Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers**	**Alzheimer's Disease Research Summit**
NINDS	***NIA***	***NIA***

- As outlined in NAPA, NIH holds tri-annual Research Summits that help establish national research priorities.
- Summits are designed to incorporate input from a range of experts (e.g. researchers, clinicians, people living with and caring for people with dementia, and others).
- NIH updates dementia research milestones following each Summit.

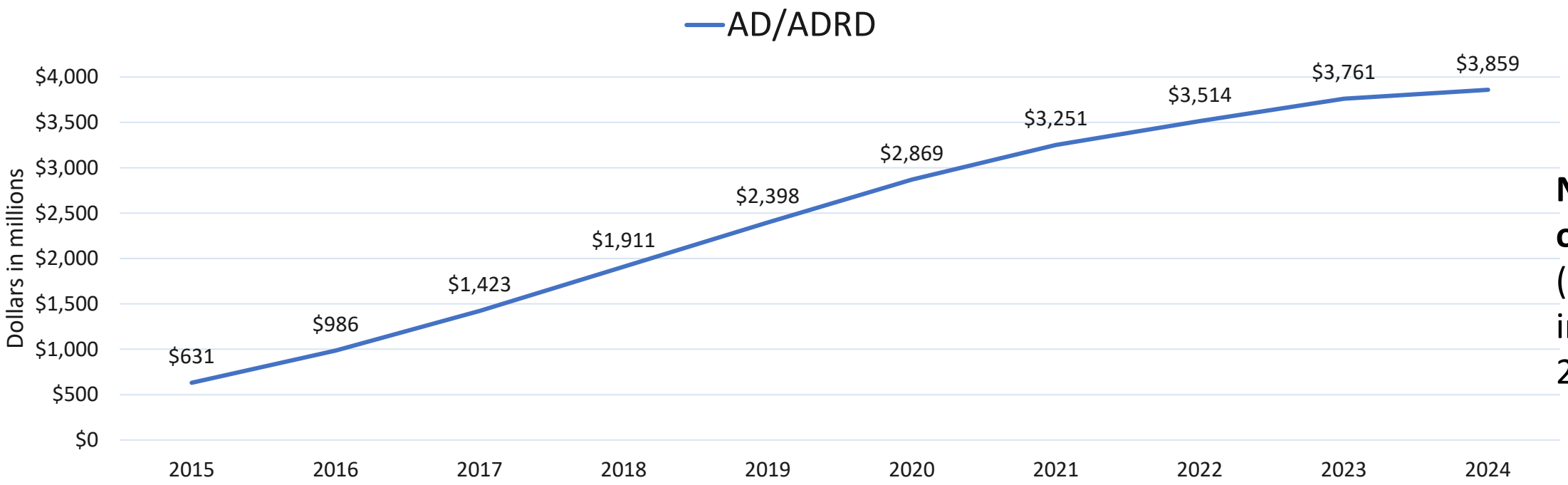
NIH Professional Judgment Budget for AD/ADRD Research

- Since 2016, in response to Congressional mandates, NIH has annually released an **Alzheimer's and Related Dementias Professional Judgement Budget** to estimate the additional funding needed to advance NIH-supported research toward achieving the goals outlined by the National Plan to Address Alzheimer's Disease.
- The report also identifies example AD/ADRD research opportunities at the forefront of science.

- NIH annually submits the Professional Judgement Budget to the President and then Congress.
- In 2024, the *Alzheimer's Accountability and Investment Act* further established the requirement for NIH to submit a professional judgment budget for AD/ADRD through 2035.

https://www.nia.nih.gov/about/professional-judgment-budget

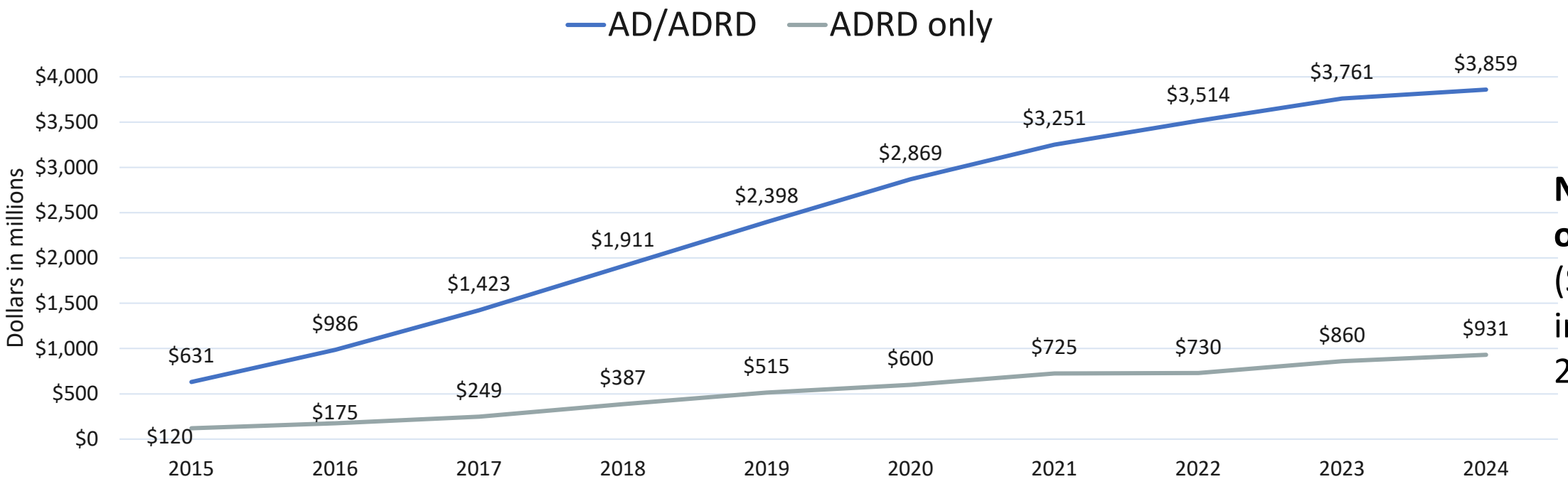
Growth in Funding Leads to AD/ADRD Advances



NIH Spending on AD/ADRD (Six-fold increase from 2015-2024)

Over the past decade, increases in Congressional appropriations for dementia research have led to tremendous progress in understanding, diagnosing, treating, preventing, and caring for people with dementia.

Growth in Funding Leads to AD/ADRD Advances



NIH Spending on AD/ADRD (Six-fold increase from 2015-2024)

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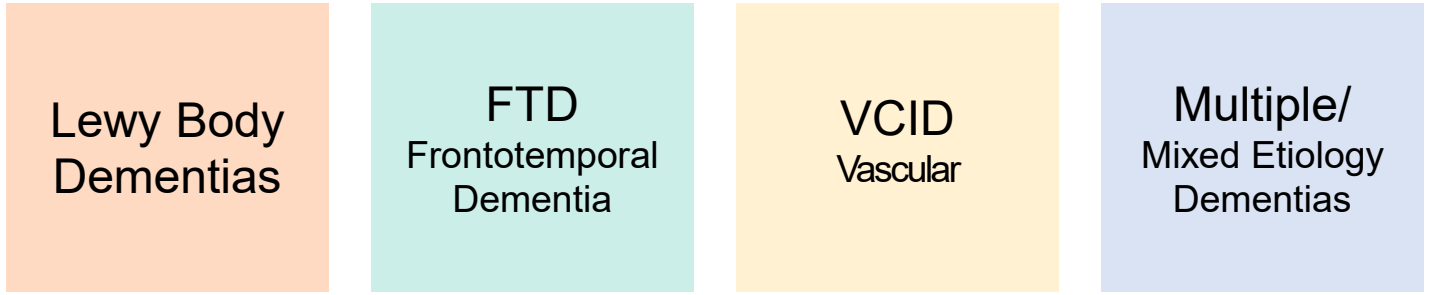
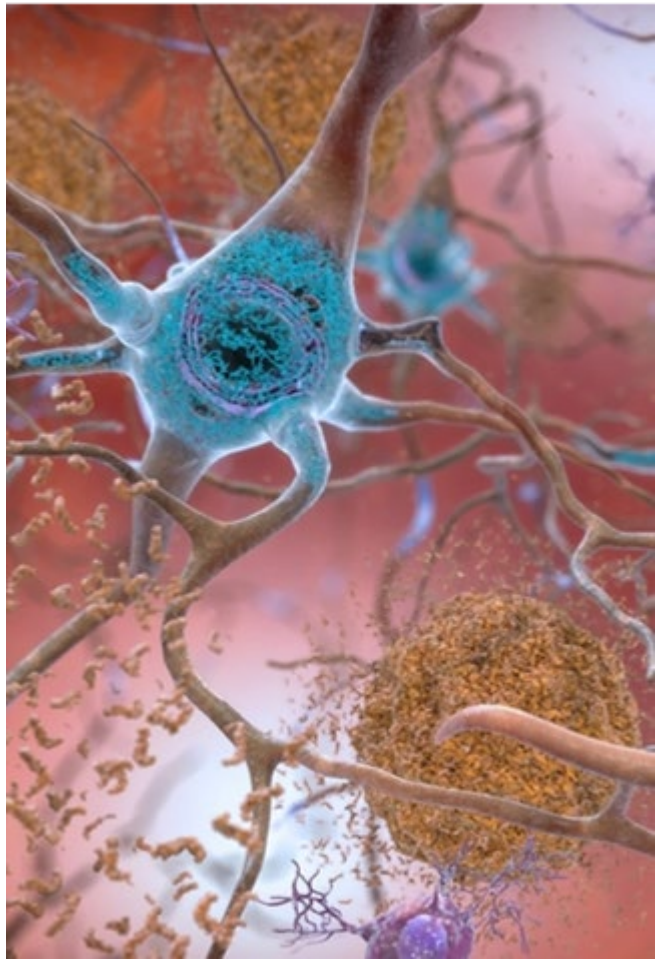
NINDS Leads Research on Related Dementias



- Alzheimer's Disease-Related Dementias (ADRD) share clinical symptoms and brain pathologies with Alzheimer's disease. ADRDs named in the National Plan include:
  - Lewy body dementias (i.e., dementia with Lewy bodies and Parkinson's disease dementia)
  - Frontotemporal dementias
  - Vascular contributions to cognitive impairment and dementia
  - Mixed-etiology dementias
- Emerging potential related pathologies include limbic-predominant age-related TDP-43 encephalopathy (LATE), chronic traumatic encephalopathy (CTE), and post-traumatic brain injury (TBI) dementia.

