2026 Alzheimer’s Association Part the Cloud - Enable the Molecule for Therapeutics (PTC-EMT) Funding Program

Program Overview
The Alzheimer's Association is pleased to announce a new funding initiative: "Part the Cloud - Enable the Molecule for Therapeutics Program" (PTC-EMT). The PTC-EMT program is designed to advance promising Alzheimer's and related disorders therapeutics through final stages of investigational new drug (IND) -enabling stages. This initiative supports high-potential therapeutic candidates, providing essential resources to expedite their translation into clinical application for Alzheimer's disease and related dementia.

Background
Alzheimer's disease (AD) represents one of the most pressing public health challenges worldwide, currently affecting more than 55 million individuals and expected to dramatically increase in prevalence in coming decades. Alzheimer's is characterized by progressive cognitive decline, synaptic dysfunction, neuronal loss, and accumulation of pathological protein aggregates, primarily amyloid-beta plaques and tau neurofibrillary tangles. Despite extensive research efforts, available treatments provide limited symptomatic relief without significantly altering disease progression.

Recent advances in understanding Alzheimer's pathology, genetics, and molecular pathways have paved the way for novel therapeutic approaches. Innovative small molecule therapeutics, biologics, and gene-editing strategies targeting fundamental disease mechanisms show promising disease-targeted therapies (DTT) or disease-modifying therapies (DMT) potential. However, the complex nature of Alzheimer's disease pathology and the rigorous regulatory requirements necessitate comprehensive preclinical evaluation to ensure efficacy, safety, and clinical relevance before entering clinical trials. The transition from preclinical discovery through lead optimization and IND-enabling studies often stalls due to resource limitations, technical challenges, and inadequate funding.

The Alzheimer’s Association Part the Cloud is a movement, founded in 2012 by philanthropist and leader Michaela “Mikey” Hoag, to accelerate therapeutic discovery and advancement. Mikey’s vision was to increase the “shots on goal”, moving research advances from the discovery phase into clinical trials, with potential to serve as therapies for those facing Alzheimer’s and other diseases by overcoming the transition of academic research discovery to clinical trial acceleration. The PTC-EMT program continues in this mission, identifying key funding gaps to move scientific discovery faster and closer to the clinic. This funding program aims to identify, overcome and fund the final stages of studies necessary to move exciting compounds through the IND-Enabling Stage of drug discovery. The IND-Enabling Stage includes comprehensive studies required to support an Investigational New Drug (IND) application, including pharmacology, toxicology, biodistribution, formulation, and manufacturing scale-up.

By strategically supporting critical stages of drug development, the Alzheimer's Association intends to expedite the transition of novel therapeutic candidates toward clinical trials, ultimately aiming to improve clinical outcomes for patients affected by Alzheimer's and related dementias.

Potential themes and Areas of Focus

The Part the Cloud–Enable the Molecule for Therapeutics (PTC-EMT) program is specifically designed to support therapeutic development for Alzheimer's disease and related dementias (ADRD) at the **IND-enabling stage** of drug development. This critical phase bridges advanced preclinical work with entry into first-in-human clinical trials.

Projects considered for this program must involve rigorously characterized therapeutic candidates that have demonstrated strong potential in disease-relevant models and are poised to initiate IND-enabling studies necessary for regulatory submission.

Entry Criteria:
Applicants must demonstrate that their therapeutic candidate meets the following prerequisites:

- A well-defined, optimized clinical candidate with demonstrated efficacy in validated in vivo models of Alzheimer's disease or related dementias, supported by a well-characterized pharmacokinetic/pharmacodynamic (PK/PD) relationship, including defined free brain concentrations that correlate with both in vivo efficacy and in vitro potency at the target site.
- Completed or near-complete in vitro pharmacology and preliminary toxicology data, including selectivity screens for potential off-target activity
- A finalized Target Product Profile (TPP), clearly outlining the proposed clinical therapeutic objective, target patient population, and intended route of administration, accompanied by a topline clinical development plan to guide progression toward clinical testing.
- A clear intellectual property (IP) strategy, including current patent status, freedom to operate, and any potential constraints.

- Optional: Established nonclinical formulation with supporting data on stability and manufacturability.

