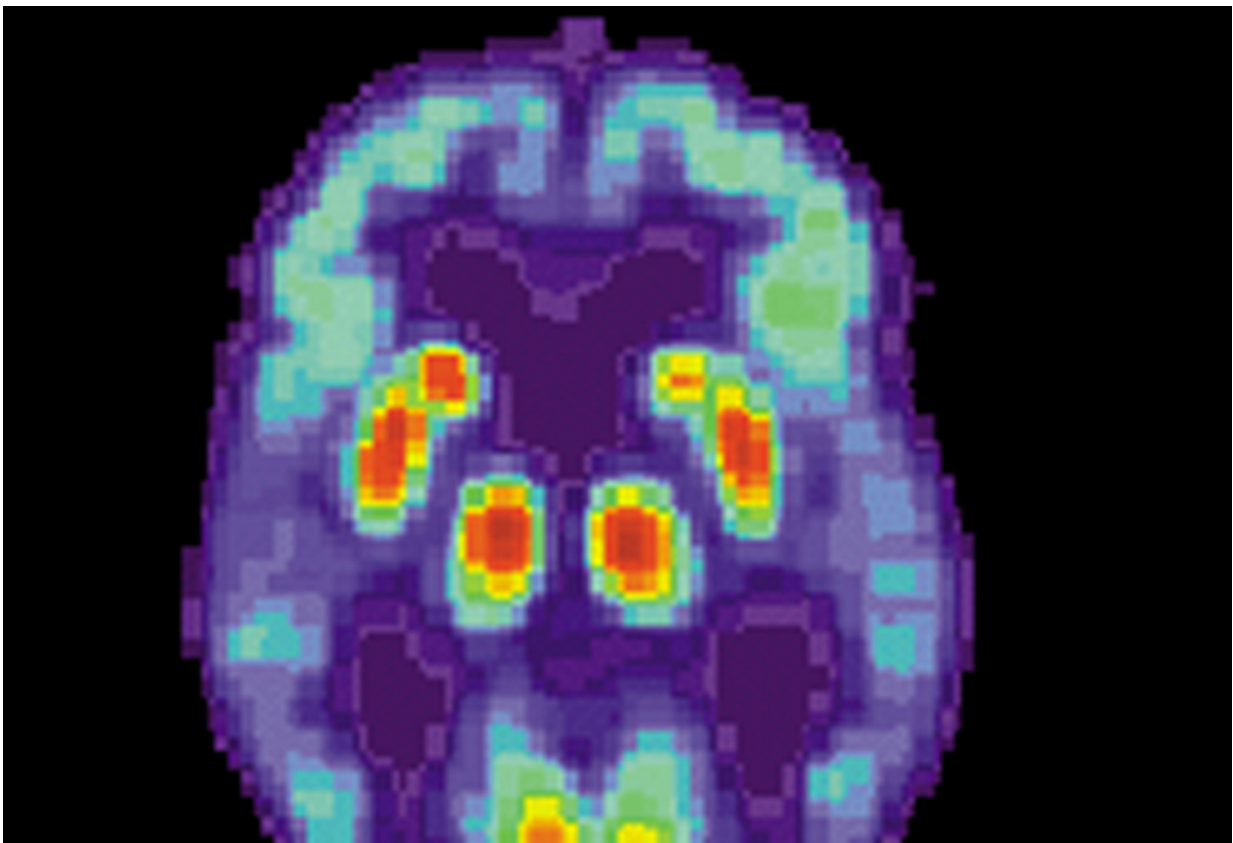


Nonprofits, federal government surpass pharma to lead Alzheimer's drug development

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PET scan of a human brain with Alzheimer's disease. Credit: public domain

Two articles published online today by *Alzheimer's & Dementia*:

Translational Research & Clinical Interventions, a journal of the Alzheimer's Association, show substantial changes in the focus and funding of clinical trials for Alzheimer's disease therapies. The newly published articles throw a greater spotlight on a decision—now before the U.S. Food and Drug Administration (FDA)—that would potentially bring a new drug therapy to Alzheimer's patients for the first time in nearly 20 years.