Multiple Etiologies of Alzheimer's Disease and Related Dementias

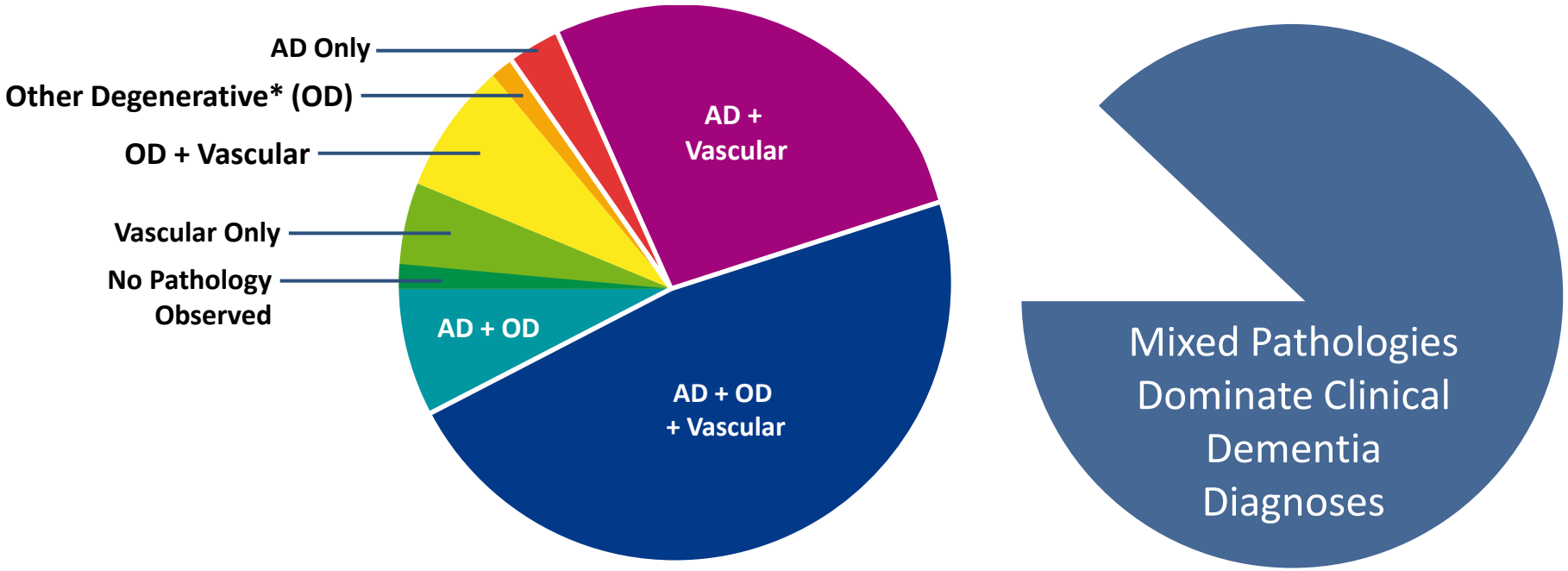
- **Global prevalence of dementia is rapidly increasing**
- **Wide-ranging and complex genetic and environmental risk factors**
- **Dementia diagnoses can have overlapping clinical presentations**
- **Multiple systems disrupted (often in the same person)**
  - Abnormal protein folding and aggregation (amyloid, tau, a-synuclein, TDP-43, etc.)
  - Inflammation and disruptions in the brain's immune response
  - Disruptions in the vascular system that supplies blood to the brain and helps clear toxic substances
  - Disruptions in cellular metabolism in the brain
  - Cellular aging and death



Traditional Perception of 1:1 Relationship Between Brain Pathologies and Clinical Dementia Diagnoses is the Exception, Not the Rule

CLINICAL DIAGNOSIS: PROBABLE ALZHEIMER'S DEMENTIA

PATHOLOGICAL DIAGNOSES:



Adapted from KAPASI A, ET AL. ACTA NEUROPATHOL. 2017 AUG;134(2):171-186. ROS/MAP (N = 447)

*Other Degenerative (OD) included neurodegenerative disease pathologies: Lewy bodies, TDP-43, hippocampal sclerosis

THIS MATTERS FOR DEVELOPMENT OF PRECISION APPROACHES & BIOMARKERS

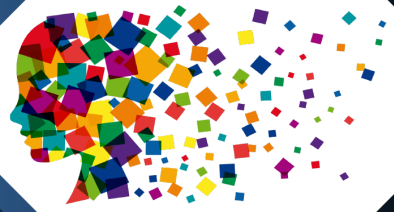
Increased recognition that more than one disease process is typically present in a person's brain should help move toward effective prevention and treatments.

NIH ADRD Summits Shape ADRD Research Priorities

National Institute of Neurological Disorders and Stroke

Alzheimer's Disease-Related Dementias Summit 2025

April 29-30 & June 2, 2025



Scientific Chair: ***Dr. Kate Possin, UCSF***
NIH Lead: ***Dr. Amber McCartney, NINDS***

NINDS ADRD Summit 2025 Report

ADRD Summit 2025 Topics

Multiple Etiology Dementias (MED):
- Research for Implementation of Discoveries into Practice
- Post Traumatic Brain Injury (TBI) AD/ADRD
- LATE (TDP-43 in Common Late-Onset Dementias)
- Basic and Clinical Discovery Research
- Impact of Exposome on AD/ADRD Risk & Outcomes

Frontotemporal Dementias (FTD)

Lewy Body Dementias (LBD)

Vascular Contributions to Cognitive Impairment and Dementia (VCID)

Research to Improve Outcomes for Representative Populations at Risk and Living with AD/ADRD

Engagement and Interaction

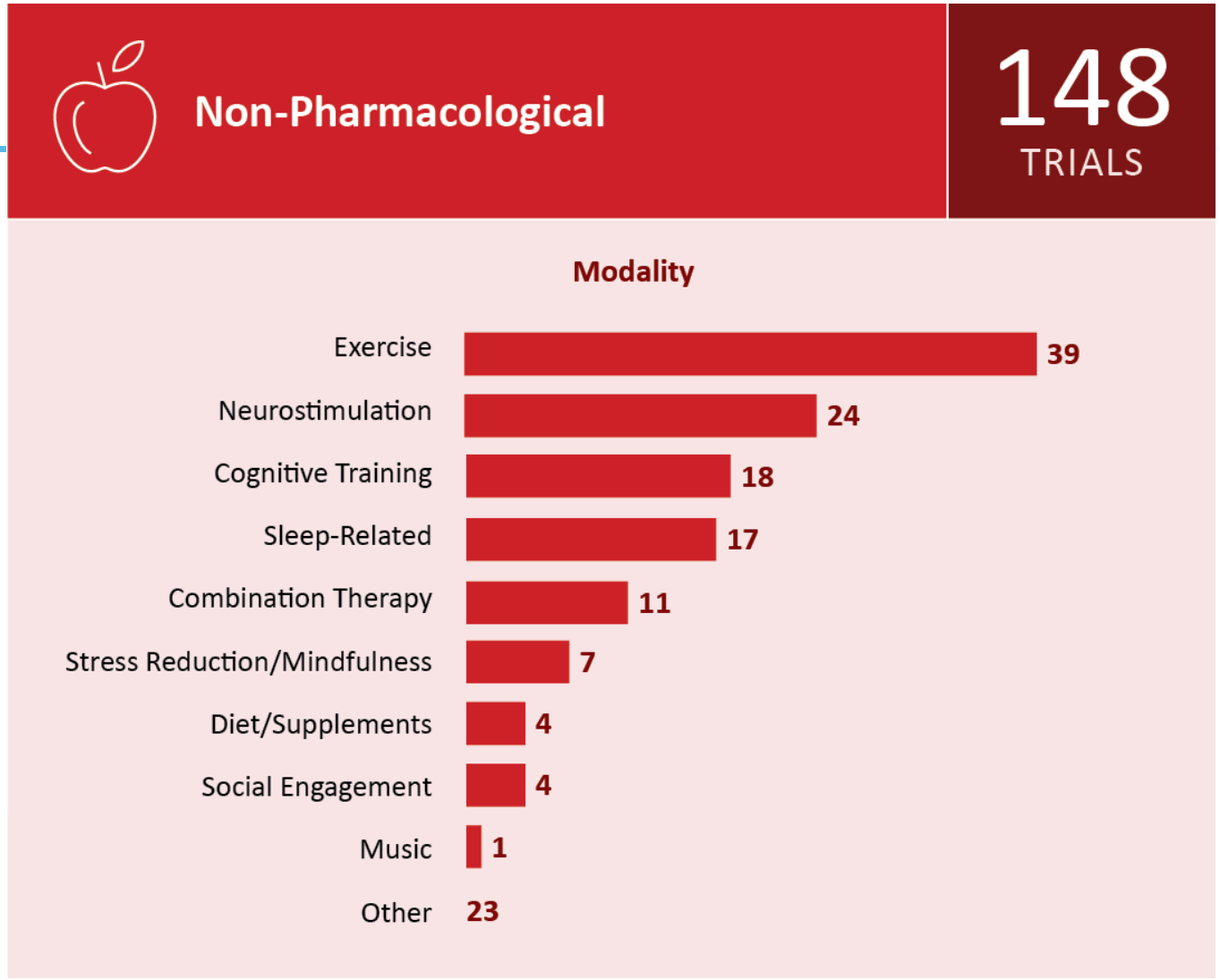
- ❑ Registration >2,500 attendees (400-900 during sessions)
- ❑ Academic, Clinical, Government, Industry, Nonprofit, PWLE & Public
- ❑ 3 days, 9 scientific sessions, 139 panelists, 48 individual talks
- ❑ 230 minutes of open microphone discussions

