2017 Part the Cloud Translational (PTC) Research for Alzheimer’s Disease Program

**Competition Objectives:** In its sixth iteration, the Alzheimer’s Association is pleased to announce the Part the Cloud Translational Research Funding initiative to increase the research efforts in Phase I and Phase II (Proof of Concept) clinical trials directed towards Alzheimer’s disease and related dementias internationally.

**Background:** There is no greater healthcare need than slowing or preventing Alzheimer’s disease. The vast increase in understanding of the neurobiology of AD in recent decades, from genetic factors to amyloid accumulation, tangle formation, cellular dysfunction and synaptic failure, has led to the identification of highly promising targets for new therapies. The process of developing candidate therapies is long and complex leading to the failure of many drug development programs. The steps from target identification to the clinic includes high-throughput screening, lead optimization, establishing target engagement in vitro and in vivo, assuring central nervous system penetration, animal toxicology and finally the three phases of human testing. The full process takes many years and substantial resources, and typically involves different groups of investigators at different stages.

While many academic investigators and companies have successfully discovered candidate therapeutics, and have succeeded in the preclinical stages of development, moving into human testing can be a major stumbling block. Most government and non-government grant mechanisms support preclinical development or mid to latter clinical trials testing drug efficacy in humans, but there are few mechanisms for supporting the critical earlier human phase studies. At present, the National Institute on Aging supports many phases of preclinical AD drug development, including basic research on target identification, animal model testing of candidate therapeutics, preclinical toxicology and proof-of-concept studies in humans. These latter human studies must be preceded by smaller, early phase studies but there are few appropriate funding mechanisms to fund the next step, Phase I trials in humans. Since its inception, Part the Cloud has enabled over $17 million in funding to more than twenty-one studies that advance diverse clinical targets into early human phase studies.

**Potential themes:** This new grant mechanism aims to fill the gap in Alzheimer’s disease drug development by providing support for early phase studies of potential Alzheimer’s therapeutics or validation of biological markers of disease progression.

**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 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 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
preclinical or symptomatic Alzheimer’s disease (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 disorder and be translational in nature. All proposals should clearly and explicitly outline the measure to be investigated, the methods for study, and outcomes. Researchers from underrepresented groups are encouraged to apply.

**Eligibility:** Both non-profit and small for-profit agencies are eligible. [Open to International Applicants](#). Small for-profit agencies 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.

**Funding and award period:** Each Part the Cloud Research grant is limited to a total of $400,000 (direct and indirect costs) for up to three years, minimum two years. However, in instances where a project may have a budget exceeding this value, please contact the Alzheimer’s Association at grantsapp@alz.org for possible special programmatic or budgetary considerations. Requests in any given year may not exceed $300,000 (direct and indirect costs). Indirect costs are capped at 10 percent (rent for laboratory/office space is expected to be covered by indirect costs paid to the institution).

**Letter of Intent (LOI) Review Procedures:**
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.

**Deadlines and award dates:** Letters of Intent (LOI) must be received by 5:00 PM EASTERN STANDARD TIME, April 12, 2017. Letters of Intent will not be accepted after this date. No exceptions will be made. All LOIs must be submitted online through Proposal Central at [http://proposalcentral.altum.com](http://proposalcentral.altum.com). No hardcopies or emails will be accepted.

Once 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.
For those invited to submit full applications, these must be received by 5:00 PM EASTERN STANDARD TIME, May 22, 2017.

The full grant application consists of the following:
1. Problem Statement – 1 page
2. Work Plan – 5 pages
3. Available Resources & Budget Justification – 2 pages
4. Biosketch (PI/Co-PI) – 4 pages each

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 from June – July 2017. The second-level review by the Alzheimer’s Association Medical & Scientific Advisory Board and subject-matter experts in August and funding is anticipated to be awarded by August 30, 2017.

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.

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 ($400,000) unless you have received special consideration by the Alzheimer’s Association. To be considered for a budget increase, please contact the Alzheimer’s Association at: grantsapp@alz.org.

Costs not allowed under this award include:
• Tuition
• Computer hardware or software for investigators
• Rent for laboratory/office spaces
• Construction or renovation costs

For more information: Contact grantsapp@alz.org

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