



Realizing the National Plan to Address Alzheimer's Disease

Leadership Toward Treatment and Prevention

ALZHEIMER'S  ASSOCIATION®

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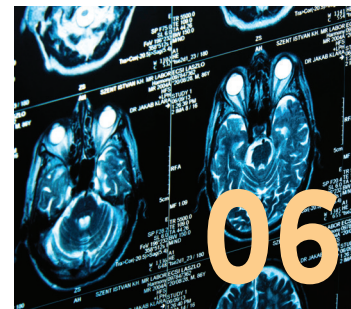
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Improving the Delivery of Care and Support

The 2011 enactment of the landmark National Alzheimer's Project Act (NAPA) ushered in a new phase of progress, changing the way our nation addresses Alzheimer's and all other dementia. Working toward the first goal in National Plan to Address Alzheimer's Disease — to prevent and effectively treat Alzheimer's by 2025 — the federal government, the Alzheimer's Association, academia, the pharmaceutical industry, the corporate sector and private philanthropists have stepped up.

Since the passage of NAPA, the Alzheimer's Association has worked with bipartisan congressional champions to increase federal research funding more than seven-fold. Added to current National Institutes of Health (NIH) spending, annual federal funding in fiscal year 2023 for Alzheimer's research will be more than \$3.7 billion. During the same time, the Association has expanded its international research grants program to fuel scientific progress at every stage — from identifying bold ideas to raising and investing dollars in high impact projects with the potential to change the field. In 2022 alone, the Association invested \$90 million to advance Alzheimer's and dementia research. These contributions to the most promising research have generated more than \$2 billion in additional funding during the last five years.

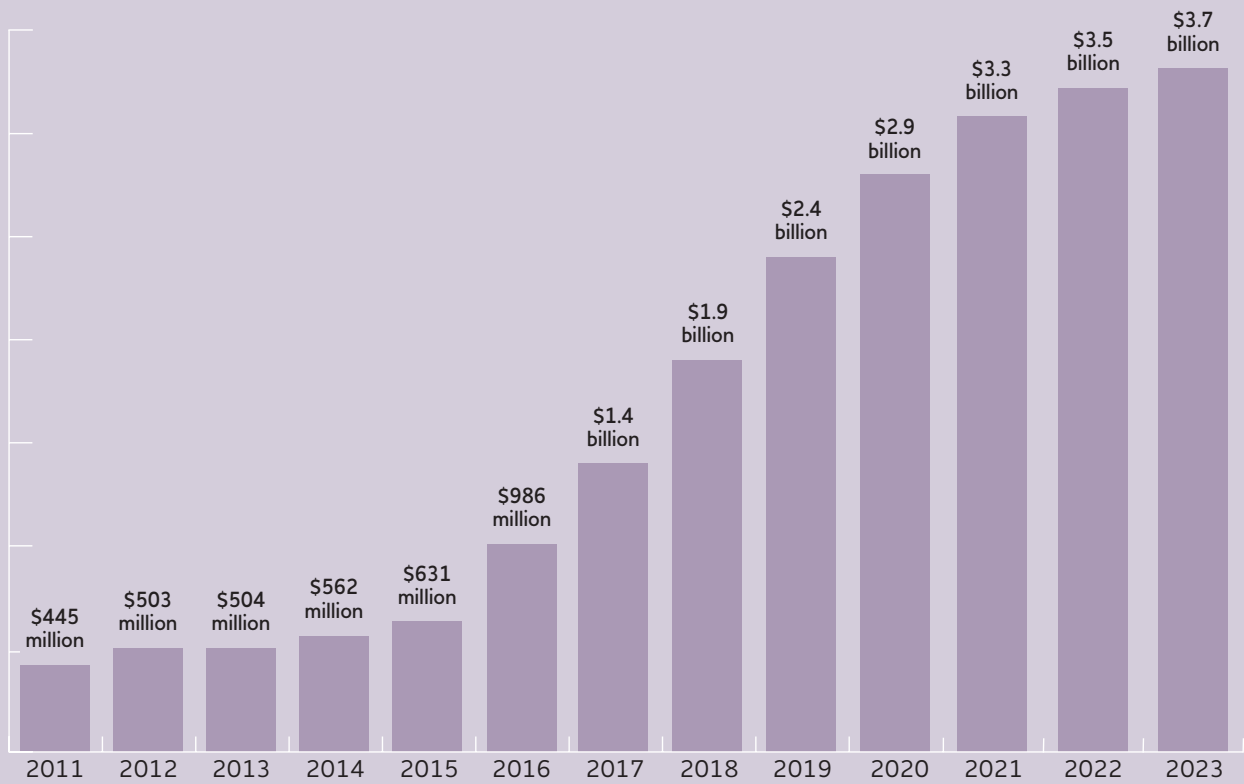
Thanks to these advancements, several treatments which address the underlying biology of Alzheimer's disease have received approval by the Food and Drug Administration (FDA). These treatments change the course of the disease in a meaningful way for people in the early stages. By slowing progression of the disease in the early stages of Alzheimer's, individuals will have more time to participate in daily life and live independently. Treatments that address the full scope of Alzheimer's biology are also advancing. Future treatments will need to address amyloid, tau and neurodegeneration as well as other brain changes that play a role in the disease and its progression.