National Institute of Neurological Disorders and Stroke

National Institute on Aging

Investing in Clinical Trials of Non-Pharmacological Approaches to Prevent & Treat Dementia

- Progress in research to understand risk has revealed numerous behavioral and lifestyle changes which may help treat or prevent cognitive decline.
- Ongoing NIH-funded research is exploring the effect of behavioral interventions on dementia onset and progression.



Active NIH-funded non-pharmacological trials as of March 2025

www.nia.nih.gov/research/ongoing-AD-trials

Building a Toolbox of Approaches

Pharmacological

63 TRIALS

50 trials

Phase I & Phase II

Targeted Disease Process

Amyloid	6	Synaptic Plasticity	4
Inflammation	5	Vasculature	4
Multi-Target	5	Oxidative Stress	3
Receptors	5	Tau	2
Circadian Rhythm	4	Proteostasis/ Proteinopathies	1
Growth Factors/Hormones	4		
Metabolism/Bioenergetics	4	Other	3

13 trials

Phase II/III, III, and IV

Targeted Disease Process

Amyloid	5	Vasculature	2
Inflammation	2	Metabolism/Bioenergetics	1
Tau	2	Multi-Target	1

Active NIH-funded pharmacological trials as of March 2025

- Diverse set of targets
- Multiple modalities
  - Small molecules, immunotherapies, gene therapies, vaccines
- Trials exploring combination approaches
- NIH also supports a robust pre-clinical & translational research portfolio, to identify novel targets and develop new drug candidates to treat dementia

www.nia.nih.gov/research/ongoing-AD-trials

NIH's AD/ADRD Translational Research Program is Expanding the Therapeutic Pipeline

- **25 new drug candidates advanced to clinical development**
  - 17 are in Phase I trials
  - 7 are in Phase II trials
  - 1 is in Phase III trial
- **53 additional drug candidates are in preclinical development**

- **Multiple therapeutic modalities**
  - Small molecules
  - Immunotherapy
  - Gene therapy
  - Antisense Oligonucleotides
  - Peptides

Targeting multiple aspects of the disease biology

- Amyloid beta
- Tau
- ApoE
- Proteostasis
- Inflammation
- Bioenergetics and metabolism
- Vascular factors
- Microbiome
- Growth factors and hormones
- Neurogenesis
- Synaptic plasticity
- Multi-target

Additional Active NIA AD/ADRD Clinical Trials

Dementia Care and Caregiving

203 TRIALS

Type

Understanding Disease Processes

32 TRIALS

Diagnostic Tools, Assessments, & Imaging Studies

18 TRIALS

Treatments for Neuropsychiatric Symptoms

2 TRIALS

Data last updated: March 2025

For more information please visit www.nia.nih.gov/research/ongoing-AD-trials

NIH National Institute on Aging

Highlighted Progress in Dementia Research

	2012	2026
Understanding disease mechanisms	Several genes and pathways known to contribute to AD/ADRD	• 80+ genetic areas associated with AD/ADRD and many different pathways identified • Mixed pathologies are the norm, not the exception • Genetic variants identified that appear to protect against developing AD
Diagnostics	Amyloid PET agent for AD	• Amyloid and Tau PET agents for AD • Commercially available blood tests to help diagnose AD • Validated behavioral assessments
Disease-modifying treatments	None (treatments for symptom management available)	• Two disease-modifying therapies available in the U.S. (donanemab & lecanemab, including an at-home injection version of lecanemab)
Prevention	No effective strategies known	• Intensive blood pressure control and multidomain lifestyle intervention (e.g., combining diet, exercise and cognitive stimulation)
Care & caregiving	Foundational work to develop and test care models	• Collaborative care models and Resources for Enhancing Alzheimer's Caregiver Health (REACH) II are interventions for care and/or caregiver support ready for broader implementation with continued evaluation

Current and Future Priorities

Save the Date and Register Now!

2026 Dementia Care and Caregiving Research Summit

March 17-19, 2026

Virtual Meeting

Registration for each day of the Summit, along with associated events, can be found at:

2026 Dementia Care and Caregiving Research Summit | National Institute on Aging

https://www.nia.nih.gov/2026-dementia-care-summit

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

- At the direction of Congress, NIA and NINDS asked the National Academies of Sciences, Engineering, and Medicine to convene an expert committee **to examine and assess the current state of research on the prevention and treatment of Alzheimer's disease (AD) and AD-related dementias (ADRD)**.

- **The resulting report was released in December 2024.**

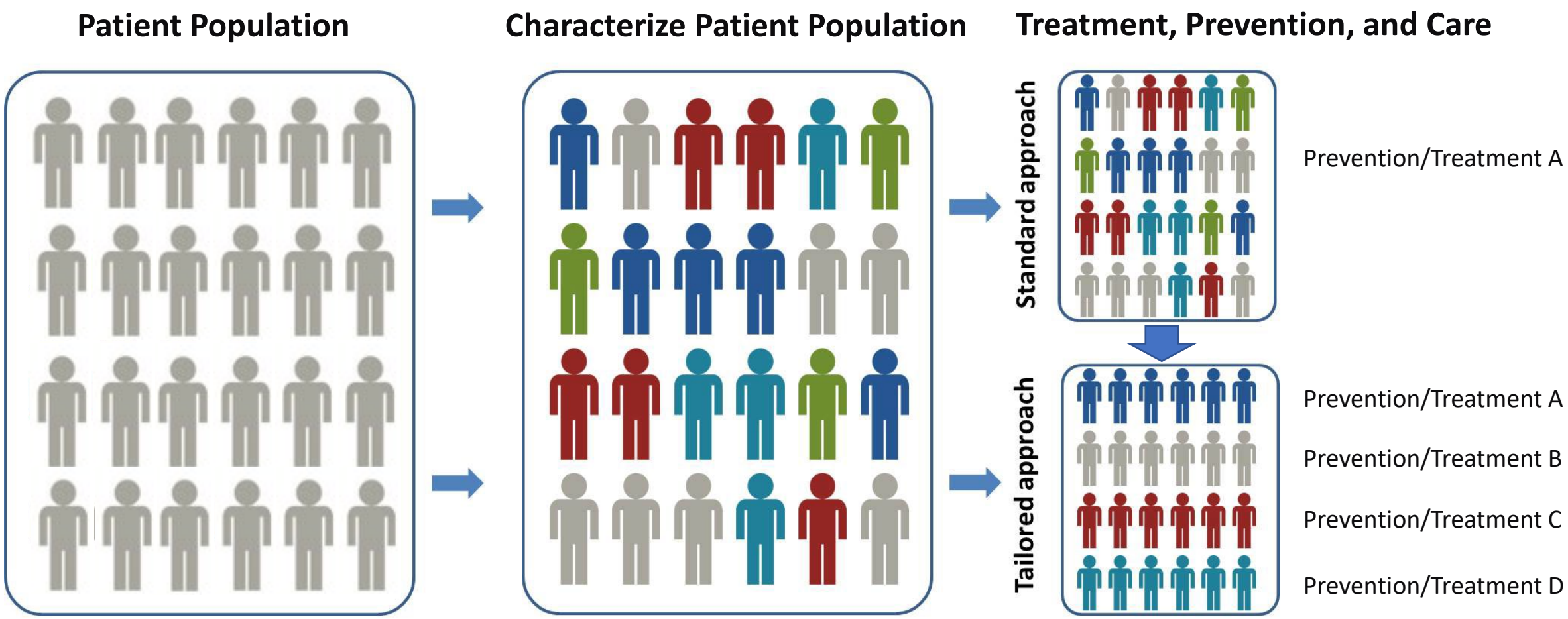
Five strategies were recommended to overcome barriers to scientific progress in AD/ADRD research:

1. Enhance longitudinal and intervention research
2. Enable multidisciplinary and collaborative research
3. Foster inclusive research
4. Increase the accessibility and usability of biological samples and data
5. Catalyze transformational change through innovative AD/ADRD research

NASEM's recommended strategies complement NIH's existing AD/ADRD Research Implementation Milestones.

