



Realizing the National Plan to Address Alzheimer's Disease

Leadership Toward Treatment and Prevention

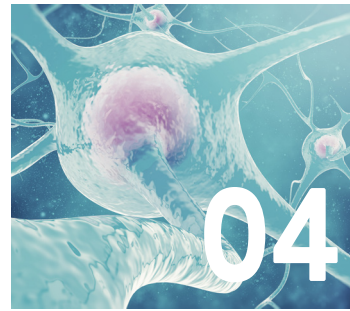
ALZHEIMER'S  ASSOCIATION®

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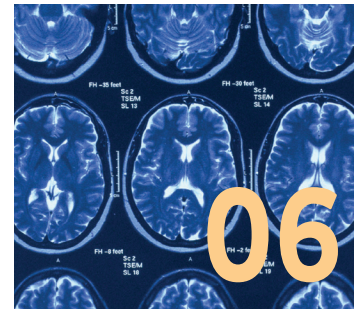
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Improving the Delivery of Care and Support

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® and the Alzheimer's Impact Movement (AIM) has worked with bipartisan congressional champions to increase federal research funding more than sevenfold. Added to current National Institutes of Health (NIH) spending, annual federal funding in fiscal year 2023 for Alzheimer's research was more than \$3.7 billion. During the same time, the Alzheimer's Association International Research Grant Program has expanded 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 2023 alone, the Association reached a milestone achievement, investing \$100 million to advance Alzheimer's and dementia research. This unparalleled commitment stands as the largest single-year investment since the organization's founding in 1980. These contributions to the most promising research have generated more than \$2 billion in additional funding during the last five years.

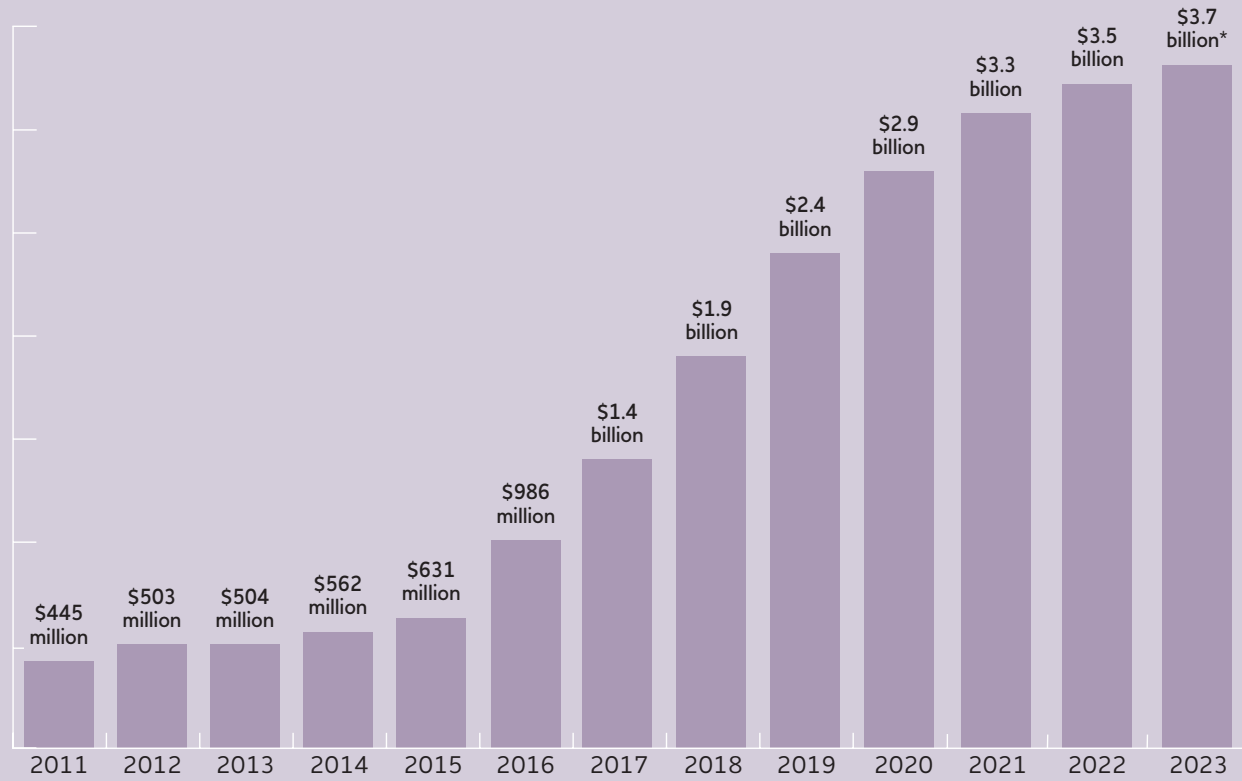
Thanks to these advancements, multiple treatments which address the underlying biology of Alzheimer's disease have received approval by the Food and Drug Administration (FDA). These treatments change the course of the disease in a meaningful way for people in the early stages. By slowing progression 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.



