San Diego Dementia Drug Discovery Collaborative Program: “Collaboration 4 Cure (C4C)”

**Competition Objectives:** The Alzheimer’s Association, in partnership with the Salk Institute (Salk), Sanford-Burnham Medical Research Institute (Sanford|Burnham), the Scripps Research Institute (Scripps), University of California, San Diego (UCSD), and the J. Craig Venter Institute (Venter), are launching the San Diego Dementia Drug Discovery Program – Collaboration 4 Cure (C4C), an innovative program to harvest the best research ideas toward effective therapy of Alzheimer’s disease and partner such projects with the translational drug discovery infrastructure at Sanford|Burnham and Scripps. The C4C program will provide services to investigators in the form of early drug discovery capabilities and is not a direct funding mechanism for individual investigator laboratories.

**Background:** The San Diego County Board of Supervisors, with the support of the mayor of the City of San Diego, the Alzheimer’s Association, and a local philanthropist, initiated the creation of a flagship funding program to support a 5-year mission to catalyze drug discovery toward cures for Alzheimer’s disease by funding San Diego projects through local support. The C4C program represents implementation of the “Cures” component of the three Alzheimer’s Project roundtables ( Cure, Care and Clinical). San Diego has a uniquely dynamic, entrepreneurial and creative science and technology heritage, with a track record of achievement in the creation, commercialization and sustainment of disruptive technologies emanating from its medical science-based companies and leading research institutes and universities. C4C is an innovative collaborative partnership amongst the Alzheimer’s Association and five institutions, the Salk, Sanford|Burnham, Scripps, UCSD, and the Venter, to provide access to world-class translational drug discovery infrastructure and expertise for collaborative, open-source, pre-competitive, early-stage research towards identifying and validating starting points for the development of new therapeutic small molecule agents that can progress to the clinical treatment for Alzheimer’s disease and related dementias.

**General Considerations:** In the first year, projects of interest will be those that will benefit from the development and optimization of high-throughput screening (HTS) assay(s), assay automation, and synthetic chemistry capabilities. Successful awardees will be provided access to the assay development & HTS teams at the Sanford|Burnham’s or Scripps’ technology cores to enable the development of screens through access to their drug discovery infrastructure. These efforts will culminate in a preliminary HTS data package, to include a pilot screen that demonstrates robustness and operating characteristics of the developed assay, and articulation of a cascade of follow-up assays needed to identify a valid “hit” compound. Projects that successfully achieve a robust “preliminary HTS data” package may be considered in subsequent years of this program for advancement through hit confirmation and validation to the screening of large chemical libraries of compounds. In parallel, it is anticipated that successful projects with robust HTS data packages may be used for joint applications to additional/alternate sources of funding, (e.g. for HTS screening of large chemical
collections or the 370,000 MLSMR compounds through NIH PAR-14-284 or additional grants from other agencies and foundations).

**Important Deadlines:** Letters of Intent (LOI) must be received by 5:00 PM Eastern Standard Time on April 16, 2015. LOIs will not be accepted after this date. No exceptions will be made. Letters of intent (LOI) are submitted through an on-line portal via proposalCENTRAL, [http://proposalcentral.altum.com](http://proposalcentral.altum.com). LOI and applicant instructions are also available via this on-line portal.

For those invited from their LOIs to submit a full proposal, these applications must be received by 5:00 PM Eastern Standard Time on June 1, 2015. Scientific and technical review will be conducted June 2015. The C4C program will make final announcements of selected recipients no later than June 30, 2015.

**A summary of important deadlines for this program are:**

- **March 19, 2015**  
  Website launch and Letter of Intent (LOI) Opens
- **April 16, 2015**  
  LOI deadline
- **May 1, 2015**  
  Full applications invited
- **June 1, 2015**  
  Full applications due
- **June 30, 2015**  
  Anticipated award notifications

**Eligibility:** Both non-profit and small for-profit agencies are eligible. The C4C program is open to any principal investigator holding a faculty appointment at any accredited, greater San Diego area-based University, academic institution, hospital, medical practice or not-for-profit medical or life sciences research institution, inclusive of stakeholder institutes: Salk, Sanford|Burnham, Scripps, UCSD, and the Venter Institutes (Venter). All applicants will be required to obtain institutional endorsement of their research application from their respective home institutions. In addition, small biotech/small-medium enterprise organizations are eligible to apply. Small for-profit agencies must submit documentation of net assets and annual earnings for consideration during the letter of intent process.

**IMPORTANT:** Consultation with either the Sanford|Burnham or Scripps Drug Discovery centers is encouraged in developing the LOI.

**Application Procedures:** Both letters of intent (LOI) and invited applications are submitted through an on-line portal via proposalCENTRAL. The first step in applying to the Alzheimer's Association for any research grant is to submit a Letter of Intent (LOI) through the proposalCENTRAL on-line application system at [http://proposalcentral.altum.com](http://proposalcentral.altum.com). Applications will not be accepted without an approved LOI. First-time users must register and fill out a Professional Profile in proposalCENTRAL to begin the application process.