We're at the moment when our knowledge and discoveries are changing the way we fight Alzheimer's and all other dementia. Our progress must continue.



Public Policy's Role in Advancing Alzheimer's Research

National Institutes of Health
Alzheimer's & Dementia Research Funding



Beginning in FY15, the NIH combined Alzheimer's and other dementia funding into one category.
Source: <https://report.nih.gov/funding/categorical-spending#/>

Alzheimer's Association Research Investment



Public Policy Victories Led by the Alzheimer's Association

2011
The Alzheimer's Association and the Alzheimer's Impact Movement (AIM) worked with bipartisan leaders in Congress to develop the **National Alzheimer's Project Act (NAPA)**. This landmark legislation required the creation of a national plan to help change the trajectory of this devastating disease.

2012
The Alzheimer's Association hosted more than 130 community events to secure and provide input to the federal government for the development of the **National Plan to Address Alzheimer's Disease**.

2014
To ensure swift movement toward the first goal of the national plan, the Alzheimer's Association and AIM secured support for the passage and enactment of the **Alzheimer's Accountability Act (AAA)**. This legislation ensures Congress hears directly from NIH scientists — through an annual professional judgment budget — on the resources needed to meet the nation's goal.

2015
Following the passage of AAA, the NIH **released its first Professional Judgment Budget (PJB)** in 2015. In its first PJB, the NIH asked Congress for a \$323 million increase in Alzheimer's and dementia research funding for the fiscal year.

2022
Key provisions of the ENACT Act were included in the Fiscal Year 2023 budget, which will help increase the participation of underrepresented populations in Alzheimer's and other dementia clinical trials by expanding education and outreach to these populations, encouraging the diversity of clinical trial staff and reducing participation burden, among other priorities.

Understanding the Biological & Molecular Factors/Causes of Alzheimer's and Other Dementia

Since Alzheimer's was first described more than 100 years ago, researchers have made progress understanding the many aspects of the disease, but major gaps in knowledge still exist. Research into the underlying biology that may cause and contribute to Alzheimer's and other dementia is essential to prevent and effectively treat these conditions.



The Alzheimer's Association, the University of Texas San Antonio, other scientific leaders and representatives from more than 25 countries — with technical guidance from the World Health Organization (WHO) — are part of **an international, multidisciplinary consortium to collect and evaluate the long-term consequences of COVID-19 on the brain**. Research indicates that some people who contract the virus also experience short- and/or long-term neurological symptoms, including those that affect their behavior, function and cognition (sometimes referred to as "brain fog"). Initial findings from one of the study teams, presented at the Alzheimer's Association International Conference® 2021 (AAIC®), suggest older adults who experience the persistent loss of smell are also more likely to have changes in their memory following recovery from COVID-19.

Since the passage of NAPA, the Alzheimer's Association has continued its leadership commitment to Alzheimer's research, awarding

734 GRANTS

through its International Research Grant Program to projects investigating the basic biological underpinnings of the disease in order to accelerate pathways to treatments.

