



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.

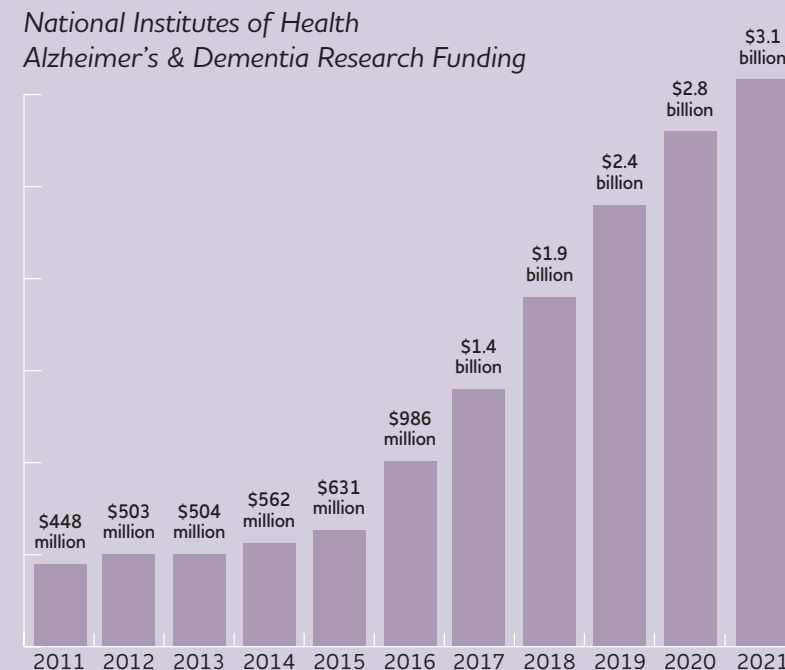
Since the passage of NAPA, the Alzheimer's Association has worked with bipartisan congressional champions to increase federal research funding more than seven-fold, with annual funding currently at \$3.1 billion. During the same time, the Alzheimer's Association has expanded its international research 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 addition to efforts made to increase federal funding, in just the last 5 years, the Alzheimer's Association has generated total impact funding exceeding \$1.4 billion. In 2020 alone, the Association invested \$63 million to advance Alzheimer's and dementia research and science.

The momentum generated by the Alzheimer's Association and the federal government has led to greater investment from other entities. This has allowed researchers to lay the foundation for breakthroughs in effective treatment and prevention.

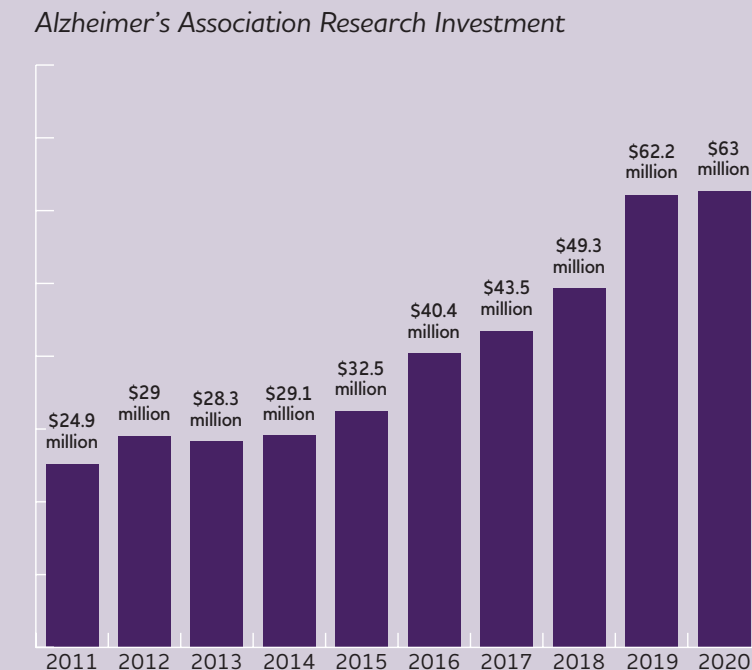
It's an exciting time for Alzheimer's and dementia research. At any given moment, discovery is happening.

Funding to transform Alzheimer's research

National Institutes of Health
Alzheimer's & Dementia Research Funding



Alzheimer's Association Research Investment



Beginning in FY15, the NIH combined Alzheimer's and other dementia funding into one category.



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.

Understanding the Biological & Molecular Contributions to 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.



A team supported by the NIH and the Alzheimer's Association discovered an individual who, despite having a dominantly inherited Alzheimer's gene, remained cognitively intact until her 70s. The individual has two copies of another rare gene mutation — known as the Christchurch variant — that the researchers believe is the source of this individual's dementia resistance. **If confirmed, this discovery could lead to new possibilities for dementia treatment.**

The Alzheimer's Association is funding **16 RESEARCH GRANTS** that aim to understand why more women than men develop the disease — and how we can treat it in both sexes.