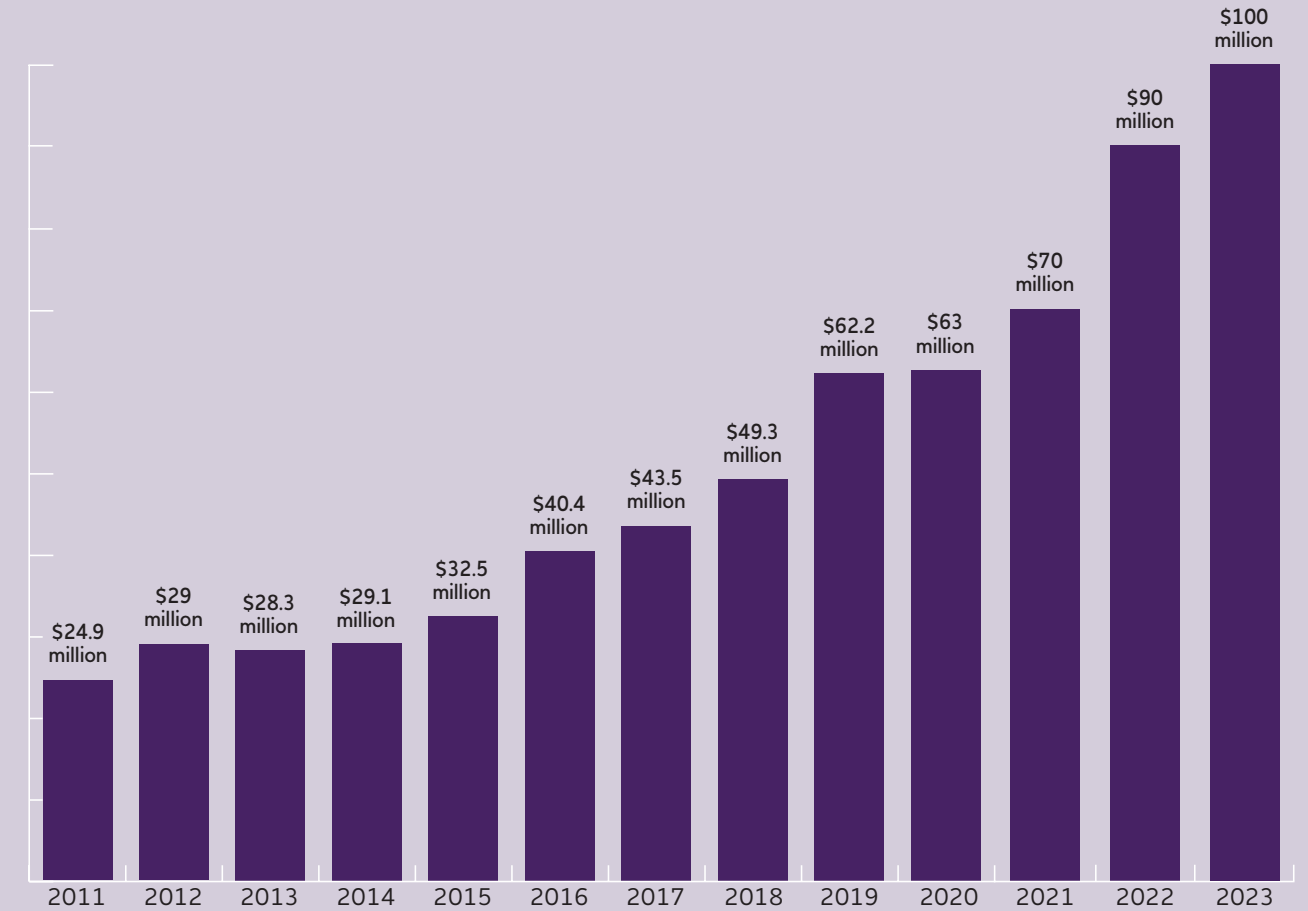
Public Policy's Role in Advancing Alzheimer's Research