Since 2016, the Alzheimer's Association has funded

22 RESEARCH GRANTS

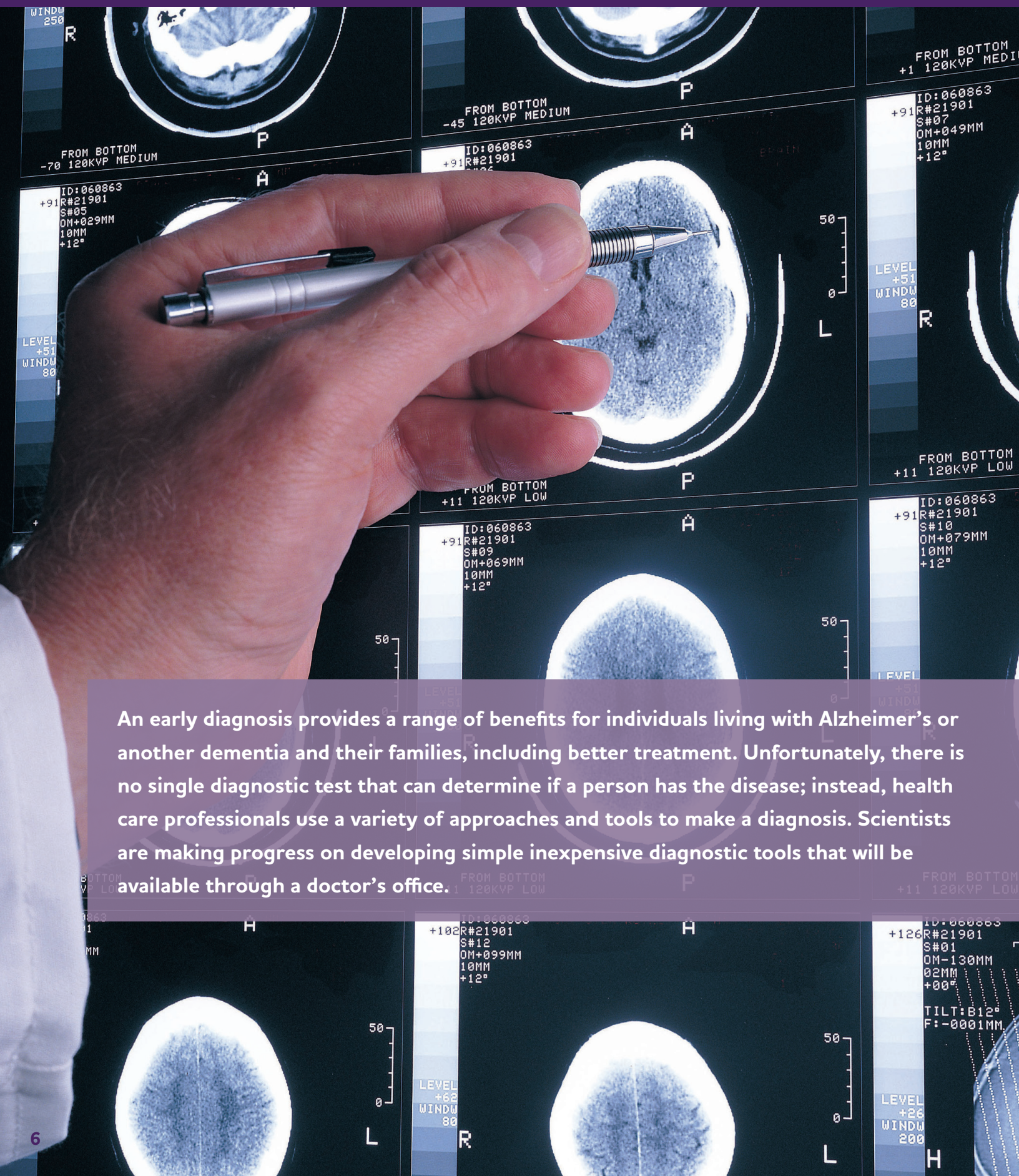
totaling more than \$4.1 million that aim to understand why more females than males develop the disease — and how we can treat it in both sexes.