https://www.nationalacademies.org/projects/HMD-HSP-23-04/publication/28588

Precision Prevention, Treatment & Care for Dementia



Resources

Alzheimer's Disease Education and Referral (ADEAR) Center

- **Free publications on Alzheimer's** and related dementias, including caregiving and home safety tips
- **Answers to specific questions** about Alzheimer's
- **Referrals** to local supportive services and Research Centers
- Information on **clinical trials**

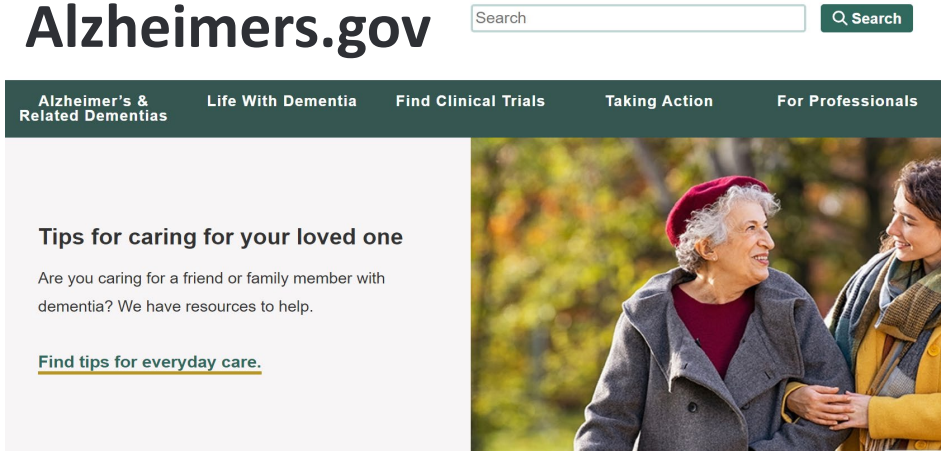
Constituents can reach the ADEAR Center at:

Phone:
800-438-4380
(Mon-Fri, 8:30am – 5:00pm ET)

Email: adear@nia.nih.gov

https://www.nia.nih.gov/health/alzheimers-and-dementia/about-adear-center

Alzheimers.gov



Educational resource and **portal to federal information** on Alzheimer's and related dementias

Contains **easy-to-read, accessible information** on dementias and living with dementia, along with links to additional federal agency resources.

Thank you!

U.S. FOOD & DRUG ADMINISTRATION

FDA Updates

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

February 9, 2026

FDA's Role in Supporting the National Alzheimer's Project Act

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

- Ensure rigorous evaluation of safety and efficacy for all AD/ADRD products
- Review and approve disease-modifying therapies and symptomatic treatments
- Facilitate clinical trial design through guidance documents and regulatory advice
- Qualify biomarkers to accelerate drug development and enable precision medicine approaches

Goal 2: Enhance Care Quality and Efficiency

- Authorize diagnostic tools that enable earlier and more accurate detection of AD/ADRD
- Advance development of blood-based biomarkers to improve accessibility of diagnosis
- Clear medical devices and digital health technologies for cognitive assessment and monitoring
- Approve imaging agents to support clinical decision-making and treatment selection

Cross-Cutting Contributions:

- Support innovation and research through engagements in the pre-competitive space
- Collaborate with NIH, CMS, and other federal partners to align regulatory pathways with research priorities

FDA Achievements since 2012: Therapeutics and Imaging

FDA

THERAPEUTICS

2023

Leqembi (lecanemab-irmb)

Converted to traditional approval after confirmatory trial verified clinical benefit (July 6, 2023).

2024

Kisunla (donanemab-azbt)

Approved for treatment of adults with Alzheimer's disease (July 2, 2024).

IMAGING AGENTS

2012–14

Amyloid PET tracers authorized

Amyvid (2012), Vizamyl (2013), and Neuraceq (2014) enabled in vivo assessment of amyloid plaque burden.

2020

Tauvid (flortaucipir F 18)

First tau PET imaging agent approved for visual detection of neurofibrillary tangles (May 28, 2020).

2025

Amyloid PET label updates

Expanded indications to support selection for amyloid beta–directed therapy; quantitative analysis added; prior limitations removed (Amyvid, Neuraceq, Vizamyl).

Together, these actions support earlier identification of amyloid/tau pathology and safe access to disease-modifying therapies.

FDA Achievements since 2012: Diagnostics and Biomarkers

FDA

CSF TESTS

2022

Lumipulse G β-amyloid ratio (1-42/1-40)

First in vitro diagnostic (De Novo) to aid early detection of amyloid plaques using CSF.

2022

Elecsys CSF Abeta42 + pTau181 (ratio)

510(k) cleared CSF assays (used as pTau181/Abeta42 ratio) concordant with amyloid PET.

2023

Elecsys CSF Abeta 42 + tTau (ratio)

Additional CSF assays cleared (used as tTau/Abeta42 ratio) to support diagnosis pathway.

BLOOD TESTS

May 2025

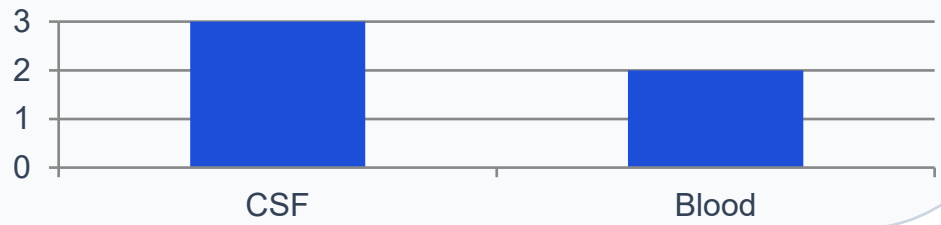
Lumipulse pTau217/β-Amyloid 1-42 (plasma)

First FDA-cleared blood test to aid in diagnosing Alzheimer's disease (ages 55+).

Oct 2025

Elecsys pTau181 (plasma)

FDA-cleared blood test for primary care to help rule out Alzheimer's-related amyloid pathology (ages 55+).



Impact

- Earlier detection and more accessible testing
- Better patient selection for therapies
- Improved clinical trial enrollment and monitoring

Impact at a Glance (2012–2025 highlights)

Earlier, more accessible detection

Shift from PET/CSF-only pathways toward scalable blood-based testing for appropriate patients.

Better patient selection for therapy

Expanded amyloid PET indications support identifying candidates for amyloid beta–directed therapies.

More treatment options for early AD

Disease-modifying therapies with demonstrated clinical benefit in early symptomatic Alzheimer's disease.

FDA Accomplishments Since 2012 - Therapeutics

Disease-Modifying Treatments:

- **2023:** Leqembi (lecanemab-irmb) - First traditional FDA approval for Alzheimer's disease treatment following confirmatory trial verification of clinical benefit
- **2024:** Kisunla (donanemab-azbt) - Approved for treatment of adult patients with Alzheimer's disease (July 2024)

Imaging Agents:

- **2020:** Flortaucipir - First radioactive tracer approved to show presence of tau protein tangles
- **2024:** Revised labeling for three amyloid PET imaging drugs (florbetapir, florbetaben, and flutemetamol) to:
  - Indicate use in selecting patients for anti-amyloid therapies
  - Enable quantitative analysis alongside visual interpretation
  - Remove previous limitations of use

FDA Accomplishments Since 2012 - Diagnostics

Blood-Based Diagnostics (2025):

- **First blood test cleared to aid in diagnosis of AD:** Lumipulse G pTau217/β-Amyloid 1-42 Plasma Ratio for identifying patients with amyloid pathology (ages 55+) who are exhibiting signs and symptoms.
- **First blood test to rule out amyloid pathology:** Elecsys pTau181 test for initial assessment of AD in primary care settings (ages 55+) in patients presenting with signs, symptoms or complaints of cognitive decline.

Cerebrospinal Fluid (CSF) Diagnostics:

- **2022:** Lumipulse G β-amyloid Ratio (1-42/1-40) - First in vitro diagnostic test for early detection of amyloid plaques associated with AD in adult patients (ages 55+) presenting with cognitive impairment
- **2022:** Elecsys CSF β-amyloid 1-42 and pTau181 tests (used as ratio)
- **2023:** Elecsys CSF β-amyloid 1-42 and tTau assays (used as ratio)


FDA
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ADMINISTRATION

The U.S. National Science Foundation

Rebecca J. Ferrell, PhD
Section Head, Neuroscience, Cognitive, and Language Sciences
Directorate for Social, Behavioral and Economic Sciences
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The U.S. National Science Foundation is an independent federal agency that supports science and engineering in all 50 states and U.S. territories.

NSF was established in 1950 by Congress to:

- **Promote** the progress of science.
- **Advance** the national health, prosperity and welfare.
- **Secure** the national defense.
- We fulfill our mission chiefly by making grants. Our investments account for about 25% of federal support to America's colleges and universities for basic research: research driven by curiosity and discovery. We also support solutions-oriented research with the potential to produce advancements for the American people.

U.S. National Science Foundation Major Initiatives

Artificial Intelligence

- NSF has invested in AI research since the early 1960s, setting technical and conceptual foundations driving today's AI innovations.

- NSF is making investments in AI that will catalyze new discoveries and translate this knowledge into the hands of the American enterprise.

Biotechnology

- NSF investments in biotechnology have accelerated scientific discovery and enabled the use of living things to create goods and services that benefit society.

- Advances built on the discovery, use and alteration of living things are growing the U.S. economy and transforming fields as diverse as medicine and manufacturing, agriculture and clean energy.

Quantum Revolution

- NSF has invested in the foundational research and development driving the quantum revolution for decades. Many technologies that leverage quantum effects have their roots in NSF investments.