Supported Activities Include but are not limited to, and should preferably include the following as appropriate for the stage of development):

- IND-enabling Good Laboratory Practice (GLP) toxicology studies in both rodent and non-rodent species

- Pharmacokinetics (PK), pharmacodynamics (PD), and ADME (absorption, distribution, metabolism, and excretion) assessments across appropriate species, with the understanding that foundational PK, ADME, and PK/PD correlation in the species used for efficacy studies should already be established at entry

- Nonclinical studies evaluating safety, tolerability, and biodistribution

- Development of cGMP-compliant manufacturing processes and scale-up activities, as appropriate to the stage of development

- Formulation optimization and stability testing for human administration

- Preparation of regulatory documentation, including Investigator Brochures, IND dossiers, and support for FDA interactions (e.g., pre-IND meetings)

Therapeutic Mechanisms:

All therapeutic modalities will be considered, including but not limited to small molecules, PROTACs, antibodies, antisense oligonucleotides (ASOs), gene therapies, and other novel biologics. Applications may target a wide range of validated or emerging disease mechanisms relevant to Alzheimer's disease and related dementias, such as amyloid, tau, neuroinflammation, synaptic dysfunction, or other neurodegenerative pathways. Only approaches with the potential for disease modification will be considered; symptomatic treatments without disease-modifying potential are not within the scope of this RFA.

Applicants should clearly specify the entry point for their proposed project within the IND-enabling timeline and provide a well-justified rationale for how the proposed work will directly support clinical advancement. Funded projects must remain strictly within the IND-enabling stage; applications that include activities from earlier discovery phases or later clinical trials will not be considered.

General considerations and Eligibility

Eligibility for this program extends to investigators from both non-profit academic institutions and small for-profit companies, with special consideration given to small businesses employing fewer than 50 staff members. Applicants are required to clearly demonstrate their organizational status by providing relevant documentation. The project's Principal Investigator (PI) must hold a full-time, paid position at the applying institution or organization; if the PI does not hold a salaried position, clear evidence must be provided demonstrating their formal affiliation and active employment within the organization. Proposals submitted by postdoctoral researchers or individuals in non-permanent roles will not be considered. For additional eligibility clarifications or specific questions, please contact the Alzheimer's Association at grantsapp@alz.org.

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 up 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. Note, budgets will be evaluated for the type of study proposed to ensure it is right sized within the allowable budget to the needs of the project.

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.

LOIs will be evaluated by a small team of experts, selected by the Alzheimer's Association, to thoroughly evaluate proposed submissions.

Each LOI is evaluated with attention to:

- Strength of the overall proposed target, application and needs to further develop the target.
- Alignment with the research priorities of the PTC-EMT request for applications.
- Current evidence and support to move the target forward, including the need for the particular request.
- Evidence of methodological rigor that addresses the needs to advance this potential therapeutic.

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 application must include the following sections:

1. Executive Summary (1-page maximum)
    - Concisely describe the project's objectives, significance, proposed activities, and anticipated outcomes. Clearly indicate the stage of the project within the IND-enabling timeline.
2. Detailed Research Strategy
    - Provide a robust scientific justification for the chosen therapeutic approach, including in-depth background information linking the therapeutic target or mechanism to Alzheimer's disease or related dementia pathology.
    - Clearly outline project goals and specific aims, methods, experimental design, and expected outcomes.
    - Discuss potential pitfalls and present alternative strategies for overcoming these challenges.
3. Preliminary Data Demonstrating Therapeutic Potential
    - Provide compelling preliminary data validating the biological target, mechanism of action, and efficacy in relevant in vitro or in vivo models.
    - Include relevant figures, graphs, or images that support scientific rigor and feasibility.
4. Comprehensive Target Product Profile (TPP)
    - Provide a detailed TPP specifying clinical objectives, intended patient population, dosage forms, route of administration, therapeutic dosing regimen, safety profile, and efficacy benchmarks.
    - Clearly link the proposed activities and milestones to achieving the defined TPP goals.
5. Team Qualifications and Roles
    - Provide detailed information about the Principal Investigator(s), co-investigators, and collaborators.
    - Outline the experience, expertise, and previous success relevant to drug discovery and development, Alzheimer's research, regulatory processes, and commercialization.
    - Clearly define roles, responsibilities, and interactions among team members, consultants, and CROs (if applicable).
6. Detailed Milestone Plan and Timeline (e.g. Gantt Chart)
    - Clearly delineate project stages and milestones, specifying critical decision points and go/no-go criteria.
    - Milestones must be quantifiable and tied to specific, measurable outcomes.
    - Include anticipated timeframes for each milestone, clearly showing progression toward IND submission or next developmental phase.