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#/>
*estimated below source

Alzheimer's Association Research Investment



Public Policy Victories Led by the Alzheimer's Association and AIM

2011

The Alzheimer's Association and 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

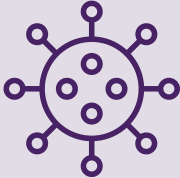
Following the passage of AAA, the NIH **released its first Professional Judgment Budget (PJB)** in 2015. In its first PJB, the NIH asked Congress for a \$323 million increase in Alzheimer's and dementia research funding for the fiscal year.

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 disease 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 are part of **an international, multidisciplinary consortium to collect and evaluate the long-term consequences of COVID-19 on the brain**. The Study on Interactions between SARS-CoV-2 infection and Ancestral genomic Variations in the Risk of Alzheimer's Disease (ISAVRAD), a longitudinal study that came out of the consortium with funding from the NIH and the Alzheimer's Association, is collecting and analyzing data to better understand how COVID-19 may increase the risk of progressive cognitive decline and Alzheimer's among older individuals.

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

866 GRANTS

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

The **Psych-AD program**, a collaboration between the NIA and the NIH National Institute of Mental Health, is researching the molecular underpinnings of neuropsychiatric symptoms in dementia, such as psychosis, agitation, depression and sleep disturbance. The program's goal is to identify better biomarkers and targets to treat these symptoms, which are relatively common in dementia.




THE 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. At the Alzheimer's Disease Genetics Global Symposium: Pathway to Translation, a virtual conference supported by the Alzheimer's Association and the NIH, the dementia research community collaborates on and discusses the impact of discoveries in genetics, such as the significant effect on biomarker development and target discovery and validation. In 2022, NIH launched the ADSP Diverse Populations Initiative. This project is designed to generate and analyze genetic data on more than 36,000 Black, Hispanic, and Asian participants as part of a strategy to enable a precision medicine approach to treatment and prevention.

Building off of the successes in genetic research on Alzheimer's and other dementia, the NIH has funded additional work that has successfully identified **genetic variants and genes associated with increased risk for frontotemporal dementias and Lewy body dementia**.

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. With new approved treatments being limited to individuals in the early stages of the disease, early and accurate detection is even more critical. In addition, there is no single diagnostic test that can determine if a person has one of the diseases that cause dementia; 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 October 2023, the **Centers for Medicare & Medicaid Services (CMS)** took action to **expand coverage of brain amyloid positron emission tomography (PET) imaging for the diagnosis of Alzheimer’s disease**. Amyloid PET scans are a proven tool and can be an important part of Alzheimer’s diagnosis and treatment, and broader access will enable earlier and more accurate diagnosis, and better care management.