- Looking forward, quantum information science and engineering outcomes promise to be even more impactful, e.g. computational power, sophisticated sensors and imaging tools.

STEM Workforce

- NSF supports efforts to increase the participation of individuals, institutions and communities across the nation — ensuring broad access to resources and opportunities for discovery and innovation.

- NSF invests in approaches that build STEM education and research capacity, catalyze new areas of STEM research, and develop strategic partnerships and alliances.

NSF-funded, ADRD-relevant research

BASIC RESEARCH

Amyloid proteins
Brain physiology & cognition
Tools in imaging, statistics, model systems

ADVANCING DIAGNOSTICS and TREAMENTS

Novel biomarker development
Early detection/prediction of MCI/AD
Modulating intracellular protein levels
Novel drug delivery mechanisms

IMPROVING QUALITY OF LIFE

Data infrastructure for caregivers
Safety and prevention systems
Socially assistive robots and AI
Caregiver/patient dynamics, well-being

Examples from 2024-2025

SBE: Idiomatic Language as a Diagnostic Marker in Alzheimer's Dementia

I-Corps: Translation potential of using artificial intelligence (AI) to diagnose Alzheimer's disease and other dementia-related disorders

HCC: Future Proofing for Age-Related Changing Cognitive Abilities using Smart Objects as Assistive Technologies

SCH: Personal Determinants of Health Enhanced Machine Learning Models for Early Prediction of Alzheimer's Disease and Related Dementias

Keyword title and abstract search at www.nsf.gov/awardsearch

Awards made 01/01/2012 or later: ~$200M across all Directorates

Partnership Opportunities and STEM Workforce

The U.S. National Science Foundation partners with other organizations to amplify its investments in research and education — increasing the foundation's economic and societal benefits to the United States.

NSF's strategic partnerships focus on accelerating discovery in science and engineering by:

- Expanding the types of questions that can be addressed.
- Enabling access to unique expertise, infrastructure or sites.
- Building and nurturing broader, more inclusive communities of researchers and educators.

Non-Academic Research Internships for Graduate Students (INTERN) Program

INTERN enables graduate students to acquire core professional competencies and skills to support careers in any sector of the U.S. economy. The program offers 6-month internships:

- Complementary, non-academic training for graduate students.
- Professional development experience in preparation for multiple career pathways.
- Opportunities that encourage the participation of the full spectrum of diverse talent in science, technology, engineering, and mathematics (STEM).

The Congressionally Directed Medical Research Programs

Alzheimer's Research Program

Melissa Miller, Ph.D., Program Manager,
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February 9, 2026

Defense Health Agency
RESEARCH & DEVELOPMENT ®

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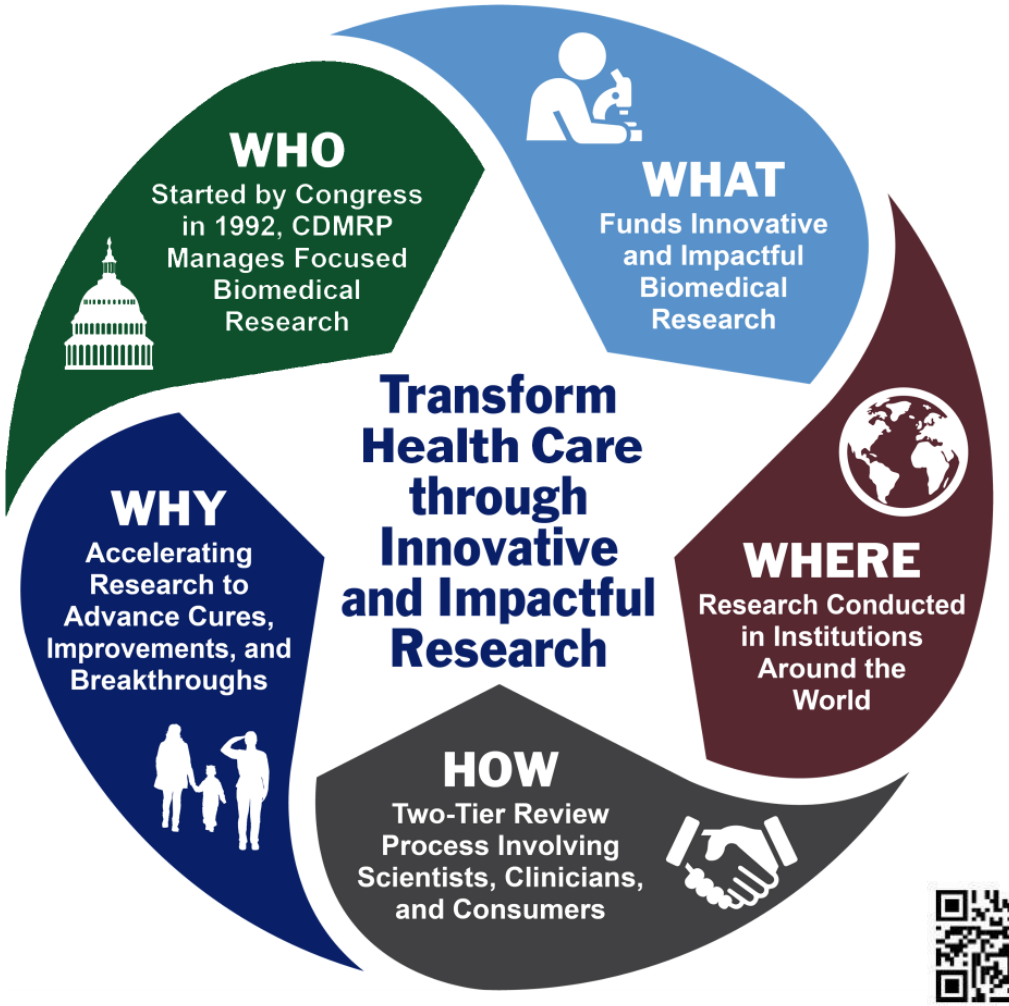
About the CDMRP

Mission

Responsibly manage collaborative research that discovers, develops and delivers health care solutions for Service Members, their Families, Veterans and the American public



https://cdmrp.health.mil

About the CDMRP – Hallmarks

IMPACT

- Funds impactful, innovative research for specific programs added by Congress to the Defense Appropriations Bill
- Targeted research fills gaps and addresses high-priority needs
- Focused on improving health, well-being and health care quality for those affected

STRATEGY

- Annually adapts each program's vision and investment strategy, allowing rapid response to changing needs, opportunities and congressional intent
- Publicly announces and competes funding opportunities
- Ensures scientific excellence and programmatic relevance through the National Academy of Medicine-recommended two-tier review process

Hallmarks, cont'd

COLLABORATION

- Integrates consumers as full participants throughout program processes and as the "True North" of the CDMRP
- Collaborates with other funding organizations – complementary, not duplicative

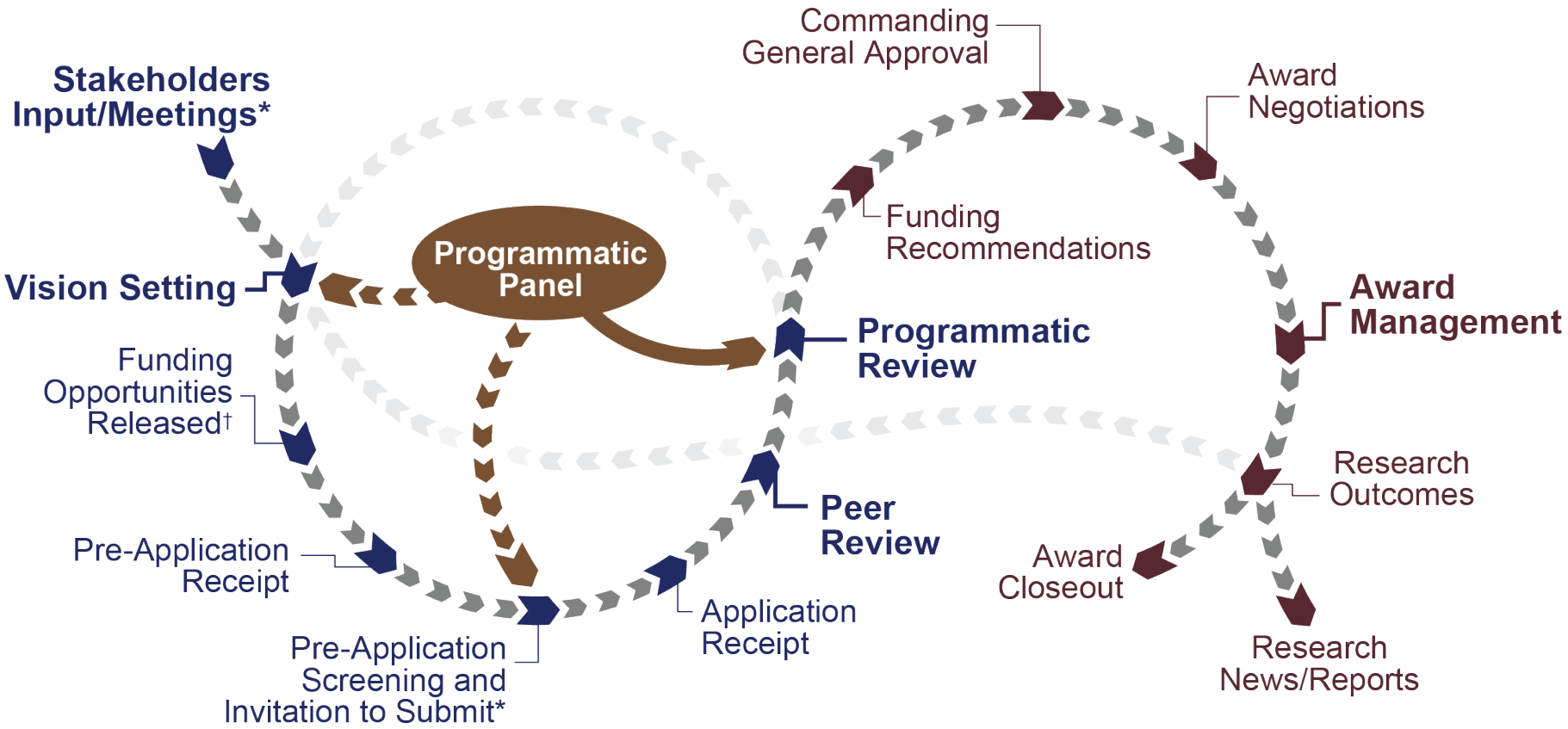
STEWARDSHIP

- Obligates funds up front; limited out-year budget commitments
- Maximizes funding available for research through low management costs and efficient processes
- Maintains transparency and accountability

