2026 Part the Cloud Translational (PTC) Research for Alzheimer's Disease Program: Phase 1 and Phase 2 Clinical Studies

Program Overview
The Alzheimer's Association is pleased to announce the next offering of the Part the Cloud Translational Research Funding initiative to increase the research efforts in Phase I and Phase II (Proof of Concept) clinical trials evaluating novel or repurposed potential medications directed towards Alzheimer's disease and related dementias internationally.

Background
Alzheimer's disease (AD) represents one of the most urgent unmet medical needs of our time. While recent decades have yielded significant progress in understanding the neurobiology of AD; from genetic contributors and amyloid accumulation to tau tangle formation, synaptic dysfunction, and cellular degeneration, translating these discoveries into effective therapeutics remains an ongoing challenge.

The drug development process for Alzheimer's disease is inherently complex, requiring a series of rigorous, resource-intensive steps that span from target identification and high-throughput screening to lead optimization, in vitro and in vivo validation, and central nervous system (CNS) penetration assessment. Subsequent phases include toxicology studies and, ultimately, the multi-phase clinical trial process required for regulatory approval. This continuum demands sustained collaboration across academic institutions, biotech companies, and clinical research teams over many years.

While numerous candidate therapies have emerged from successful preclinical programs, many face a critical bottleneck when transitioning into first-in-human studies. Existing funding mechanisms, including those from governmental and non-governmental sources, often support either early discovery work or late-stage clinical trials. However, there is a notable lack of support for Phase I clinical trials, which are essential for establishing safety, dosage parameters, and preliminary pharmacokinetics in human subjects. This funding gap presents a significant barrier to advancing novel therapeutic candidates with promising disease-modifying potential.

This program seeks to bridge this gap by providing targeted support for early-phase human clinical studies. By enabling this crucial transition from preclinical development to human testing, the Alzheimer's Association aims to accelerate the delivery of innovative treatments to individuals living with Alzheimer's disease and related dementias.

Potential themes
This new grant mechanism aims to fill the gap in Alzheimer's disease and related dementia clinical trials for advancing potential therapeutics forward by providing support for early phase studies (Phase 1 and Phase 2).

General considerations and Eligibility
Applications will be accepted from academic investigators and small companies with lead candidate therapeutic agents that require early stage testing prior (Phase 1) to Proof of Concept (POC) Phase 2 or 3 efficacy studies, or with lead therapeutic agents that have already established human safety data and require a small-scale pilot Proof of

Mechanism (POM) study in humans to begin proving the scientific concept in humans. This award will support Phase 1 studies or pilot small- scale Phase 2a studies for repurposed drugs in normal individuals or individuals with symptomatic or symptomatic Alzheimer's and related dementia (i.e. early human studies to set the stage for efficacy studies), including single and multiple dose studies to establish safety, brain penetration and/or target engagement and POM in preparation for larger proof of concept trials. In addition, proposals may be considered that are POC to validate biological marker(s) of disease progression in a clinical trial environment. Any proposal must have a clear focus on Alzheimer's disease and related disorders and be translational in nature. All proposals should clearly and explicitly outline the measure to be investigated, the methods for study, the study population, and outcomes. Researchers from underrepresented groups are encouraged to apply.

Studies funded by Part the Cloud with results justifying further development (e.g. Phase 2b, or 3) may be eligible to apply to the Alzheimer's Clinical Trials Consortium (ACTC) (U24 AG057437). ACTC provides comprehensive infrastructure and expertise on ADRD clinical trials. ACTC and the proposer will work in collaboration to develop a grant application to National Institute on Aging, NIH. If funded, ACTC will conduct the trial. Mentorship and Principal Investigator training in Alzheimer's Clinical Trials is provided by ACTC. Read more at: https://www.actcinfo.org/submit-a-proposal.

Both non-profit and small for-profit organizations are eligible. **Open to International Applicants**. Small for-profit organizations must submit documentation of net assets and annual earnings during the letter of intent process as a part of the review process. Not-for-profit organizations must submit documentation verifying status during the letter of intent process.

Applications will be accepted from organizations conducting studies around the world. Researchers with full-time staff or faculty appointments are encouraged to apply. Applications from post- doctoral candidates will not be accepted. For questions as to whether an investigator or organization is eligible, please contact the Alzheimer's Association at grantsapp@alz.org.

Note: Alzheimer's Association grants are generally open to scientists and researchers across the globe; however, as a U.S.-based charity, the Alzheimer's Association is subject to, and complies with, U.S. law. As a result, the Alzheimer's Association cannot award, and will not award, grants in violation of applicable U.S. statutes and regulations. This means, among other things, that the Alzheimer's Association cannot, and will not, fund any individual or entity (i) that is subject to U.S. comprehensive or targeted sanctions or if awarding funding would result in a violation of such sanctions, (ii) that is on the U.S. List of Specially Designated Nationals or entities owned or controlled by such persons, or (iii) when doing so is otherwise prohibited by U.S. laws related to combating terrorism.

Funding and award period

Each grant is limited to $1,000,000 (direct and indirect costs) over two or three years. Indirect costs are only allowed for not-for-profit institutions, and are capped at 10 percent (rent for laboratory/office space is expected to be covered by indirect costs paid to the institution). No indirect costs are allowed for profit organizations.