Researchers analyzed [clinicaltrials.gov](#), the U.S. National Library of Medicine's database, and five years of annual Alzheimer's pipeline reviews published by UNLV School of Integrated Health Sciences research professor Jeffrey L. Cummings and colleagues. The results capture the well-publicized retreat of pharma from Alzheimer's clinical trials, especially early phase [human trials](#), and the emergence of federal agencies and nonprofit organizations as the primary drivers of growth and innovation.

In the first study, "Who Funds Alzheimer's Disease Drug Development?," Cummings and colleagues found that the number of Alzheimer's clinical trials supported by [pharmaceutical companies](#) has decreased over the past five years, while trials supported by federal government sources and public-private partnerships (PPP) have increased. The authors observe that pharma companies are not increasing their involvement in Alzheimer's trials and [drug](#) development except through PPP, enabling them to distribute the cost and risk. And they largely engage only in late-stage (Phase 3) clinical trials.

The researchers found that the trials gap is increasingly being filled by academic medical centers (AMCs). Trials by AMCs are up 78% over the past five years, primarily funded by the U.S. National Institutes of Health (NIH) and programs of the National Institute on Aging (NIA), Alzheimer's Association, and Alzheimer's Drug Discovery Foundation (ADDF), including the Alzheimer's Association's Part The Cloud

initiative.

"Nonprofits and the NIH are making a huge difference in [drug development](#) for Alzheimer's and all other dementia," Cummings said. "Recent years have been a time of pharma retrenchment after multiple negative clinical trials, but also a time of innovation in early-stage trials and re-evaluation of previously under-resourced ideas. We found in our review that, in the newer early-stage clinical trials, the therapeutic mechanisms are more diversified, biomarkers are more regularly used, and repurposed agents are being explored—increasingly led by academic researchers and funded by NIH, the Alzheimer's Association, and ADDF.

A second paper, "Alzheimer's Disease Drug Development Pipeline: 2021," also by Cummings and colleagues, including a student, Justin Bauzon, from the UNLV School of Medicine, reinforces these trends by showing that, despite pharma's retreat from Alzheimer's, the total number of agents in Alzheimer's clinical trials has been relatively steady over the last five years. The total is up slightly from 2020, driven by additional agents in Phase 2 studies. There is also increasing diversity of targets and therapeutic mechanisms of drugs in the Alzheimer's pipeline, driven by innovative Phase 1 and 2 [trials](#).

"Alzheimer's Association funding, partnerships—including the NIA and ADDF—and advocacy for federal Alzheimer's research funding are now the primary drivers of growth in Alzheimer's [clinical trials](#), filling the gap left by pharma's retreat, and growing and diversifying the front end of the drug pipeline," said Maria C. Carrillo, Alzheimer's Association chief science officer.

The NIA now distributes more than \$3 billion annually for Alzheimer's and dementia research, up from \$500 million just a few years ago. "This great victory is almost completely due to Alzheimer's Association

legislative efforts, our grassroots advocates, and our champions in Congress," Carrillo said.

The FDA is reviewing aducanumab (Biogen) for the treatment of Alzheimer's disease. A decision is expected by June 7.

"If pharma companies do not see a clear path to FDA approval, they will continue not to invest in Alzheimer's," Cummings said. "This further highlights the importance of the decision before the FDA at this moment."

There are four drugs approved and commonly used to treat the symptoms of Alzheimer's dementia, plus a combination therapy that includes two of these drugs. There are currently no approved drugs that change the course or delay the progression of the disease or that delay or stop clinical decline. No new drugs have been approved for Alzheimer's since 2003.

The article authors say, "If new therapies are approved by regulatory authorities, more sponsors and more funding may be attracted to Alzheimer's research with accelerated innovation."

The two studies were supported by the Chambers-Grundy Center for Transformative Neuroscience at UNLV, dedicated to advancing clinical trial methods to get better treatments to patients faster.

Provided by Alzheimer's Association

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