CDMRP FY24, FY25, FY26 Appropriations

Research Program	FY24 $M	FY25 $M	FY26 $M	Research Program	FY24 $M	FY25 $M	FY25 $M
Alcohol and Substance Use Disorders	$4.0		$4.0	Multiple Sclerosis	$20.0		$15.0
Alzheimer's	$15.0	$15.0	$15.0	Neurofibromatosis	$25.0		$25.0
Amyotrophic Lateral Sclerosis	$40.0	$40.0	$40.0	Ovarian Cancer	$45.0	$15.0	$20.0
Arthritis	$10.0		$10.0	Pancreatic Cancer	$15.0		$50.0
Autism	$15.0		$8.0	Parkinson's	$16.0		$20.0
Bone Marrow Failure	$7.5		$7.5	Peer Reviewed Cancer, 22 Topics	$130.0	$130.0	$16.0
Breast Cancer	$150.0	$130.0	$145.0	Peer Reviewed Medical, 56 Topics	$370.0	$150.0	$165.0
Combat Readiness Medical	$5.0		$5.0	Peer Reviewed Orthopaedic	$30.0		$370.0
Duchenne Muscular Dystrophy	$10.0	$12.5	$12.5	Prostate Cancer	$110.0	$75.0	$75.0
Epilepsy	$12.0		$12.0	Rare Cancers	$17.5	$17.5	$17.5
Glioblastoma	$10.0			Reconstructive Transplant	$12.0		$12.0
Hearing Restoration	$5.0		$5.0	Spinal Cord Injury	$40.0		$33.0
Joint Warfighter Medical	$20.0		$10.0	Tick-Borne Disease	$7.0		$7.0
Kidney Cancer	$50.0		$15.0	Toxic Exposures	$30.0	$15.0	$15.0
Lung Cancer	$25.0		$20.0	Traumatic Brain Injury and Psychological Health	$175.0		$40.5
Lupus	$10.0		$10.0	Tuberous Sclerosis Complex	$8.0		$10.0
Melanoma	$40.0	$40.0	$40.0	Vision	$20.0		$10.0
Military Burn	$10.0	$10.0	$10.0	**TOTAL =**	$1.509B	$650M	$1.270B

Program Cycle



*As needed
†Pending Congressional appropriation

Consumers are the "True North" and Foundation of the CDMRP

The CDMRP includes consumers – patients, survivors, family members and/or caregivers – in every aspect of the program lifecycle.

Consumers serve as full voting members on peer review and programmatic panels.

Through their lived experiences, consumers add valuable perspectives, a sense of urgency and important input to the program mission, investment strategy and research focus.

Program Lifecycle

- Stakeholder Meeting
- Vision Setting
- Pre-App Screening
- Peer Review
- Programmatic Review
- Funding Recommendations
- Award Execution
- Awards Management/ Closeout

FY24 Consumer Involvement

82 consumers* served as programmatic panel members and ad hoc reviewers representing **72** consumer advocacy organizations, Service Members or Veterans

883 consumer reviewers** assigned to panels, nominated by **345** consumer advocacy organizations

Participate on research teams for funded projects

19 programs offered funding opportunities that incorporate consumer participation in the research project

* All unique individuals
** 775 unique individuals

CDMRP Award Mechanisms

- Funding opportunities are program announcements or program-specific broad agency announcements
  - Grants/cooperative agreements; few contracts/other transactions
- Numerous types of award mechanisms
  - Tailored to the goals of each program
  - Programs, topics and focus areas may vary from year to year
  - Fund the full continuum of research

Initial Concepts

- Concept
- Discovery
- Exploration–Hypothesis Development

Early and Maturing Ideas

- Idea
- Idea Development
- Investigator-Initiated

Pre-Clinical and Translational

- Translational Research
- Technology/ Therapeutic Development

Clinical

- Clinical Trial
- Clinical Research
- Outcomes Research

Team Science

- Consortium
- Focused Program
- Translational Partnership

Research Capacity

- Virtual Academy/ Center
- New Investigator
- Early Career

Alzheimer's Research Program

- Initiated by Congress in FY11, CDMRP-managed FY14-present
- **$228M** in appropriations to date, including **$15M** in FY25 and **$15M** in FY26

- **Vision:** Mitigate the impact of Alzheimer's and related dementias associated with TBI, military and diverse risks
- **Mission:** Fund impactful, solution-oriented research to address critical needs and improve quality of life for Service Members, Veterans, their Families and the public who are living with Alzheimer's disease and related dementias

Incidence/Prevalence

- 6.9 million living with AD/ADRD today
- 1 in 9 over age 65 will develop and receive a diagnosis of AD/ADRD

Mortality

- Always fatal – no curative treatments
- Life expectancy after diagnosis is 4-8 years
- 7th leading cause of death in the U.S.

Costs

- $335B annually plus $340B in unpaid caregiver labor
- 11 million unpaid caregivers, 49% represent spouse/family

Risk Factors

- Genetics
- Sex
- Racial and ethnic background
- Age
- Cardiovascular disease
- Military service

