Alzheimer's drug development pipeline: Positive results, new insight on biomarkers position 2024 as 'learning year'

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Dr. Jeffrey Cummings, research professor and director, Chambers-Grundy Center for Transformative Neuroscience at UNLV. Credit: Josh Hawkins/UNLV

The world of Alzheimer's treatments is at an inflection point as more
potential drugs make their way out of clinical trials.

On the heels of newly FDA-approved drugs Aduhelm (aducanumab) in 2021 and Leqembi (lecanemab) in 2023, a UNLV researcher says that 2024 is a "learning year" for Alzheimer's drug development.

"There are a large number of drugs in the pipeline that have very diverse actions on the brain," said Dr. Jeffrey Cummings, a leading Alzheimer's clinician-scientist and research professor in UNLV's School of Integrated Health Sciences.

Cummings leads the Alzheimer's drug development observatory within UNLV's Department of Brain Health, a robust database of all clinical trials results he began in 2016. It is the only observatory of its kind in the world.

While nearly 7 million Americans are living with Alzheimer's disease and are in need of better treatments, Cummings remains encouraged by the results of this year's pipeline developments—including the recent inclusion of biomarkers, which are often found in blood and signal normal or abnormal processes, or a condition or disease. Alzheimer's biomarkers can now be measured in the blood.

"Most of our biomarkers for Alzheimer's and dementia have been discovered only within the past three years. They provide information on the drug's impact," he said. "Biomarkers will be featured in nearly all clinical trials moving forward to guide the process."

**Biomarker studies highlight current treatment pipeline**

Cummings's annual report is featured in Alzheimer's & Dementia:
Translational Research & Clinical Interventions. According to this year's data, there are 164 active trials and 127 unique treatments, a roughly 10% decrease from the previous year that saw a record-high 187 active trials and 141 unique treatments.

Some of this year's results include:

- 76% are disease-modifying treatments that aim to slow the decline of memory
- 34% are biological therapies given intravenously or through some other injection
- 12% are cognitive enhancing agents that are intended to improve memory
- 13% are drugs for behavioral symptoms, such as agitation
- 31% are repurposed agents approved for other diseases, such as cancer or Parkinson's disease

"One prediction we can make with confidence is that we should be prepared for more complex biological therapies that require [intravenous infusion](https://en.wikipedia.org/wiki/Intravenous_infusion) and vigilant monitoring for side effects; more like cancer therapies," Cummings said.

Cummings attributes the decrease in overall clinical trials and unique treatments to a lack of funding on the federal level and from less private investment from the biopharmaceutical industry.

"Simply put, we need more investments from the government and from the pharmaceutical companies to fight this trend of declining clinical trials," Cummings said, adding that the purpose of his annual Alzheimer's drug development pipeline report is to keep policymakers, health care systems, and patients apprised of the updates taking place among Alzheimer's clinical trials.
A lack of participants for clinical trials has also inhibited results, as nearly 51,400 participants are needed for all active trials. Still, Cummings said the newest Alzheimer's treatments in the pipeline, including results from 35 phase 2 trials and 12 from phase 3—the final phase before FDA review—will offer critical information as newer drugs continue to be developed.

"Eight of the drugs with reported data from phase 2 for this year are all anti-inflammatory drugs and the biomarkers included in the trials will allow us to dissect the importance of the individual aspects of inflammation," he added. He said that mounting results from multiple drugs focusing on one target will lead to new and potentially helpful information that could advance multiple related trials.

"The pipeline of potential new Alzheimer's treatments is diverse, offering a future with new, safe, and effective treatments and powerful combination therapies," said Maria C. Carrillo, Ph.D., Alzheimer's Association chief science officer. "The recent FDA approvals for Alzheimer's, and the diversity of the pipeline, provide hope to those impacted by this devastating disease."

"The Alzheimer's Association has long been committed to advancing all evidence-based potential treatment avenues, and to combining diverse approaches," Carrillo said.

**Hopeful for the future**

In addition to the FDA-approved Aduhelm and Leqembi, Cummings is confident that the FDA will approve the use of donanemab, which yielded positive results in its clinical trials before FDA review was halted for further evaluation.

"Development successes are emerging, which is why I think we are
experiencing such a breakthrough in the world of Alzheimer's treatment," he said. "It takes a decade to advance a drug from phase 1 to phase 3 and then nearly two more years for FDA review, so these processes take time. We know that most drugs fail, but not all of them. Even drugs that fail in the clinical trial can still tell us a lot."


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