Realizing the National Plan to Address Alzheimer’s Disease
Leadership Toward Treatment and Prevention

ALZHEIMER’S ASSOCIATION
The 2011 enactment of the landmark National Alzheimer’s Project Act (NAPA) ushered in a new era, changing the way our nation addresses Alzheimer’s and all other dementia. Working toward the first goal in the National Plan to fight Alzheimer’s — to prevent and effectively treat Alzheimer’s by 2025 — the federal government, the Alzheimer’s Association, the pharmaceutical industry, academia, 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 NIH spending, annual federal funding in fiscal year 2022 for Alzheimer’s research will be more than $3.4 billion. During the same time, the Alzheimer’s Association has expanded its international research grants program to fuel research 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 2021 alone, the Association invested $70 million to advance Alzheimer’s and dementia research. These contributions to the most promising research have generated more than $1.4 billion in the last five years.

Thanks to these advancements, in June 2021 the Food and Drug Administration (FDA) granted accelerated approval to aducanumab, the first FDA-approved therapy to address the underlying biology of Alzheimer’s disease. History has shown us that approval of the first drug in a new category leads to more investment and more innovation: At least four additional treatments are expected to be reviewed by the FDA in the coming few years.

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.

It’s an exciting time for Alzheimer’s and dementia research. At any given moment, discovery is happening.

### Public Policy Victories Led by the Alzheimer’s Association

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<td>2011</td>
<td>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.</td>
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<td>2012</td>
<td>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.</td>
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<td>2014</td>
<td>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.</td>
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<td>2015</td>
<td>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 2017.</td>
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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 630 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 men 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. Through this sequencing project, which has a global reach involving more than 340 international investigators at 60 institutions, NIH seeks to identify genes that increase or decrease the risk for Alzheimer’s across diverse populations. Increased support for genetics research has led to the discovery of more than 20 individual genes linked to increased risk of late-onset Alzheimer’s.

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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 working to rectify this, making progress toward 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, PrevivityAD 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. This is the first CSF diagnostic for Alzheimer’s cleared by the FDA. Lumbar puncture tests are less expensive and more accessible than other currently available diagnostics like PET scans.

In 2022, NIH launched the Health & Aging Brain Study – Health Disparities (HABS–HD) as the first large-scale, community-based project to simultaneously study each of the AT(N) defined biomarkers across the three most prevalent racial/ethnic groups in the U.S., African Americans, Mexican Americans, and Non-Hispanic Whites.

**20 Phase I**

**14 Phase II**

**4 Phase III**

**DIAGNOSTIC IMAGING AGING AGENTS**

REGISTERED ON CLINICALTRIALS.GOV AS OF APRIL 2022

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 positron emission tomography (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.
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 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. With GHR Foundation and Edward Jones, the Association pledged $14 million in support of the DIAN-TU Primary Prevention Trial, allowing researchers to test whether gantenerumab — an investigational antibody — can clear beta amyloid in the brain, and as a result, prevent dementia due to Alzheimer’s.

Studies released at AAC indicated that improving air quality may improve cognitive function and reduce dementia risk. Results cited evidence that reducing pollution, especially fine particulates in the air and pollutants from the burning of fuel, is associated with lower risk of all-cause dementia and Alzheimer’s disease.

The NIH-supported SPRINT MIND Study found that intensive medical treatment to reduce blood pressure can significantly reduce the occurrence of mild cognitive impairment (MCI). The study showed a 19% reduction in risk of MCI in participants with a targeted systolic blood pressure goal of less than 120 mm Hg, versus 140 mm Hg. The Alzheimer’s Association is contributing funding to SPRINT MIND 2.0 to further examine the impact of blood pressure on dementia risk.

At the Clinical Trials on Alzheimer’s Disease (CTAD) conference, researchers reported results from the NIH-funded COSMOS-Mind study that suggests taking a multivitamin daily for three years was linked to a 60% slowing of cognitive aging among older study participants. The effects may be more pronounced for those with cardiovascular disease.

The NIH and Eisai Inc. are funding the AHEAD Study, the first Alzheimer’s trial to recruit people as young as 55 years old who are at risk of developing symptoms of the disease as they age. The study consists of two different clinical trials testing the same investigational treatment, BAN2401 (lecanemab). 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.

The NIH is funding a clinical trial to evaluate computerized games designed to improve brain speed and determine if this brain activity can reduce mild cognitive impairment or dementia. The trial is also looking into whether the presence of risk factors for Alzheimer’s, such as amyloid plaques, make the brain games less effective.
The Alzheimer’s Association is funding and implementing U.S. POINTER, a two-year 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. Five sites across the U.S. have been selected and recruitment for the trial began in 2019. The NIH is funding add-on studies in neurovascular, sleep, PET imaging, and microbiome.