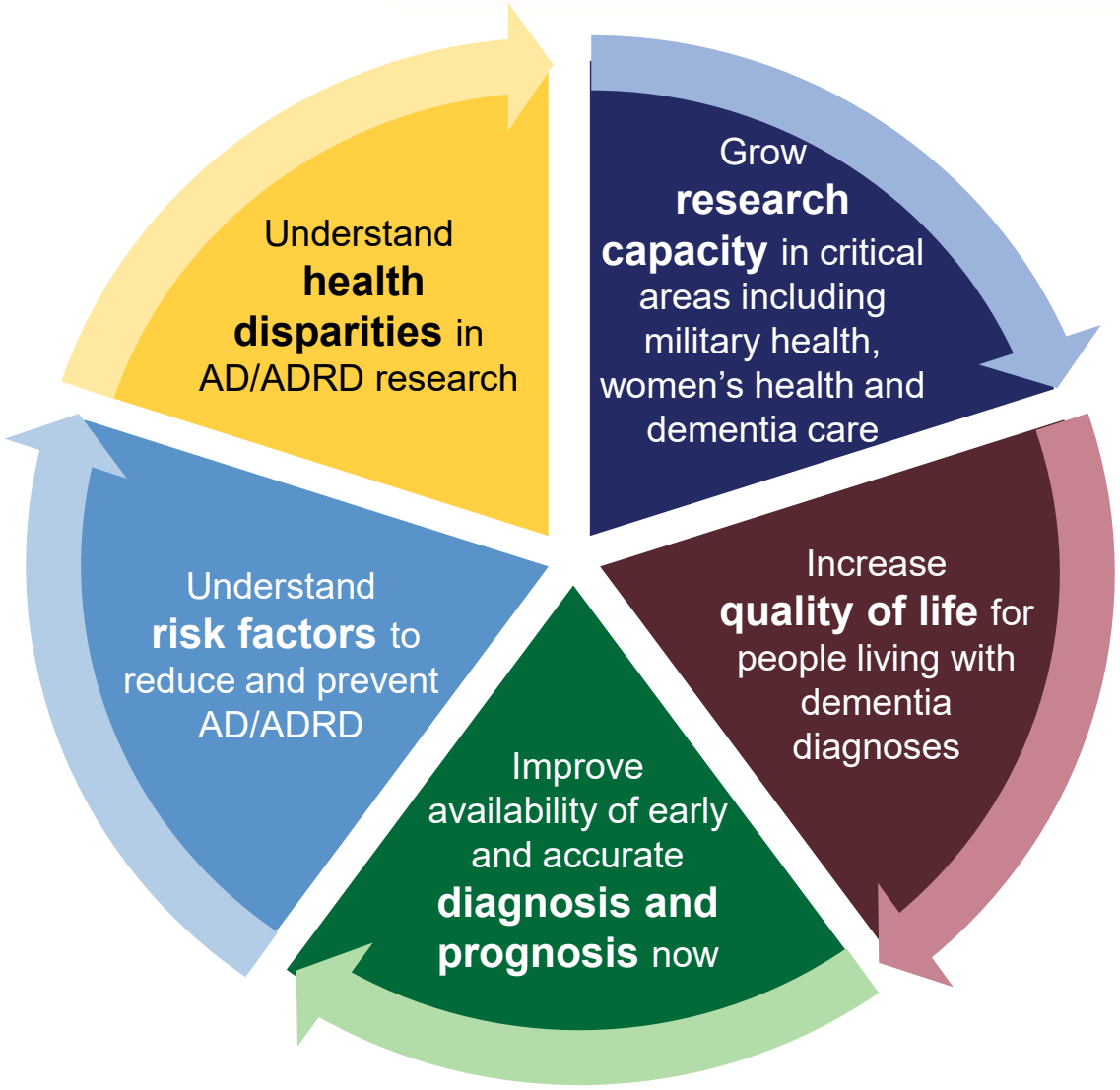
TBI Increases AD/ADRD Risk

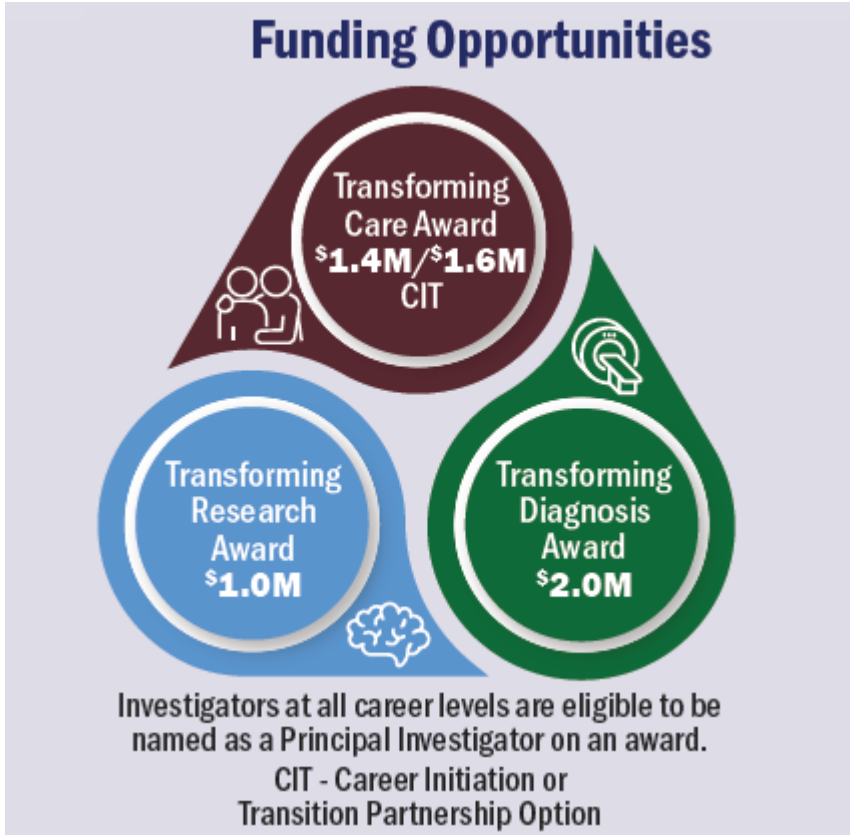
- **70%** increased risk of dementia following TBI
- Veterans are **2X-8X** more likely to develop dementia post-TBI than the general U.S. population.

*References available upon request

Melissa Miller, Program Manager, melissa.r.miller56.civ@health.mil

AZRP Priorities and Funding Strategies





The AZRP requires all clinical research awards to include **Community Collaboration** to promote high impact, culturally acceptable research

Melissa Miller, Program Manager, melissa.r.miller56.civ@health.mil

Examples of Funded Research

Quality of Life

REACH-Hope: Intervention for Dementia and TBI Caregivers

Linda Nichols, Ph.D, Memphis VA Medical Center

- Clinical testing of the VA Resources for Enhancing All Caregivers Health, or REACH, program in combination with the DOD Virtual Hope Box mobile application
- The combined REACH-Hope intervention successfully reduced caregiver burden and anxiety, with increased efficacy in severe cases*

*Nichols et al., *Rehabil Psychol* (2025), https://doi.org/10.1037/rep0000632.

Diagnostics and Prognostics

Gryphon's Out-of-Hospital Sampling and Testing Solution, GOHST

William Haskins, Ph.D, Gryphon Bio, Inc.

- A home-based prognostic biomarker assay requiring a finger prick and a few drops of blood before sending off to a lab for analysis to detect subclinical disease progression
- Relies on a marker of astrocytic debris clearance in TBI/post-traumatic epilepsy patients, enabling minimally invasive longitudinal monitoring of patients in pre-hospital, hospital and post-hospital settings

Melissa Miller, Program Manager, melissa.r.miller56.civ@health.mil

Examples of Funded Research, cont'd

Risk Factors

Dementia Risk in Veterans

Kristine Yaffe, M.D., San Francisco VA Medical Center

- Epidemiological investigation into the interconnection of military risk factors, social determinants of health, sex, race and ethnicity on the risk of dementia among older Veterans
- Veterans living in neighborhoods categorized as "disadvantaged" by the Area Deprivation Index showed a significantly increased risk of developing Alzheimer's*
- Additional research is ongoing, specifically evaluating dementia risk factors for Native Americans with a history of military service

*Dintica et al., *JAMA Neurol* (2023), https://doi.org/10.1001/jamaneurol.2023.2120.

Health Disparities

Racial Disparities in Vulnerability to AD

Igor Akushevich, Ph.D, Duke University

- Retrospective study to identify whether race, social determinants of health and other environmental factors contribute to the risk of developing AD/ADRD after TBI
- Vulnerability to hypertension identified as the most powerful contributor to AD/ADRD risk in Black Americans versus White Americans, indicating a need for early cardiovascular-based interventions*
- Additional research is ongoing, focused on creating a multi-domain model that can fully account for health disparities in dementia risk in Veterans compared to non-Veterans

*Akushevich et al., *Am J Hypertens* (2022), https://doi.org/10.1093/ajh/hpac063.

Questions

QUESTIONS?

For more information, please visit:

cdmrp.health.mil

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

February 2026

CMS: Scope

- CMS is the largest purchaser of health care in the world.
- CMS programs provide health care coverage to over 170M people, or 1 of every 2 Americans (Medicare, Medicaid, CHIP, Marketplace).
- In 2024, more than 67M people were enrolled in Medicare, with more than 82M enrolled in Medicaid and CHIP.
- More than 12 million people are enrolled in both programs, and these individuals have very high rates of chronic illness; most with multiple chronic conditions.
- Most Medicare beneficiaries - over 80% - are over age 65.
- Some people come into Medicare first, typically through age, and others become beneficiaries because of disability or other health status (e.g., renal disease).

Who We Serve: The American People

67.8 M

Medicare Beneficiaries (2024)

82.3 M

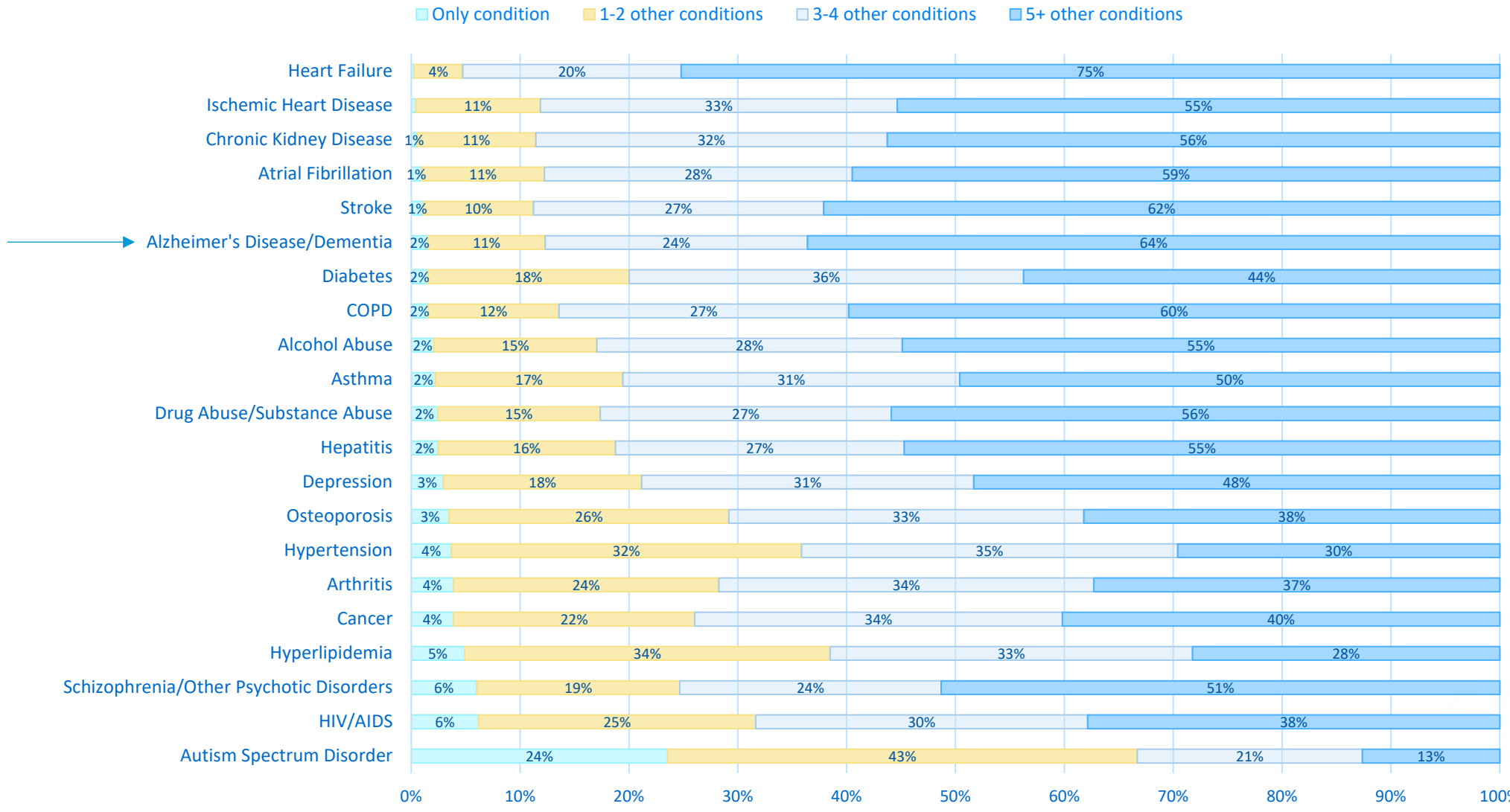
Medicaid Beneficiaries (2024)