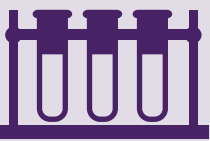
NIH-FUNDED ALZHEIMER'S DISEASE SEQUENCING PROJECT

supports genetic research to discover long-term treatments for Alzheimer's disease and related dementia. This sequencing project, involving more than 345 international investigators at 62 institutions, seeks to identify genes that increase risk for Alzheimer's and those that provide protection to identify possible avenues to prevent and treat Alzheimer's disease.

Enabling Accurate and Timely Diagnosis



An early diagnosis provides a range of benefits for individuals living with Alzheimer’s or another dementia and their families, including better treatment. Unfortunately, there is no single diagnostic test that can determine if a person has the disease; instead, health care professionals use a variety of approaches and tools to make a diagnosis. Scientists are making progress on developing simple inexpensive diagnostic tools that will be available through a doctor’s office.



In recent years, major advancements in **blood “tests” detecting the proteins amyloid and tau** — hallmark brain changes of Alzheimer’s — have been realized. Today these tests are mainly being used for research purposes but some are being incorporated into large-scale clinical trials. In 2020, PrecivityAD became the first blood test available to specialists as a tool to predict the likelihood of the presence of amyloid in the brain. Developed in part with NIH funding, specialists can now send blood samples to be analyzed, providing them with a new biomarker tool to evaluate their patients with cognitive disorders.

In May 2022, **the FDA approved a new diagnostic tool that clinicians can use to detect amyloid levels in cerebrospinal fluid (CSF) via a lumbar puncture**, which can be predictive of amyloid changes in the brain. Lumipulse is the first CSF diagnostic tool for Alzheimer’s cleared by the FDA. Lumbar puncture tests are less expensive and more accessible than other currently available diagnostic tools like PET scans.

22 Phase I
14 Phase II
7 Phase III

DIAGNOSTIC IMAGING AGING AGENTS

REGISTERED ON CLINICALTRIALS.GOV AS OF APRIL 2023

In a major step forward for Alzheimer’s biomarker tests, **the FDA approved the first diagnostic agent for measuring tau tangles in 2020**. Flortaucipir, a radioactive diagnostic agent, binds to dense tau tangles and can be visualized on a PET brain scan. The amount and location of tau tangles detected through a brain scan while participants were alive showed a strong similarity to those detected in the brain tissue examined after death.



The NIH-funded Health and Aging Study – Health Disparities (HABS-HD) is the first-ever multi-ethnic study of Alzheimer’s disease pathological markers. This program is designed to understand the biological, social, and environmental factors that impact brain aging across diverse populations.

Progress Toward Effective Means of Prevention



Researchers around the globe are exploring how to prevent Alzheimer’s and other dementia. Identifying ways to prevent Alzheimer’s could save millions of lives and greatly reduce health care costs for families and Medicare and Medicaid. While research is ongoing, science has shown that we can take action to reduce risk of cognitive decline.

New data from AAIC suggests **eating a large amount of ultraprocessed food can significantly accelerate cognitive decline.**

The study found that people who consume the highest amount of ultraprocessed foods — defined as more than 20% of daily caloric intake — have a 28% faster decline in global cognitive scores, including memory, verbal fluency and executive function.

Results from the NIH-funded **COSMOS-Mind study** of more than 2,200 older adults found that taking a daily multivitamin-mineral supplement resulted in a statistically significant cognitive benefit. This is the first positive, large-scale, long-term study to show that multivitamin-mineral supplementation for older adults may slow cognitive aging.

The NIH-funded **COSMOS-Mind ancillary study** was the first large scale, long-term clinical trial to assess the potential cognition-enhancing effects of a cocoa-extract supplement and a multivitamin/mineral supplement in older women and men. This study resulted in a statistically significant cognitive benefit, showing that multivitamin/mineral supplementation for older adults may slow cognitive aging.

The Alzheimer’s Association is funding and implementing **U.S. POINTER**, a clinical trial to evaluate whether lifestyle interventions that simultaneously target many risk factors protect cognitive function in older adults who are at increased risk for cognitive decline. Representation of our communities is essential to the success in U.S. POINTER. The recruitment process specifically aimed to increase participation by historically underrepresented communities in research, with a priority focus on **achieving racial and ethnic diversity and including rural populations.**

The Alzheimer’s Association worked with partners to fund expansions of the NIH-funded Washington University’s Dominantly Inherited Alzheimer’s Network Trials Unit (DIAN-TU), a series of trials in people living with and at risk for dominantly inherited Alzheimer’s disease. In **partnership with GHR Foundation, the Association committed \$14 million to Tau NexGen**, an expansion to allow the trials unit to evaluate multiple potential treatments at one time, accelerating the studies. This is one of the first combination trials testing an anti-amyloid and anti-tau.