**Health Coaching**

**Exercise**

**Cognitive Engagement**

**Nutrition**

**Neurovascular**

The NIH is providing up to $10 million to study how changes in blood flow and blood vessels affect brain health.

**Sleep**

Up to $5.5 million over 5 years to study impact of sleep quality.

**PET Imaging**

Up to $47 million over 5 years to study PET imaging.

**Microbiome**

As part of a larger microbiome analysis, NIH is also funding up to $750k for this add-on study.

**PLUS**

The NIH is funding four add-on projects to further study:

- Diversity is essential to the success of U.S. POINTER. The recruitment process is designed to increase participation by historically underrepresented communities in research, with a priority focus on achieving racial and ethnic diversity and including rural populations. The aim is for at least 23% of participants to be from racial/ethnic minority groups, with an equal number of females and males. Intervention oversight teams in five geographically diverse regions of the U.S. will each include research clinic team members and community partners. The nearest Alzheimer’s Association chapter will assist with coordination of intervention delivery.
“The increased NIH Alzheimer’s funding has allowed me to quickly expand my lab after joining my new institution, so we can now be faster in making new discoveries. It is allowing us to study the molecular mechanisms driving the effects of comorbid amyloidosis and cardiovascular risk factors on the cerebral vessels. We also have novel drugs in the translational pipeline that could soon be applied in Alzheimer’s disease clinical trials.”

SILVIA FOSSATI, PH.D.
Associate Professor and Associate Director, Alzheimer’s Center at Temple (ACT)
Temple University

“Increased NIH funding has enabled me to build research programs around new areas of research. Today, I’m working on research with the goal to understand the regulation and function of the cell’s trash system in aging and Alzheimer’s. With this funding, I’m also able to work to translate our research on the underlying biology discoveries to disease modifying therapy.”

HUI ZHENG, PH.D.
Huffington Foundation Endowed Chair in Aging
Baylor College of Medicine

“The increased funding has allowed me to test and validate digital and neurobehavioral markers detecting preclinical states earlier, understand health disparities as a complex life course process, and create intentional pathways to improve the recruitment of historically minoritized groups into research.”

GANESH M. BABULAL, PH.D.
Assistant Professor, Department Of Neurology
Washington University in St. Louis

“The increased funding for research related to Alzheimer’s and other forms of dementia is encouraging to me, families and individuals. I now have funding to explore innovative and meaningful strategies to support families facing dementia, especially families from racial and ethnic minority groups.”

FAYRON EPPS, PH.D., RN, FAAN
Assistant Professor
Nell Hodgson Woodruff School of Nursing
Emory University
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 diversity 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 diversity among research professionals and future principal investigators in the field.

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

The Alzheimer’s Association is working with government agencies such as the NIH, as well as industry and other nonprofit organizations, in the Accelerating Medicine Partnership Alzheimer’s Disease (AMP-AD), an effort to revolutionize the current model for discovering new diagnostics and treatments for Alzheimer’s disease. An NIH-supported research team created a ranking system of 80 compounds, including 33 FDA-approved drugs, with the potential to anticipate which drugs can inhibit Alzheimer’s disease. Using data from AMP-AD, the team ranked the compounds based on their probability of being active against specific Alzheimer’s-related genetic mechanisms.

In June 2021, aducanumab was granted accelerated approval as a treatment for Alzheimer’s disease from the U.S. Food and Drug Administration (FDA). This is the first FDA-approved therapy to address the underlying biology of Alzheimer’s by removing beta-amyloid, one of the hallmarks of the disease, from the brain. It is reasonably likely that aducanumab reduces cognitive and functional decline in people living with early Alzheimer’s.

Projects funded by NIH’s Alzheimer’s Drug Development Program led to the development of 12 new clinical drug candidates targeting multiple disease processes such as brain inflammation, proteostasis, synaptic plasticity, neurogenesis and different aspects of amyloid toxicity. Most of these drug candidates are being tested in human trials supported by the NIH.

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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 is currently funding 60 projects, including some of the most promising clinical trials in the field.

Across all trials, including diagnostic agents:
- 35.2% were industry sponsored
- 64.8% were collaboratively funded (academia, industry, NIH, Alzheimer’s Association and others)

**AGENT AND DEVICE CLINICAL TRIALS**

100 Phase I
186 Phase II
60 Phase III

REGISTERED ON CLINICALTRIALS.GOV AS OF APRIL 2022
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 — benefits individuals, families and care providers.

178 NIH-SUPPORTED
Alzheimer’s and related dementia care and caregiver intervention trials as of May 2022.

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 nine projects 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.

$27.3 MILLION:
Proposed FY23 additional NIH investment in research on care and caregiver support.

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 persons with dementia. AA-ISRI works to broaden dementia knowledge among researchers in these fields in order to support a more diverse workforce. In 2021, 24 researchers received an award to join the institute. AA-ISRI is supported by the NIH.
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®.

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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