60+ NIH RESEARCH PROJECTS

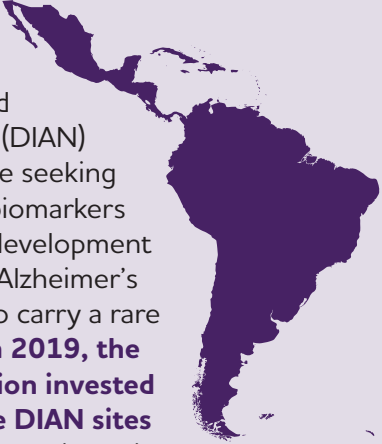
seeking to understand differences in risk for men and women.

Since the passage of NAPA, the Alzheimer's Association has continued its leadership commitment to Alzheimer's research, **awarding 392 grants through its International Research Grant Program** to projects investigating the basic biological underpinnings of the disease in order to accelerate pathways to treatments.



According to data reported by the Alzheimer's Association, Hispanics are about 1.5 times more likely to develop dementia than non-Hispanic Whites. **New research shared at the Alzheimer's Association International Conference® 2020 (AAIC®), using data from the NIH-supported Study of Latinos-Investigation of Neurocognitive Aging (SOL-INCA), found genetic predictors of Alzheimer's risk may differ among Hispanics of different backgrounds, and between Hispanic and White individuals.** APOE-e4, the gene with the strongest impact on Alzheimer's risk for White, European-descended populations, appears to be a less accurate predictor of risk in most Latin American populations. Importantly, this indicates that the use of APOE-e4 as a covariate in trials may impact the accuracy of the outcomes for certain racial/ethnic groups.

Through the NIH-supported Dominantly Inherited Alzheimer Network (DIAN) study, researchers are seeking to identify potential biomarkers that may predict the development of younger-onset Alzheimer's disease in people who carry a rare genetic mutation. **In 2019, the Alzheimer's Association invested \$1 million to add five DIAN sites in Latin America.** Comparing this population's cognitive assessments and brain scans with those of other DIAN participants promises to yield valuable insights into how race, environment, genetics and other factors may contribute to cognitive decline.



Research Dementia Latin America (ReDLat) is seeking to identify the unique genetic and socioeconomic determinants of health that contribute to Alzheimer's and other dementias in Latin America. ReDLat launched with support of a \$2.5 million grant from the NIH; the Alzheimer's Association, the Tau Consortium and the Global Brain Health Institute (GBHI) provided additional funding to triple the original award.

Enabling Accurate and Timely Diagnosis



At AAIC 2020, scientists, including those funded by the NIA, reported results of multiple studies showing advances in blood “tests” detecting the protein tau in the brain — one of hallmarks of Alzheimer’s. One such test may be able to detect changes in the brain 20 years before dementia symptoms occur. In particular, the studies focused on a form of tau known as p-tau217, which seems to be the most specific to Alzheimer’s and the earliest to show measurable changes.

The Centers for Medicare and Medicaid Services (CMS) is funding, with Alzheimer’s Association support, New IDEAS to build upon learnings from the original IDEAS Study. **New IDEAS will expand the study population to include more diverse populations, as well as participants having “typical” (i.e., progressive amnesic) or “atypical” clinical presentations of Alzheimer’s disease.** The study will investigate whether the results of PET imaging have an impact on health care management and outcomes.

24 Phase I
14 Phase II
3 Phase III

DIAGNOSTIC IMAGING AGENTS

REGISTERED ON CLINICALTRIALS.GOV AS OF JANUARY 2021



The Imaging Dementia — Evidence for Amyloid Scanning (IDEAS) Study, led by the Alzheimer’s Association and managed by the American College of Radiology, is assessing the impact brain amyloid PET imaging has on outcomes for people with cognitive impairment. Initial **results found a positive scan was associated with changes in medical management**, and another analysis found amyloid PET was associated with a 4.5% relative reduction in hospitalizations.

A new diagnostic tool that measures amyloid levels in cerebrospinal fluid (CSF) via a lumbar puncture is being considered by the FDA. If approved it would be 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.

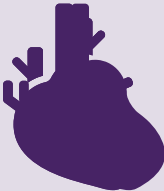
An early diagnosis provides a range of benefits for individuals living with Alzheimer’s or another dementia and their families. In addition, an accurate diagnosis means better treatment. Unfortunately, there is no single diagnostic test that can determine if a person has the disease; instead, health 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.



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 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 funding SPRINT MIND 2.0 to further examine the impact of blood pressure on dementia risk.