The NIH and Eisai are funding the **AHEAD Study, the first Alzheimer’s trial to recruit people as young as 55 years old** who are asymptomatic and at risk of developing the disease as they age. The study consists of two different clinical trials testing the treatment lecanemab (Leqembi®). Participants will receive a tailored dose based on the level of amyloid in their brain. The Alzheimer’s Association, along with GHR, has made a new funding commitment to provide essential resources to support **community-based recruitment initiatives of diverse individuals** for this study and to leverage this work to establish a nationwide infrastructure for ongoing community-based engagement of diverse groups in clinical studies.

PRagmatic EVALuation of evENTs And Benefits of Lipid-lowering in oldEr adults (PREVENTABLE), funded by two NIH institutions, is seeking to determine if taking a statin could help older adults live well for longer by preventing dementia, disability or heart disease. Approximately 20,000 older adults are participating in this study, with a team of researchers and clinicians at enrollment sites including over 50 participating Veterans Administration medical centers.

“Increased NIA funding for Alzheimer’s, in conjunction with INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) Project, has helped us build the infrastructure needed to conduct clinical trials for Alzheimer’s disease in people with Down syndrome (who are genetically predisposed to develop Alzheimer’s disease) and to bring the latest advances in Alzheimer’s disease diagnostics and therapeutics to this population.”

MICHAEL RAFII, MD, PH.D.
Medical Director, Alzheimer’s Therapeutic Research Institute, Professor of Neurology, Keck School of Medicine, University of Southern California



“The additional NIH research funding for Alzheimer’s disease and related dementias (ADRD) has allowed me to produce more scholarly work, extend my research, and engage outreach efforts to address the needs of African Americans who are disproportionately impacted by ADRD. This increased funding will support research identifying the precursors of dementia onset and the risk and protective factors that mitigate cognitive disparities in African Americans.”

DEANNAH R. BYRD, PH.D.
Assistant Professor
Arizona State University

“Increased NIH funding is critical for not only myself, but for other new PIs who are trying to grow their careers, their labs and their novel ideas. This extra funding allows for more high-risk, yet high-reward, projects to be supported, particularly from junior PIs who need the chance. This type of funding has helped me to expand my scientific horizons to tackle challenging, interdisciplinary and cutting-edge questions, which would not be possible in other funding environments. It also gives me the breathing room to expand and thrive as I build my seniority.”

RACHEL BUCKLEY, PH.D.
Assistant Professor, Department of Neurology, Massachusetts General Hospital/Harvard Medical School



“The increased federal funding to support Alzheimer’s research has allowed me to work closely with local culturally and linguistically diverse communities as well as bring together and lead a multidisciplinary team to create a community-engaged research network dedicated to addressing and advancing our understanding of health disparities. It has also enabled me to work closely with other early career investigators and trainees committed to equitable research on Alzheimer’s disease and related dementias.”

LUIS D. MEDINA, PH.D.
Director, Collaborative on Aging Research and Multicultural Assessment (CARMA),
Department of Psychology, University of Houston

Realizing Progress for Everyone



Alzheimer’s and other dementia develop differently in everyone, expanding the number of symptoms that need to be treated. In addition, multiple treatments are needed to address different forms of dementia. It is also critical that future treatments and means of prevention are effective in all populations.

To move toward more effective treatments, scientists need to understand the genetic, biological and clinical processes involved in early-onset Alzheimer’s disease. The NIH is funding the **Longitudinal Early-Onset Alzheimer’s Disease Study (LEADS)**, a two-year observational study to explore the development of early-onset Alzheimer’s disease and how it compares to late-onset Alzheimer’s. Selection of study sites will support innovative recruitment and strategies to reach diverse communities. The Alzheimer’s Association, is collaborating on the implementation of this study and provided additional funding. In September 2021, the Alzheimer’s Association, with funding support from the NIH, convened a virtual meeting for LEADS families to share their experiences, hear from experts on the science and have an opportunity for support groups.