The LOI will consist of a two (2) page LOI that should address the following:

- **Background/Rationale** – why is the target important, indication, genetics, proof of concept and citations
- Preliminary Data – target modulation-phenotype & assays (use/cite figures from key publication(s))
- Experimental plans (approach, assay concept, format and cascade of hit progression assays)
- Readiness of home grown reagents and assay (necessary reagents created, qualified and available)

In addition, the applicant may include up to two (2) reference documents (in PDF format) to support their LOI. Each reference document may only include one paper, abstract or other documentation. Multiple references combined into one (1) PDF will not be accepted. LOIs will be evaluated and select investigators will be invited to submit full applications. Additional information regarding review evaluation for LOIs and applications is included in “Review Process” section below.

For those LOI applicants invited to submit full project proposals, the application materials, including the application format, templates, and instructions, will be available online at proposalCENTRAL.

**Review Process:** Letters of Intent (LOI) will be reviewed by a Joint Review & Operations Committee (JROC) comprising representatives from the Alzheimer’s Association, the Alzheimer’s Medical and Scientific Advisory Council and the five San Diego Drug Discovery Consortium stakeholder institutions. The project will be reviewed based on:

- Plausibility of the project based on known biology of proposed target and therapeutic agent for Alzheimer’s disease or related dementias.
- Status of intellectual property, “competition”, freedom-to-operate or prior art of a process or reagent.
- Appropriateness of target for chemical modulation (“druggability”) and pre- or clinical proof-of-concept (POC) studies.
- Technical feasibility of the project proposed, including the readiness of investigator-created reagents and current benchtop assays for screening.

**Available Funding:** The primary purpose of the C4C program is to provide access to early drug discovery capabilities rather than direct transfer of funds to individual investigator laboratories. Award will provide services to investigators in the form of early drug discovery capabilities and is not a direct funding mechanism for individual investigator laboratories. Successful applicants will partner with, and obtain access to resources and services of the Sanford Burnham or Scripps drug discovery centers including assay automation, HTS, and synthetic chemistry capabilities, which can be applied to the discovery and development of innovative first-in-class compounds that have the potential to be developed into therapeutics. The funds will be administered by the Alzheimer’s Association and directed to these partnered centers.

In certain cases, with approval of the Joint Steering Committee limited funds may be made available to a PI laboratory to enable, for example, scale-up production of unique
critical reagents or key assays or services that only the PI’s laboratory can perform. Indirect costs are limited to 10%. Please note that the C4C program is a unique funding opportunity that provides access to resources or specific supplemental funding to achieve drug discovery and translational critical path items and is NOT meant to replace or augment an operating grant directed towards basic research or to recruit new research personnel, launch major new research directions, fund general operating support for the lab or purchase equipment with applications beyond the project.

**Mechanism of award, reporting requirements and allowable costs:** The mechanism of the award is to provide access to early drug discovery capabilities rather than direct transfer of funds to individual investigator laboratories. It is expected that successful applicants will confer monthly or as needed with the project team and JROC. Quarterly milestones will be evaluated for each awardee by the Joint Steering Committee and project continuation will be linked to the attainment of milestones. In addition, financial reports of expenditures will be required before additional funds are released. Continuation of the funding of the project’s duration is contingent upon the timely receipt of scientific progress and financial reports.

**Budget and Duration:** For this first year, the C4C program anticipates funding multiple awards with service equivalent budgets of $35,000 - $65,000 for each project, depending on assay complexity. Duration of awards is one (1) year and contingent upon attainment of specific milestones. In future years, it is envisioned that projects that successfully achieve a robust preliminary HTS data package may be advanced for funding of full-scale HTS, hit confirmation, validation and expansion in the subsequent year (year 2), through an expedited, competitive review.

**Confidentiality:** Consistent with the Alzheimer’s Association policies, members of all committees will not share the information provided by applicants through the registration and application process except with directors, officers and/or representatives of stakeholder institutions, as deemed necessary. Nonetheless, applicants should not provide confidential information, such as chemical structures, at the LOI stage.

**Materials and Data Sharing:** Awarded applicants will be required to provide necessary, unique reagents that are not commercially available and necessary for their proposal, such as cells expressing recombinant enzymes/proteins, primary and secondary antibodies, tagged peptide substrates, and available positive controls (e.g., a known inhibitor of the target).

**Intellectual Property:** All pre-existing intellectual property will remain the exclusive property of the party that created it prior to or independent of the funded research. During the term of the funding period, new inventions will be subject to the Alzheimer’s Association’s Patent Policy existing with or to be signed with the grantee institutions at time of award.

For more information about any of the grant schemes or the application process, please contact the Alzheimer’s Association at grantsapp@alz.org or (312) 335-5862.