In a study group including more than 700 African Americans, NIA-supported researchers found that having diabetes, high blood pressure, or two or more heart health risk factors in adolescence or young adulthood was associated with significantly worse late-life cognition.

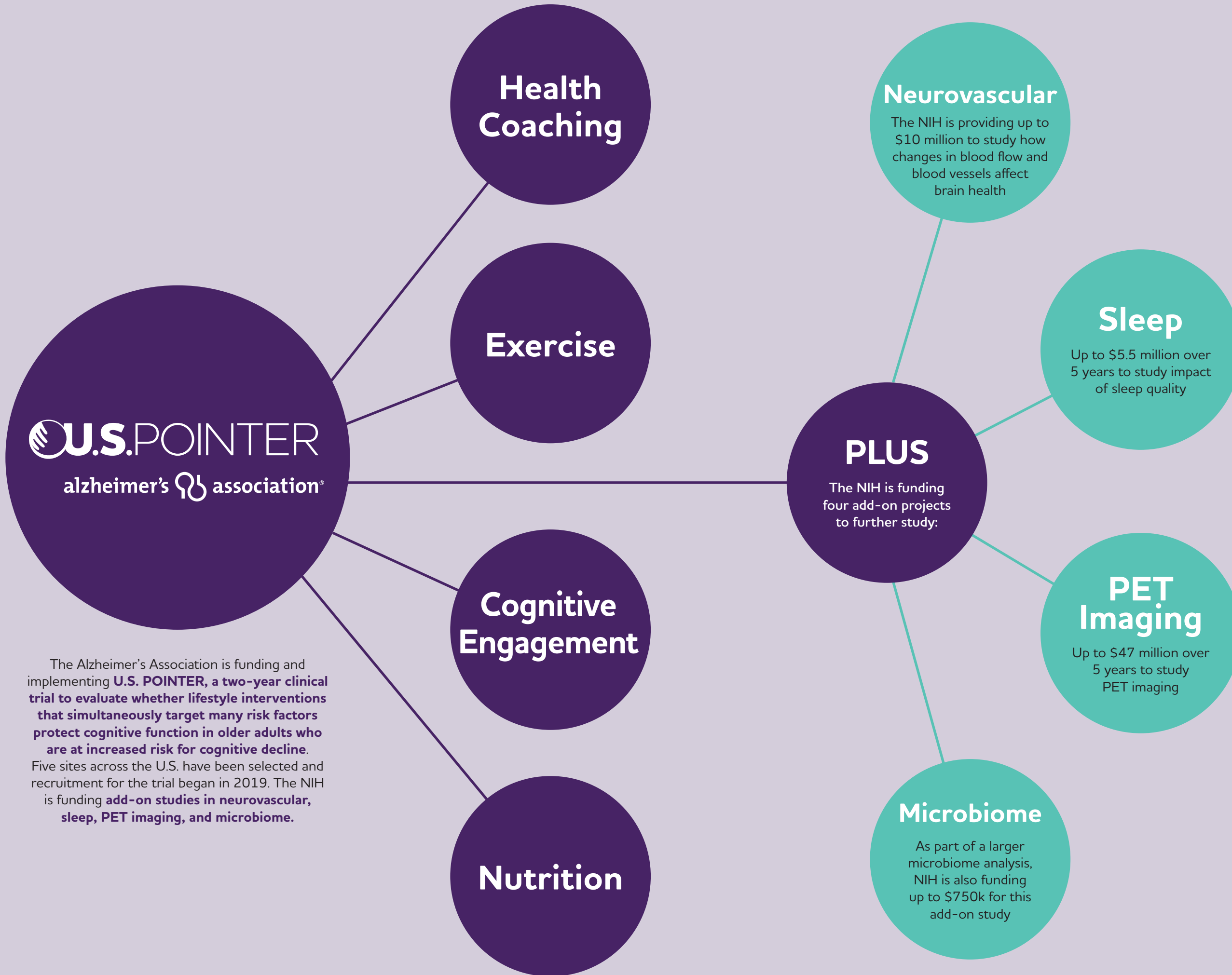


The Alzheimer's Association was named as the **BOLD Public Health Center of Excellence on Dementia Risk Reduction by the Centers for Disease Control and Prevention (CDC).** The Association will lead a national effort to develop and disseminate public health strategies and resources aimed at reducing risk of cognitive decline and dementia.

NIH-supported researchers at Columbia University found that higher body mass index in early adulthood was associated with higher late-life dementia risk.