The **Imaging Dementia — Evidence for Amyloid Scanning (IDEAS) Study** and the **New IDEAS Study**, were a collaborative effort to better understand how amyloid PET improves accurate diagnosis and appropriate treatment of Alzheimer’s and other dementias in real clinical situations and in diverse and underserved populations. In the IDEAS Study, patient management changed in 60.2% of mild cognitive impairment (MCI) and 63.5% of dementia patients. Data from the IDEAS Study are now available through the **Global Alzheimer’s Association Interactive Network (GAAIN)**, the first and largest federated Alzheimer’s disease data discovery platform. Researchers across industry and academia at all career stages can now request and access data to advance research into the causes, prevention and treatment of Alzheimer’s and other neurodegenerative diseases.

32 Phase I

23 Phase II

11 Phase III

DIAGNOSTIC IMAGING AGING AGENTS

REGISTERED ON CLINICALTRIALS.GOV AS OF JANUARY 2024

The Alzheimer’s Association is leading the translation of the 2011 diagnostic guidelines and the 2018 research framework into the **newly proposed diagnostic criteria**. These criteria are a reflection of updates in the science of the disease, in particular reflecting our better understanding of the changes in Alzheimer’s biomarkers throughout the course of the disease. The draft diagnostic criteria propose an updated numeric clinical staging approach that includes six stages. Also incorporated into the proposed criteria is **blood-based biomarkers**, which have excellent diagnostic performance and have been developed and clinically validated. Their ease of use and low cost will allow them to be accessible to a wide variety of people, including underserved and rural populations. The Alzheimer’s Association is also in the process of updating **Appropriate Use Recommendations (AUR) for Blood Biomarkers in Alzheimer’s Disease**.

Through data sharing and collaboration in the **Alzheimer’s Disease Neuroimaging Initiative (ADNI)** — which is celebrating its twentieth year in 2024 — researchers identified a potential novel biomarker for Alzheimer’s. Data published in 2023 in the *Annals of Neurology* found an association between lower levels of NPTX2, a synaptic protein in the brain, in cerebrospinal fluid and earlier time to MCI symptom onset, and when combined with other established Alzheimer’s biomarkers, they found that NPTX2 improved the prediction of Alzheimer’s symptom onset. More research is needed to confirm and validate this potential biomarker in larger and diverse populations.

Progress Toward Effective Means of Prevention



Researchers around the globe are working to uncover ways to prevent Alzheimer's and other dementia. Identifying methods of prevention could save millions of lives and greatly reduce health care costs for families, Medicare and Medicaid. While we have no definitive answers at this time, research has shown that we can take action to reduce risk of cognitive decline.

The Alzheimer's Association, in collaboration with research teams across the country, 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 diverse communities is essential to the success of U.S. POINTER. The recruitment process specifically aimed to increase participation by historically underrepresented communities in research, meeting a goal of 30%, with a priority focus on **achieving racial and ethnic diversity and including rural populations**. Care has also been taken to include individuals across the spectrums of age, socioeconomic status and education level.

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. As of 2023, **the Association has committed more than \$44 million to accelerate and enhance the different stages and progression of DIAN-TU**. The first DIAN-TU trial, which launched in 2012, is now in the open-label extension phase. Additionally, the most recent commitment by the Alzheimer's Association is helping expedite the launch of DIAN-TU Primary Prevention, the world's first primary prevention trial for Alzheimer's.

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. One of the largest **ongoing studies** in individuals over the age of 75, with a goal of enrolling approximately 20,000 older adults, the effort **involves** a team of researchers and clinicians at enrollment sites including more than 90 participating medical centers.

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 AHEAD Study has incorporated the use of blood tests for measures associated with Alzheimer's to identify individuals more likely to meet the trials inclusion criteria of elevated brain amyloid on PET scans. This addition increases the efficiency of the study in being able to move faster, spend less money on imaging and identify participants that are more likely to have the brain changes needed to enroll in the study.