Recognizing the need to support the training and recruitment of scientists from diverse backgrounds, the Alzheimer’s Association offers targeted programs to expand the representation of researchers in the field, including fellowships through our International Research Grant Program. The Association and NIH also co-fund **IMPACT-AD (Institute on Methods and Protocols for Advancement in Clinical Trials in Alzheimer’s Disease and Related Disorders)** to educate and promote representation among research professionals and future principal investigators in the field.

The NIH-funded Alzheimer’s Clinical Trials Consortium (ACTC) **seeks to accelerate and expand testing of therapies at all stages of Alzheimer’s and other dementias**. ACTC — composed of 35 sites across the U.S. — is developing strategies for the inclusion of diverse populations in clinical trials. An extension, ACTC-DS, expands testing among people living with Down syndrome.

The NIH has funded the addition of new Alzheimer’s Disease Research Centers (ADRCs). This includes two centers to support research areas including **risk factors for Alzheimer’s and other dementias and ways to understand and reduce the burden on underrepresented groups** including Black Americans and Hispanic Americans.

The Alzheimer’s Association and American College of Radiology are actively recruiting for the **New IDEAS: Imaging Dementia-Evidence for Amyloid Scanning Study**, an extension of the IDEAS Study that showed that positron emission tomography (PET) brain imaging can be a powerful tool to improve the accuracy of Alzheimer’s diagnosis by detecting amyloid buildup. With a focus on recruiting Black and Hispanic participants at 350 sites across the United States, New IDEAS aims to demonstrate the diagnostic value of amyloid PET scans among diverse populations that are historically underrepresented in dementia research. The New IDEAS Study is advised by the Centers for Medicare & Medicaid Services.

The Alzheimer’s Association, the Global Brain Health Institute and the Alzheimer’s Society (UK) have invested \$650,000 for 26 small-scale projects as part of the **Pilot Awards for Global Brain Health Leaders**. The awards drive pilot projects that address disparities in dementia diagnosis, treatment and care for vulnerable populations and their families. Recipients span 18 countries across five continents and join a total of 114 pilots in 36 countries.

The Alzheimer’s Association, with funding from the NIH, hosted **Promoting Diverse Perspectives: Addressing Health Disparities Related to Alzheimer’s and All Dementias**, a conference to advance health equity research. The free online event brought together more than 1,300 attendees from over 40 countries to explore disparities in the prevention, diagnosis and treatment of Alzheimer’s among underserved and underrepresented communities.

Working Toward Effective Treatments

For decades, millions of Americans and their families have waited for improved and effective therapies for Alzheimer’s and other dementia. Around the globe, researchers are working to find solutions for those facing the crushing realities of these relentless conditions. Today’s unprecedented levels of funding mean scientists are exploring a wide variety of pathways that could yield potential therapies.

Through the NIH-funded **Alzheimer’s Drug Development Program**, researchers are developing new potential treatments that address many different biological processes impacted in Alzheimer’s and other dementias. Twelve candidate drugs have advanced to human trials and over a dozen more are in preclinical development.

The Alzheimer’s Association is working with government agencies such as the NIH, as well as industry and other nonprofit organizations, on the **Accelerating Medicines Partnership® Program for Alzheimer’s Disease (AMP® AD)**. This is an effort to revolutionize the current model for discovering new diagnostics and treatments for Alzheimer’s. Using AMP AD data, an NIH-supported research team discovered several molecular sub-types of Alzheimer’s that will be important for developing a precision medicine approach to treatment.

In January 2023, lecanemab (Leqembi®) was granted accelerated approval for the treatment of early Alzheimer’s disease from the FDA. This is the **second effective FDA-approved therapy that addresses the underlying biology of Alzheimer’s** by removing beta-amyloid, one of the hallmarks of the disease, from the brain. By slowing progression of the disease when taken in the early stages of Alzheimer’s, individuals will have more time to participate in daily life and live independently.

Part the Cloud, a movement founded by philanthropist Michaela Hoag, works in partnership with the Alzheimer’s Association to fund research that accelerates findings from the laboratory through trials and into possible therapies. **Part the Cloud has provided funding to 65 projects**, including some of the most promising clinical trials in the field.