New research announced at AAIC 2020 suggests flu and pneumonia vaccination — especially multiple vaccinations over time — are associated with a lower risk of Alzheimer's. One study found **at least one flu vaccination was associated with a 17% reduction in Alzheimer's prevalence, and more frequent flu vaccination was associated with another 13% reduction.**



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.**

“The increased funding for Alzheimer’s research over the past few years is having a dramatic impact on our field. It is an exciting time to be working and we are making incredible new discoveries almost on a weekly basis. My hope for the future is quite bright.”

PETER SNYDER, Ph.D.
Professor & Vice President
for Research and Economic Development
University of Rhode Island



“Based on my early work funded by the Alzheimer’s Association, I’ve gone on to receive my most recent major federal grant to continue studying Alzheimer’s disease in nonhuman primates. The substantial increase in federal research funding provided vital resources necessary to advance my current primate research.”

HENRIETA SCHOLTZOVA, M.D., Ph.D.
Department of Neurology
New York University Grossman School
of Medicine

“The increased federal funding allows us to conduct clinical trials to find therapies for this disease.”

REMA RAMAN, Ph.D.
Director of Biostatistics
Keck School of Medicine USC



“With just a little bit of [increased NIH] funding I’m expanding my Alzheimer’s study to make sure we’re hearing the voices of diverse participants from across the entire state of Wisconsin.”

MEGAN ZUELSDORFF, Ph.D.
University of Wisconsin - Madison
Alzheimer’s Disease Research Center

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 has provided additional funding.



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 NIH-funded Alzheimer's Clinical Trials Consortium (ACTC) **seeks to accelerate and expand testing of therapies of all stages of Alzheimer's and other dementias.**

ACTC — composed of 35 sites across the U.S. — is developing strategies for 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); most recently, four exploratory ADRCs to **broaden research initiatives with underrepresented populations such as African Americans, Native Americans and those in rural communities** — all of whom have different risk factors for developing Alzheimer's and other dementia.



In 2018, the NIH, in collaboration with the Alzheimer's Association, released the **National Strategy for Recruitment and Participation in Alzheimer's and Related Dementias Clinical Research.** This detailed pathway outlines the steps needed to address the challenges and opportunities to include previously underserved populations in clinical research.

Working Toward Effective Treatment

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 NIH plays an important role in developing new treatments for Alzheimer’s. As of July 2020, there were **10 NIH-funded drug candidates being tested in clinical trials.**

For the first time in more than a decade, a new treatment for cognitive decline related to Alzheimer’s is being reviewed by the FDA. **Aducanumab is a new type of Alzheimer’s treatment which may address the underlying biology of Alzheimer’s disease.** If approved, it would be the first available therapy to demonstrate that removing amyloid from the brain may reduce clinical decline in people living with Alzheimer’s.

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 58 projects,** including some of the most promising clinical trials in the field.

Recently, Bill Gates and Part the Cloud partnered to accelerate research investigating specific brain changes that may contribute to the development of Alzheimer’s and dementia. This **partnership funds 18 high-risk studies exploring areas of neurodegeneration, neuroinflammation and immune response.**

**97 Phase I
166 Phase II
55 Phase III**

HIGH-POTENTIAL AGENT AND DEVICE CLINICAL TRIALS

Across all trials, including diagnostic agents:

30.9%
Industry

69.1%
Collaborations/Partnerships
(Academia, Industry,
NIH, Alzheimer’s
Association, and others)



The Alzheimer’s Disease Data Initiative (ADDI), launched in November 2020, is a new global effort that **connects Alzheimer’s researchers with the data needed to generate insights and inform the development of improved treatments and diagnostic tools.** ADDI was created by a coalition of partners including Bill Gates, the NIA and the Alzheimer’s Association.

REGISTERED ON CLINICALTRIALS.GOV AS OF JANUARY 2021

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 — benefits individuals, families and care providers.



65 NIH-SUPPORTED Alzheimer’s and dementia care and caregiver intervention trials



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 examining care for people living with dementia and their care partners. The program will create an international consortium of researchers and stakeholders that will review existing measures, identify and address gaps, and disseminate these results via permanent online repositories.

\$39.5 MILLION The proposed FY22 NIH investment in care and caregiving support

The Alzheimer’s Association provides Project ECHO® (Extension for Community Healthcare Outcomes), a telementoring program that uses videoconferencing to train care providers and accelerate the sharing of knowledge across the care field. The Association hosts two Project ECHO programs; the first focuses on helping primary care practices increase timely diagnoses of Alzheimer’s and dementia, while the second helps assisted-living communities adopt the Association’s Dementia Care Practice Recommendations. Project ECHO provides a forum to explore real case studies from the field in order to better address common challenges.



The Alzheimer’s Association, including its Minnesota-North Dakota Chapter, is a **lead partner and subgrantee for the Public Health Center of Excellence on Dementia Caregiving**, which will be based at the University of Minnesota.

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®.

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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