The Alzheimer's Association, which has served as the BOLD Public Health Center of Excellence on Dementia Risk Reduction since 2020, is working with a team at Wake Forest School of Medicine to review how **social determinants of health (SDOH), such as economic disadvantage, air pollution and racism, can impact Alzheimer's and dementia**. Through a series of workshops and roundtables, the center has convened experts to review evidence of SDOH as risk factors for dementia and potential public health solutions to address these disparities. In August 2023, the Centers for Disease Control and Prevention (CDC) announced 43 award recipients for the BOLD Public Health Programs to Address Alzheimer's Disease and Related Dementias. This critical work would not have been possible without the hard work of the Alzheimer's Association and AIM.

“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



“NIH funding has enabled the largest ongoing trial enrolling older adults in the U.S. to date — the PREVENTABLE trial. This funding has brought together clinicians across specialties to test the hypothesis that new initiation of a commonly used heart medication (statin) can prolong functional survival and lessen the occurrence of Alzheimer’s or other forms of dementia.”

KAREN P. ALEXANDER MD

Professor of Medicine, Division of Cardiology,
Duke University
PI Preventable Clinical Coordinating Center



“The NIH funding increases have catalyzed exciting advancements in Alzheimer’s disease research, resulting in the first FDA-approved therapies. This journey has just begun, and we anticipate even more breakthroughs on the horizon. These investments have also attracted expertise and perspectives from diverse fields, facilitating our collective effort to combat dementia.”

CHENXI QIU

Research Fellow, Harvard Medical School



“The increased NIH funding has allowed us to conduct inclusive randomized clinical trials to identify safe and effective treatments across all stages of Alzheimer’s disease (AD) and AD-related dementias (ADRD). These funds have also helped create training and infrastructure programs to establish a national network of investigators and research teams who will lead, design, and conduct the next generation of AD/ADRD clinical trials.”

REMA RAMAN, PH.D.

Professor of Neurology, Director of Biostatistics & Recruitment, Engagement and Retention (RER), Alzheimer’s Therapeutic Research Institute (ATRI), Keck School of Medicine, University of Southern California



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.

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. With seed funding from the Alzheimer's Association, LEADS is now expanding internationally to five sites.

The Association and NIH 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 **Alzheimer's Association Interdisciplinary Summer Research Institute** provides an immersive, no-cost opportunity for early career researchers in psychosocial care and public health to launch a career in dementia science and accelerate breakthroughs. In 2023, 24 researchers received an award to join the institute. AA-ISRI is supported by the NIH.

The NIH plans to fund the addition of two Alzheimer's Disease Research Centers (ADRCs) bringing the total number to 35. 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, 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 16 countries across six continents and join a total of 163 pilots in 45 countries.

The **Alzheimer's Association** hosted **AAIC® Advancements: Toward Health Equity in Alzheimer's Disease and Related Dementias** in partnership with NIH. The no-cost event, hosted in San Antonio and online, brought together more than 1,000 attendees from over 60 countries to explore disparities in the prevention, diagnosis and treatment of Alzheimer's among underserved and underrepresented communities.

To address the need for informed communication practices and appropriate use of language in Alzheimer's and dementia research, the Association assembled a workgroup of experts in health disparities to create the **Alzheimer's Association Inclusive Language Guide**. The document, which underwent a public comment period, outlines minimum standards and guidance for labeling and communicating about social identities, characteristics of individuals, and populations and health disparities.

The fourth **Latinos & Alzheimer's Symposium**, examined challenges including underrepresentation in clinical trials, barriers to care and the impact of biomarkers on treatment options in Latino/a/e/x populations.

In partnership with the National Football League Alumni Association (NFLA), the Association has convened two annual **Black Men's Brain Health Conference** events, bringing together scientists, clinicians, former and current athletes, and community members to understand and address issues that lead to poor brain health outcomes in Black men.

