GATEWAY GRANT APPLICATION REQUEST

Gateway for Cancer Research℠ is a nonprofit 501(c)(3) organization committed to funding innovative cancer research. Thanks to generous underwriting, 99 cents of every dollar Gateway receives directly funds Phase I and Phase II treatment-based investigator initiated clinical trials treating cancer. Since 1991, Gateway has supported more than 180 clinical trials and funded over $90 million in breakthrough cancer research.

PURPOSE

The oncology community must continue to urgently respond to the significant disruption of clinical trials caused by the COVID-19 pandemic. To that end, Gateway for Cancer Research is committing funding resources to advance solutions that better ensure continuity of patient access to investigational studies during this public health crisis or any future exogenous events that threaten the execution of clinical trials.

The impact of this pandemic on clinical studies and the patients who depend on them have dramatically underscored the vulnerabilities of a clinical trial model that centralizes the delivery of investigational protocols and requires patients to “go to the trial.” The pandemic’s deleterious effect on the field’s ability to conduct trials makes it clear that the status quo is no longer an option. Instead, Gateway is actively seeking innovative ideas that put those facing cancer at the center of clinical trial design and will fund studies that leverage technology-informed virtual or decentralized strategies that “bring the trial to the patient.”

The following criteria will inform the development of proposals for submission. Note that these guidelines are not intended to be overly prescriptive; we seek to inspire a broad range of innovative ideas that push the bounds of clinical studies that make investigational therapies available to patients in decentralized settings.

Successful proposals will:

- Advance a treatment-based clinical trial in oncology
- Emphasize the delivery of the investigational treatment in a decentralized setting, ideally home-based
- Define compelling primary and secondary endpoints
- Creatively leverage one or more innovative technologies (telemmedicine, wearables, remote monitoring, medical record review, e-consent, etc.)
- Have been reviewed with your CTO Administrative Director for regulatory, data management, and safety considerations related to implementation
- Integrate mobile clinician management as needed
• Incorporate rigorous and methodical collection, management, and analysis of trial-related data
• Utilize clinical resources in proximity and convenient to patients for any trial-related procedures that cannot practicably be carried out in a decentralized setting (e.g. imaging, interventional radiology, complex infusion, etc.)
• Leverage strategic inter- and/or intra-institutional collaboration, including commercial (e.g. biopharmaceutical, CRO, home health companies, etc.)

FUNDING AVAILABLE

Gateway will provide grants in the range of $400,000 to $600,000 in funding for direct costs of the research. The grant application may be submitted at any time, please contact Research@GatewayCR.org to receive instructions on how to access our grant management system.

Once awarded, in order to facilitate start-up, Gateway provides 20% of the Grant as seed money at the beginning of the trial. Gateway then uses a “pay-per-patient” method for grant payments based upon patient enrollment in the study and semi-annual reporting. A final payment of $20,000 is held until the final report is submitted to Gateway.

KEY DATES

Online Applications Open: Currently Open
Full Applications Due: Friday, June 22
Notification of Award: Thursday, July 30
Grant Term: Three Years

ELIGIBILITY

Applications may be submitted by entities that engage in cancer research including:

• Higher Education Institutions
• University Medical Centers
• Nonprofits Other Than Institutions of Higher Education
• Government Organizations (may include medical centers and hospitals that have access to resources and infrastructure to support a research project)
• Foreign Institutions are eligible to apply

The sponsoring organization must have a track record in scientific leadership, collaboration, and demonstrate depth and breadth in its research. The organization must assure support for the proposed research project. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and resources that can contribute to the planning process and implementation of the project. The sponsoring organization must assure to provide protected time to the Principal Investigator.
Principal Investigators (PIs)

- Must have a doctoral degree (including MD, PhD, MD/PhD, DO, DC, ND, DDS, DVM, ScD, DNS, PharmD, or equivalent doctoral degree) in the biomedical sciences.
- Must be a full-time employee of the sponsoring institution.
- Has individual experience serving as PI, Co-PI or collaborator on human research protocols.
- Has demonstrated ability to carry out the responsibilities of PI, including administrative management of protocols.
- Physicians must have a valid, active medical license in the country where the research will be conducted at the time of application and during the entire period of the grant.
- Be able to commit sufficient time and effort to assure successful progress of the clinical trial (applies to total research, not just the proposed project) during the award period.
- Only one application per Lead PI will be accepted for this Gateway Grant, although individuals may serve as a co-PI or contribute to more than one application.
- Postdoctoral or clinical research fellows or the equivalent who are working under the auspices of a scientific mentor are not eligible to apply.
- There are no citizenship or geographic requirements. However, by submitting an application, an applicant applying from an institution located in a country in which he/she is not a citizen or a permanent resident assures that the visa status will provide sufficient time to complete the project and grant term at the institution from which he/she applied.

Members of the Project Team

- Gateway funded trials must involve patient advocates: Investigators are required to consult with patient representatives and advocates to gather and incorporate their input into the trial design.
- The Team should include a statistician.
- Other collaborators and partners are encouraged, especially those that have expertise in telehealth.

Peer Review of Applications

Applications are peer-reviewed by Gateway’s Research and Grant Committee which is comprised of senior researchers, a statistician and patient advocates.

The Committee will consider the following criteria when reviewing applications and determining funding decisions:

- Strength of the hypothesis-driven proposal with a focus on telemedicine-informed
  - Significance and originality of the proposed study and hypothesis
  - Appropriateness, feasibility, and adequacy of the proposed experiment and methodology
  - Appropriate and detailed statistical analysis plan
- Access to patient population sufficient to demonstrate high potential for virtual enrollment success
- Meaningful virtual involvement of patient representatives and advocates
- Qualifications, experience, and productivity of the Principal Investigators including experience in telehealth
- Ability to conduct the clinical trial in compliance with all applicable regulatory requirements including e-Consent and letter of support from your CTO Administrative Director
• Availability of institutional resources to support the proposed project

**Award Process**
The Gateway Research and Grants Committee will make recommendations to the Gateway Board of Directors (BOD) for the final approval of the Grant. If selected for a grant, the successful applicant will be notified by Gateway. The official award announcement will be made by Gateway by Thursday, July 30.