7. Budget and Justification
    - Provide a detailed, itemized budget including personnel, supplies, contract research organization (CRO) costs, and other direct expenses.
    - Provide clear justification for all expenses, demonstrating that requested funds are appropriate for achieving the outlined milestones.
    - Indicate any additional sources of complementary funding that will enhance or supplement this project's goals.
8. Intellectual Property (IP) Status and Commercialization Plan
    - Clearly describe the current IP status related to the project, including patent filings, issued patents, or any existing IP constraints.
    - Outline a strategy for securing, protecting, and potentially licensing intellectual property.
    - Provide a commercialization strategy, including the potential pathway for future clinical trials, manufacturing, and collaboration with industry partners.
9. Data Management and Sharing Plan
    - Outline how data generated through this project will be managed, stored, and shared.
    - Specify repositories or platforms to be used, methods of data dissemination, and anticipated timelines.
    - Describe any limitations or constraints on data sharing, if applicable, and justify these clearly.

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 December and funding is anticipated to be awarded by **November 15, 2025**

Key Considerations for Proposal Development:

Applicants are encouraged to clearly address the following key aspects in their proposal to enhance clarity and facilitate comprehensive evaluation:

Therapeutic Target and Biological Mechanism
Clearly identify the biological target and/or pathway your therapeutic aims to modify. Explain briefly how this target or pathway is implicated in Alzheimer's disease or related dementias.

Innovative Aspects and Differentiation
Provide a clear description of the unique aspects of your proposed therapeutic approach. If similar treatments or therapies exist, specify how your candidate differs in terms of mechanism of action, potential efficacy, safety profile, or other distinguishing features.

Scientific Rationale and Supporting Evidence
Describe the scientific evidence including genetic, biochemical, pharmacological, or other relevant data supporting your hypothesis that modulating your chosen target or pathway will

positively impact disease progression. Include evidence from preclinical models and explain how your chosen animal models closely reflect human Alzheimer's pathology.

Biomarkers and Clinical Translation:
Describe any established biomarkers or clinical assessments that can reliably predict therapeutic efficacy or clinical outcomes. Indicate how these biomarkers have been or will be validated for use in your proposed preclinical or eventual clinical studies.

Intellectual Property (IP) Status:
Detail the intellectual property landscape of your therapeutic candidate or related technology, including issued patents, filed applications, or other relevant protections. If patents exist, provide relevant patent numbers or application references. Describe any IP constraints or barriers that might influence future commercialization or licensing.

Anticipated Safety and Risk Management:
Identify foreseeable safety concerns related to your therapeutic target, molecule, anticipated dose, or delivery method. Outline your plan to evaluate, mitigate, or manage potential risks, including immunogenicity, toxicity, or other liabilities.

Pathway to IND and Commercialization:
Outline the next key steps necessary to move your candidate towards IND submission and eventual commercialization. Clearly describe the challenges you anticipate in manufacturing, quality control, and regulatory approval, and how these will be addressed through specific next steps or strategies.

Evaluation Criteria:

Evaluation of proposals will focus on the following key areas:

1. **Scientific Rationale and Impact**
    - Clear articulation of the scientific hypothesis.
    - Compelling rationale connecting the proposed molecular target or therapeutic strategy to Alzheimer's disease or related dementias.
    - Evidence or justification indicating how success could substantially influence the field or clinical practice.
2. **IND-Specific Entry Criteria**
    - Clearly identified clinical candidate with comprehensive preliminary data, including efficacy, preliminary ADME and toxicity profiles, and readiness for regulatory interactions and IND submission.
3. **Innovation and Differentiation**
    - The approach should demonstrate substantial novelty or a meaningful improvement over existing therapies in development or marketed treatments for Alzheimer’s disease and related dementias.
    - The applicant must describe clearly what differentiates their therapeutic approach from existing therapies or competitors.
4. **Feasibility and Risk Management**

- Identification of potential risks in the proposed approach and a clear plan to address or mitigate these risks.
- Realistic timelines and deliverables, supported by clearly outlined milestones.

5. **Resource Availability and Institutional Support**
    - Adequate resources, including laboratory facilities, equipment, and experienced personnel, to complete the proposed studies within the stated timelines.
    - Clear identification of any collaborators, consultants, or CROs and a rationale for their involvement.
6. **Potential for Clinical Translation and Commercialization**
    - Demonstration of clinical relevance, translational feasibility, and market potential.
    - Preliminary IP position and strategy to secure intellectual property that supports commercial development and does not present barriers.

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 device 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.

Intellectual Property and Resource Sharing

Applicants must clearly outline their intellectual property status, noting any restrictions. Successful projects must agree to transparent data sharing with Alzheimer's Association-approved repositories, adhering to a comprehensive Data Management and Sharing Plan.

Contact Information: for inquiries and assistance: Email: grantsapp@alz.org

The Alzheimer's Association is committed to advancing therapies capable of altering the course of Alzheimer's and related dementias through innovative research support and strategic partnerships.

Made possible through the generous funding from Part the Cloud, benefiting the Alzheimer's Association.