The **AAIC Satellite Symposium** brought together nearly 700 researchers from 54 countries in Mexico City and online to discuss research advances in public health, diagnosis and treatment within Latin America. Over 53% of attendees were based in low- and middle-income countries.

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. Unprecedented levels of funding mean scientists are exploring a wide variety of pathways that could yield potential therapies. Today, we’re seeing results as new therapies addressing the underlying biology of Alzheimer’s disease are now available to patients.



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. Since 2006, the program has supported 50 drug development projects, with 12 candidate drugs having advanced to human trials.

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.

Researchers are exploring ways to repurpose treatments alone or in combination with other therapeutics. The NIH is funding the **Advancing Combination Therapy and Drug Repurposing for Alzheimer’s Disease (ACTDRx AD)** program to identify and evaluate FDA-approved drugs and candidate drugs from failed Phase II and Phase III trials for the potential treatment of Alzheimer’s or other dementias.

The NIH-funded Alzheimer’s Clinical Trials Consortium (ACTC) **seeks to accelerate and expand testing of therapies in 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 Alzheimer’s Network (ALZ-NET) is a voluntary health care provider-enrolled patient network that collects clinical and safety data for patients treated with new FDA-approved Alzheimer’s disease therapies, and tracks the long-term health outcomes associated with their use in real-world settings. ALZ-NET is currently enrolling clinical sites across the country. In October 2023, the Alzheimer’s Association announced a \$5 million funding program to support the development, expansion and alignment of real-world data globally.