The Alzheimer’s Network (ALZ-NET) is a voluntary provider-enrolled patient network that collects longitudinal diagnostic, treatment and care data from patients being evaluated for or treated with new FDA-approved Alzheimer’s treatments in real-world clinical practice.



99 Phase I
189 Phase II
60 Phase III

AGENT AND DEVICE CLINICAL TRIALS

Across all trials, including diagnostic agents:

34%
were industry sponsored

66%
were collaboratively funded
(academia, industry, NIH,
Alzheimer’s Association
and others)

Improving the Delivery of Care and Support



The delivery of high quality care and support for families facing Alzheimer’s is critically important. Needs change swiftly based on the stage of the disease, and each situation is unique. Research and education around new measures of care and support — as well as improved outcomes — benefit individuals, families and care providers.



450 NIH-SUPPORTED

Alzheimer’s and related dementia care and caregiver intervention trials as of September 2022.

ALZHEIMER’S ASSOCIATION | LINC-AD

In November 2019, the NIH awarded a grant to the Alzheimer’s Association to fund Leveraging an Interdisciplinary Consortium to Improve Care and Outcomes for Persons Living with Alzheimer’s and Dementia (LINC-AD).

The goal of LINC-AD is to strengthen the current framework for psychosocial research that examines care for people living with dementia and their care partners. As part of LINC-AD, the Alzheimer’s Association collaborated with Brain Canada Foundation to launch the Advancing Research on Care and Outcome Measurement (ARCOM) funding program, which has advanced 18 projects over two cycles to address significant gaps in care and outcome measurement. ARCOM also advances research so care providers can ensure that they are implementing evidence-based practices and achieving desired outcomes.

There are more than 190 NIH-supported clinical trials of dementia care and caregiving interventions as of March 2022. Several recently launched studies take place where people live and receive care, including many of those being conducted through the NIH IMbedded Pragmatic Alzheimer’s Disease (AD) and AD-Related Dementias (ADRD) Clinical Trials (IMPACT) Collaboratory. Established in 2019, the IMPACT Collaboratory focuses on real-world applicability of models and developing the capacity to advance research in care intervention in our nation.

The Association’s Alzheimer’s and Dementia Care Project ECHO® (Extension for Community Healthcare Outcomes) Program connects dementia care experts with health care teams from primary care practices in a free continuing education series of interactive, case-based video conferencing sessions. The program enables primary care providers to better understand Alzheimer’s and other forms of dementia and emphasizes high-quality, person-centered care in community-based settings. Nearly 100 primary care practices and over 300 health care providers completed this ECHO training since 2018, influencing more than 370,000 lives.



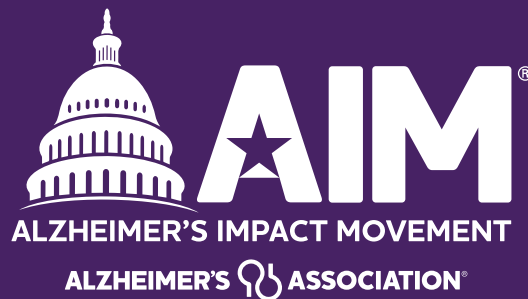
The Alzheimer’s Association Interdisciplinary Summer Research Institute (AA-ISRI) focuses on key subfields of psychosocial research and public health research as they relate to the diagnosis, prevention, treatment and systems of care for people with dementia. AA-ISRI works to broaden dementia knowledge among researchers in these fields in order to support a more representative workforce. In 2022, 24 researchers received an award to join the institute. AA-ISRI is supported by the NIH.

ALZHEIMER'S ASSOCIATION®

The Alzheimer's Association leads the way to end Alzheimer's and all other dementia — by accelerating global research, driving risk reduction and early detection, and maximizing quality care and support.

Our vision is a world without Alzheimer's and all other dementia®.

800.272.3900 | alz.org®



The Alzheimer's Impact Movement (AIM) is a separately incorporated advocacy affiliate of the Alzheimer's Association. AIM advances and develops policies to overcome Alzheimer's disease through increased investment in research, enhanced care and improved support.

alzimpact.org