

Researchers identify urgent need for Alzheimer's drug development

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Researchers at the Cleveland Clinic Lou Ruvo Center for Brain Health have conducted the first-ever analysis of clinical trials for Alzheimer's disease (AD), revealing an urgent need to increase the number of agents entering the AD drug development pipeline and progressing successfully towards new therapy treatments. The paper, "Alzheimer's Disease Drug Development Pipeline: Few Candidates, Frequent Failures," was published today in the journal *Alzheimer's Research & Therapy*.

A comprehensive look at all clinical trials underway shows:

- There are relatively few drugs in development for Alzheimer's disease.
- The failure rate for AD <u>drug development</u> is 99.6 percent for the decade 2002-2012.
- The number of drugs has been declining since 2009.

"Our goal was to examine historical trends to help understand why Alzheimer's disease treatment development efforts so often fail," said Jeffrey L. Cummings, M.D., ScD, Director of the Cleveland Clinic Lou Ruvo Center for Brain Health. "With an estimated 44 million people living worldwide with the condition, the study shows that the Alzheimer's disease drug development ecosystem needs more support given the magnitude of the problem."

Using the advanced search mechanisms of ClinicalTrials.gov, a government website that records all ongoing <u>clinical trials</u>, Dr.



Cummings, along with Kate Zhong, M.D., Senior Director of Clinical Research and Development, and Touro University medical student Travis Morstorf, constructed a comprehensive analysis to examine all trials since 2002.

"By analyzing both completed as well as on-going trials and currently active compounds, we were able to provide insight into longitudinal trends in drug development," said Dr. Zhong. "What we found was that the investment in AD drugs and therapies is relatively low compared to the challenge posed by the disease. The pipeline is almost dry."

This comprehensive analysis illustrates the high rate of failure of compounds and the need for a constant supply of new drugs or a higher focus on repurposing, which can be assessed for efficacy in AD. With AD more expensive to the U.S. economy than cardiovascular disease or cancer, the Lou Ruvo Center for Brain Health research team believes the system of AD drugs must be supported, grown and coordinated to improve the success rate and development of new therapies.

In order to accelerate the drug development process and reduce the need to constantly invent new drugs, researchers note the need for more repositioning studies, which involve studying an already-approved drug in a new use or condition. For example, researchers at the Cleveland Clinic Lou Ruvo Center for Brain Health are leading a landmark Phase IIa clinical trial to determine if bexarotene (TargretinTM), a drug currently FDA approved to treat skin cancer, can remove a protein build-up in the brains of Alzheimer's patients, as it did in a recent animal study.

Provided by Cleveland Clinic

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