Letter of Intent (LOI) Review Procedures

All applicants must submit a Letter of Intent (LOI) through Proposal Central. Hard copies or email submissions will not be accepted. First-time users must register and complete a Professional Profile before submission. The LOI must be submitted by a single Principal Investigator (PI) and within the active grant cycle; late submissions will not be considered. The LOI ensures applicant eligibility and alignment with program priorities while aiding in the review process. Applicants must provide essential details, including PI and institution information, project title, area of focus, and a brief project description (up to 1,000 characters each, including spaces) covering methodology, aims, innovation, and anticipated impact. ORCID ID and a signed institutional W9 or W8 form are required, along with a biosketch for the PI. Budget details are not required at this stage.

All LOIs will be evaluated prior to invitation to submit a full application. Only LOIs that meet program specific guidelines as outlined in this request for applications will be invited to submit full applications**.**

Letter of Intent Deadline: **Letters of Intent (LOI) must be received by 5:00pm EST, August 6, 2025** Letters of Intent will not be accepted after this date. No exceptions will be made. If the on-line LOI is approved and invited to submit a full proposal, an email notification will be sent from Proposal Central granting access to the on-line application. The online system must be used to submit a grant application; hard copies of the application will not be accepted.

Each LOI is evaluated with attention to:

- Demonstrable innovation/novelty of the proposed project (especially in the context of the PIs recently funded work)
- Alignment with the research priorities of the PTC request for applications and the Alzheimer's Association
- Impact of project on Alzheimer's and all other dementia research
- Evidence of methodological rigor that address the research question(s) being proposed

Full Application Requirements

Once an LOI is approved, applicants will be invited to submit a full application through Proposal Central. Detailed instructions and templates will be available in the system. Submissions must be completed by the specified deadline, and late or incomplete applications will not be considered.

For those invited to submit, Full applications must be received by 5:00pm EST, September 24, 2025.

The full grant application consists of the following:

1. Problem Statement – 1 page
2. Work Plan – 5 pages; Efficacy should not be the primary outcome for studies at phase 1 and phase 2; however, it may be an exploratory outcome. All applications should have clear Go/No Go criteria to the next phase of clinical development of the therapy, which should be clearly outlined in the application. The application must demonstrate how data from the proposed study will inform future trials.
3. Available Resources & Budget Justification – 2 pages; If awarded, a full budget of planned expenses will be required.
4. Data Management and Sharing Plan – 3 pages; we recommend using the provided amended NIH template. When data sharing may be limited, applicants must explain such limitations at the time of application.
5. Recruitment Plan - 1 page; the Association expects all trials to match or exceed the diversity of their local population at a minimum. **Award must maintain representation of the community the study is being conducted.**
6. Milestones – 3 pages max
7. Reference and Citations – 1 page
8. Response to review comments – For resubmissions only – 1 page
9. Therapeutic Rationale – 1 page
10. Gannt Chart – 1 page (Optional)
11. Biosketch (PI/Co-PI/Key Personnel) – 5 pages max for each
12. Research Project Leadership Plan – 5 pages max

Applications will be reviewed with special attention to:

- Significance of the question being studied & rationale of the target being pursued
- Applicant information
- Quality of the proposed trial design
- Quality and adequacy of available resources and budget
- Impact-Risk

Scientific and technical review will be conducted in **October 2025 – November 2025**. The second level review by the Alzheimer's Association and subject matter experts in November and funding is anticipated to be awarded by **November 15, 2025**.

Deadlines and Award Dates:

Date	Activity
June 1	Letter of Intent Launch
August 6	LOI submission deadline
August 20	Full proposal invitations
September 24	Application submission Deadline
September/October/November	Application Review
November 15	Award Notification

The Letter of Intent and application must be submitted by 5:00 PM Eastern Time on the respective deadlines. Late submissions, hard copies, or email submissions will not be accepted

Reporting requirements: Awardees will be required to provide sixth month milestones and have bi-annual discussions with the Alzheimer's Association. Annual scientific progress and financial reports are required. Continuation of the grant over the awarded duration is contingent upon meeting the scientific milestones, and upon timely receipt of scientific and financial reports. Representation of study participants should be reflective of the communities that are being engaged for this study.

Budget: A budget summary for the proposed research project is required and must be submitted with the application and within the allowable page limits. However, if the application is to be awarded, a more detailed budget will be required and must be approved before the disbursement of funds. Your budget must not exceed the maximum amount of the award, $1,000,000 (inclusive of direct and indirect) over two or three years. Costs associated with the management and sharing of research data are allowable Costs related to participant remuneration should follow the recommendations proposed by the National Alzheimer's Coordinating Center (NACC) located here: https://files.alz.washington.edu/documentation/remuneration-guidelines.pdf

Costs not allowed under this award include:

- Computer hardware or software for investigators (e.g. Microsoft Office, mouse, monitor, computer parts)
- Laboratory equipment such as freezers, ultracentrifuges, RT-PCR, Microscopy/imaging equipment
- Service contract fees of equipment
- Construction or renovation costs
- Tuition
- Rent for laboratory/office spaces
- Expenses such as Data Network Recharges and Computing and communication devise support services
- General liability insurances, such as GAEL
- Wire and currency exchange fees
- Salary and/or compensation for Alzheimer's Association Staff or current members of the Alzheimer's Association Medical and Scientific Advisory Group (MSAG) and the International Research Grant Program (IRGP) Council. A complete list of MSAG and IRGP Council members can be found on our website alz.org/grants.

For more information: Contact grantsapp@alz.org

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Part the Cloud, benefiting the Alzheimer's Association.