



Quest for CURES

The Leukemia & Lymphoma Society (LLS) is proud to announce The Quest for CURES (QFC), a new series of Request for Proposals (RFPs) to identify and develop safer, more effective treatment paradigms for patients with hematological malignancies. LLS has formed a partnership with Celgene to create the first set of such RFPs that will build the foundation of this new LLS initiative. This initiative will identify and fund priority research areas, with support from biotechnology and pharmaceutical partners in order to address significant unmet medical needs. The near-term goal of this program is to advance the scientific and medical understanding of the various hematological malignancies.

The Leukemia & Lymphoma Society (LLS) is the world's largest voluntary health agency dedicated to blood cancer. The LLS mission: Cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families. LLS funds lifesaving blood cancer research around the world and provides free information and support services to patients and their families.

Celgene is a global biopharmaceutical company committed to improving the lives of patients worldwide by delivering innovative and life-changing drugs for our patients. With more than 300 clinical trials, Celgene has focused on delivering novel therapies for patients with incurable hematological malignancies, including multiple myeloma, myelodysplastic syndromes, chronic lymphocytic leukemia (CLL), non-Hodgkin's lymphoma (NHL), and myelofibrosis.

Description of the Awards:

With evolving technologies and emerging treatment options, this RFP is focused on defining subgroups of patients with a given diagnosis, understanding the role and improving detection of minimal residual disease (MRD) in hematological malignancies and using this information to guide treatment intervention. In addition, understanding which patients are more likely to transition from a pre-malignant state to full malignancy may provide new routes for early therapeutic intervention. **LLS and Celgene RFP topics available for funding with this RFP are the following:**

- 1. Defining treatment algorithms that rely on predictive/prognostic biomarkers and molecular MRD surrogates to select standard or experimental therapies for patients with indolent lymphoid malignancies, particularly follicular NHL or early phase CLL, as well as patients with pre-malignant conditions such as MGUS, low risk MDS or MPNs (PV or ET). Research proposals might focus on, but are not limited to:**
 - a. Identification of biomarkers in both treatment naïve patients, as well as those treated with standard or novel agents, to predict clinical benefit of either a watch and wait strategy or initiation of a therapeutic intervention
 - b. Identification of biomarkers that will guide specific therapeutic intervention with an

- approved or experimental agent(s) or identify a novel therapeutic target
- c. Analysis of samples from patients treated with standard or novel agents to identify treatment-related molecular changes that may predict long-term clinical benefit
 - d. Novel approaches to measure and track MRD that provide actionable information regarding the selection of subsequent therapy, if required
 - e. New experimental targeted therapies that may be safe and effective in blood cancer patients with early-stage disease
- 2. Characterizing hematopoietic events in the elderly that may predispose them to chronic pre-leukemic myeloid disorders and/or to progression from these states to frank hematologic malignancy. Proposal topics of interest might include, but are not limited to:**
- a. Studies to determine how age-related changes in hematopoietic progenitor subsets interact with changes in the bone marrow or lymph node microenvironment and in the circulating levels of the cytokines that are commonly/frequently observed in older individuals
 - b. Identification of the spectrum of mutations, chromatin modifications and/or changes in immune function in elderly patients that identify those at high risk of transitioning from chronic pre-leukemic disorders to acute leukemias

This RFP represents a new LLS research grant paradigm; QFC projects should, if successful, have a measurable impact on the diagnosis or treatment of patients with hematologic malignancies over the next 5 to 10 years. Proposals must include specific timelines, milestones and deliverables that researchers believe are achievable with their proposed funding. The range of funding available is from \$200,000 to \$400,000 annually, for research to be completed in a period of 2 years.

Additional funding for projects that have demonstrated exceptional progress in the initial 2 years may be available, subject to review by LLS and Celgene. Additional funding is not guaranteed for any of the projects, but is contingent on the achievement of the project goals. The LLS Research Department staff will work with researchers to monitor progress and provide insight and expertise to each project.

Both Celgene and LLS are committed to supporting early stage, foundational research as well as new therapy development. Researchers and institutions should note that Celgene considers each funded project as having the potential for further development as a therapeutic or diagnostic for patients.

Special Considerations for Grantees and Their Institutions:

In addition to LLS's standard terms and conditions for academic grant awards, QFC also includes the following requirements. In partnership with Celgene and their funding, academic

institutions and researchers will have to agree to provide Celgene with first rights to negotiate for intellectual property deriving from or reduced to practice during each project. Should Celgene choose to negotiate for rights to IP, Celgene shall have an exclusive period for this negotiation. If an agreement is not reached the Institution and researcher may not enter into an agreement with terms any less favorable than what was last offered by Celgene for a certain period of time. Please inquire with LLS for disclosure of those time periods. Also, if after said period of time, the Institution has not entered into another agreement, Celgene shall have the right to elect to enter into another exclusive dealing period. During the period of the grant and the periods when Celgene exercises its rights the institution is prevented from disclosing intellectual property rights outside normal activity or enter into negotiations with a third party. These specified periods for negotiation will be spelled out in the contract and available for review during the application process. **Each applicant to the QFC is required to have his or her institution certify agreement with the IP terms and Celgene Rights at the time of application submission.** For questions regarding this policy, please contact Allison Formal VP, Research Business Development at allison.formal@lls.org or at 914-282-2753.

Timeline:

Call for Proposals	February 2014
Letter of Intent Deadline	June 3, 2014, 3:00 PM ET
Full Application Deadline	July 15, 2014, 3:00 PM ET
Scientific Peer Review Committee	September 2014
Notification of Awards	October 2014
Anticipated Funding Start Date	January 2015

For additional questions regarding LLS grant programs, eligibility and application processes, Please contact Nikay Thomas, Director of Research Administration at Nikay.Thomas@lls.org or 914-821-8301.