21.4 M

Healthcare.gov (2024)

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR CLINICAL STANDARDS & QUALITY

Percentage of Medicare FFS Beneficiaries with 21 Selected Chronic Conditions: 2023



Some Medicare Services Used by Older Adults

- Chronic Care Management
- Complex Chronic Care Management
- Principal Care Management
- Transitional care management
- Cognitive Assessment & Care Planning
- Caregiver assessment
- Caregiver Training
- Advance Care Planning
- Annual Wellness Visit and Welcome to Medicare
- Psychotherapy
- Annual Depression screening
- Alcohol Misuse Screening and Counseling
- Screening, Brief Intervention, and Referral to Treatment (SBIRT)
- Tobacco Use Cessation Counseling
- Behavioral Health Integration
- Home Health
- Hospital
- Skilled Nursing Home Care
- Hospice
- Durable Medical Equipment
- Outpatient Therapies (PT/OT/Speech)
- Opioid Treatment Programs and SUD Bundle
- Chronic Pain Management and Treatment
- Principal Illness Navigation
- Community Health Integration
- Chronic Pain Management and Treatment
- Social Determinants of Health Risk Assessment
- Safety Interventions
- Post Discharge Telephonic Follow-Up Contacts Intervention
- Digital Mental Health Treatment
- Advanced Primary Care Management Services
- Direct Care Caregiver Training Services
- Individual Behavior Management/Modification Caregiver Training Services
- Interprofessional Consultation Billed by Practitioners to Treat Behavioral Health Conditions

Cognitive Assessment and Care Planning

- Code is: 99483
- People with Medicare who have been diagnosed with any type of dementia or mild cognitive impairment are eligible, and so are individuals without a clinical diagnosis who, in the judgment of the clinician, may be cognitively impaired
- Services last about 60 minutes and can be billed once every 180 days
- Elements include evaluation, functional assessment, dementia staging via standardized instrument, medication reconciliation and review, safety evaluation, neuropsychiatric/behavioral (e.g. depression) evaluation; caregiver needs, knowledge, willingness; advance care planning; care planning including referral to community resources, etc.
- CMS Resources are here and a video is here; NIH resources here

Quality Measures

The present list of dementia measures, Qualified Clinical Data Registries (QCDRs) and Improvement Activities (IAs) include the following:

MIPS QM 281	Dementia: Cognitive Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.: Process Measure
MIPS QM 282	Dementia: Functional Status Assessment: Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.: Process Measure
MIPS QM 286	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia: Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there ..: Process Measure
MIPS QM 288	Dementia: Education and Support of Caregivers for Patients with Dementia: Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.: Process Measure
IA_PM_27	Improving Detection of Cognitive Impairment in Primary Care: Population Management: Process Measure
IA_PMS_21	Advance Care Planning: Population Management: PRO-PM

CMS National Alzheimer's Project Act (NAPA) Review of Accomplishments for 2025

Goal 1: Prevent and Effectively Treat Alzheimer's Disease and Related Dementias by 2025

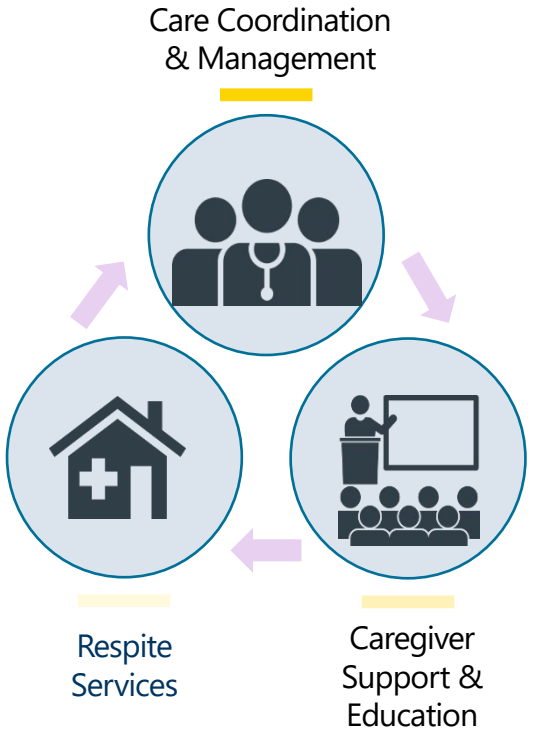
- Medicare has continued to cover the monoclonal antibodies approved by the FDA for the treatment of Alzheimer's Disease, under coverage with evidence development (CED) in the national coverage determination (NCD) for anti-Aβ mAbs. Four studies have been approved under CED, including the Anti-Aβ mAb CED Study which utilizes the National Patient Registry (NPR). The medications presently included in the registry include Leqembi™ (lecanemab), approved July 6, 2023, and Kisunla™ (donanemab) approved July 2, 2024.
- https://www.cms.gov/medicare/coverage/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad.

Goal 2: Enhance Care Quality and Efficiency

- The CMS Innovation Center develops and tests health care payment and service delivery models to improve patient care, lower costs, and align payment systems to promote patient-centered practices. The Guiding an Improved Dementia Experience (GUIDE) Model is a voluntary, nationwide model testing the impact of providing comprehensive services and supports for people with dementia and their caregivers. This model began on July 1, 2024, with the GUIDE Model New Program Track launched in July 2025 with 241 New Program Track Participants actively enrolling new patients into the program. The model has achieved comprehensive geographic coverage across all 50 states and the District of Columbia, including both traditional healthcare facilities and virtual healthcare providers, significantly enhancing access to dementia care services for Medicare beneficiaries and their caregivers.
- https://www.cms.gov/priorities/innovation/innovation-models/guide
- The Age-Friendly attestation in the Hospital Inpatient Quality Reporting (IQR) Program promotes the evaluation of cognition in the acute care setting. The measure collection started with the CY 2025 reporting period/FY 2027 payment determination. The Hospital IQR Program is a pay for reporting program. This is a measure stewarded by the American College of Surgery. In Domain 3, Frailty and Screening and Intervention, systems are required to use validated screening for cognition, delirium, mobility and malnutrition and generate a management plan based on the screening results.
- https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/inpatient-reporting-program

GUIDE Model Purpose and Overview

The GUIDE Model is testing whether a comprehensive package of care coordination and management, caregiver support and education, and respite services can **improve quality of life for people with dementia and their caregivers** while **delaying avoidable long-term nursing home care** and **enabling more people to remain at home** through end of life.



Care Coordination & Management

Beneficiaries will receive care from an **interdisciplinary team** that will develop and implement a comprehensive, person-centered care plan for **managing the beneficiary's dementia and co-occurring conditions** and provide **ongoing monitoring and support.**

Caregiver Support & Education

GUIDE participants will provide a **caregiver support program**, which must include caregiver skills training, dementia diagnosis education, support groups, and access to a personal care navigator who can help problem solve and connect the caregiver to services and supports.

Respite Services

GUIDE participants will be eligible to receive payment for respite services, up to a cap of **$2,500 per year per beneficiary,** for qualifying beneficiaries. These services may be provided to beneficiaries in a variety of settings, including **their personal home, an adult day center, and facilities that can provide 24-hour care** to give the caregiver a break from caring for the beneficiary.

Getting Involved with GUIDE

Want to get involved? On the CMS website, the Where Innovation is Happening page allows users to identify and locate Participants across CMS Innovation Center models, including the GUIDE Model. Additionally, the GUIDE Model website houses many resources for those interested in learning more about the model, including an up-to-date list of all organizations participating in the GUIDE Model that includes contact information.

Goal 3: Expand Supports for People with Alzheimer's Disease and Related Dementias and Their Families

- CMS, in keeping with longstanding practice, codified requirements for Program of All-Inclusive Care for the Elderly (PACE) organizations to submit risk adjustment data to CMS. Additionally, Alzheimer's disease and related dementias (ADRD) are qualifying conditions for a Chronic Condition Special Needs Plan (C-SNP), a type of Medicare Advantage plan. These plans provide specialized, coordinated care for individuals with severe, chronic conditions.
- https://www.cms.gov/newsroom/fact-sheets/2026-medicare-advantage-and-part-d-rate-announcement
- https://www.medicare.gov/health-drug-plans/health-plans/your-health-plan-options/SNP

CMS National Alzheimer's Project Act (NAPA) 2026

GUIDE Model

- CMS continues to administer and expand the GUIDE Model and has implemented a direct patient outreach initiative by mailing informational letters to eligible Medicare beneficiaries. These communications serve to educate patients about available dementia care services through the GUIDE Model and help connect them with participating doctors and care teams.