**104 Phase I
208 Phase II
57 Phase III**

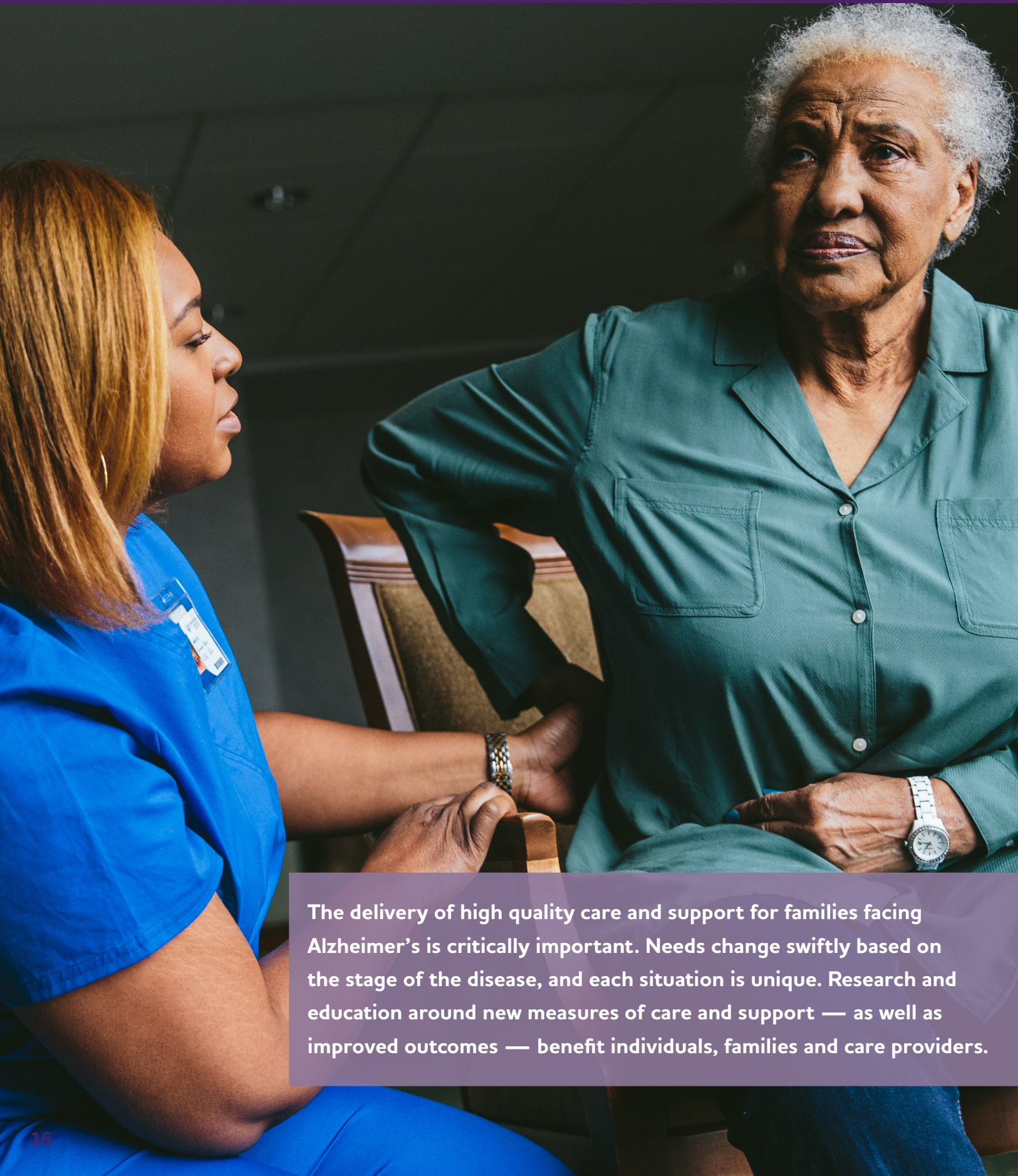
AGENT AND DEVICE CLINICAL TRIALS

Across all trials, including diagnostic agents:

31.98%
were industry sponsored

68.02%
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.



228 NIH-SUPPORTED

Alzheimer's and related dementia care and caregiver intervention trials as of December 2023.

ALZHEIMER'S ASSOCIATION | LINC-AD

With support from the Alzheimer's Association and NIH funding, the **Leveraging an Interdisciplinary Consortium to Improve Care and Outcomes for Persons Living with Alzheimer's and Dementia (LINC-AD)** is working to usher in the next phase of 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.

In NIH's **IMbedded Pragmatic Alzheimer's Disease (AD) and AD-Related Dementias (ADRD) Clinical Trials (IMPACT) Collaboratory**, scientists are conducting research in the places where people with dementia live and receive care. Research projects include helping nurses in emergency departments improve detection of dementia in patients and finding ways to improve dementia training and care management across interdisciplinary teams.

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. Over 150 primary care practices and over 400 health care providers completed this ECHO training since 2018, influencing more than 440,000 lives.

The Alzheimer's Association is partnering with the American Association for Men in Nursing (AAMN) to pilot a **caregiver education program focused on reaching male caregivers**. The partnership aims to raise concern and awareness of Alzheimer's and all other dementia particularly among men, with a focus on those in underserved communities, and provide care and support for people impacted by dementia.

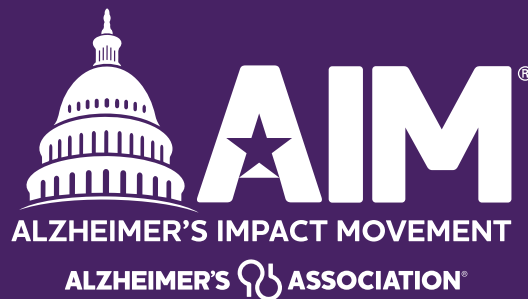
CMS is launching an initiative to improve the way dementia care is delivered for people living with Alzheimer's disease and other dementia. This test initiative, the **Guiding an Improved Dementia Experience (GUIDE) Model**, will be run through the Center for Medicare & Medicaid Innovation (CMMI). The GUIDE Model is consistent with a bipartisan bill championed by the Alzheimer's Association and AIM to provide access to dementia care management, which is an important tool to improve the quality of care, ease the challenges of Alzheimer's caregiving and reduce costs.

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