Clinical Cancer Research with Patients as Partners New Grants Program: Kenya & Uganda Request for Proposals

Planning Grants - USD\$20k followed by

Research Implementation Grants – up to USD\$250k (over 2-3 years)

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Executive Summary:

<u>The Rising Tide Foundation for Clinical Cancer Research</u> is pleased to announce a two-stage grants program providing support to researchers and affiliated institutions in Kenya and Uganda. This program aims to propel clinical cancer research forward in partnership with patients, with the ultimate goal of improving patient outcomes within Kenya and Uganda in the near term.

Only applicants from within Kenya or Uganda may apply; however, applicants may include consultation and/or support roles from anywhere around the globe.

Stage I grants will be issued at fixed-amount of USD\$20,000 to support a 10-month period of performance focused on conducting a needs assessment and planning for implementation of clinical cancer research with patients as partners.

Grantees who successfully complete Stage I grants with quality will be invited to compete for Stage II grants of up to USD\$250,000 distributed over a two to three-year period to implement patient-centered clinical cancer research building on Stage I efforts. All awards will be selected through a peer-review process involving both patients and researchers from the respective countries.

Timeline & Quick Facts:

Stage I: Needs Assessment and Planning Grants

October 1, 2023: Request for Proposals (RFP) Issued

December 1, 2023: Applications due

January 19, 2024 Grantees Selected and Awards Issued

December 1, 2024: Final Reports Due

Award Type: Fixed amount, \$20,000, deliverable-based.

Stage II: Implementation Grants for Clinical Cancer Research with Patients as Partners

January 17, 2025: Stage I grantees invited to apply based on Stage I outcomes

March 2, 2025: Full Research Applications due May 2025: Grantees Selected and Awards Issued

Quarterly from Date of Award: Technical & Financial Reporting

Period of Performance: 24 to 36 months

Award Type: Incremental funding tied to milestones, up to \$250,000.

Background and Rationale:

To date, there has been a significant lack of international grants programs offering substantial support for cancer research in sub-Saharan Africa, particularly where African researchers and institutions take the leading role in the research process.ⁱ

As a whole, sub-Saharan Africa not only faces some of the greatest levels of poverty, but also some of the highest cancer-related mortality rates in the world. In fact, of the 25 countries with the highest cancer mortality rates for persons 54 & under, twenty-one are found in sub-Saharan Africa.

While meaningful support for cancer research in Africa has been lacking, donor nations and prominent foundations have made significant and unparalleled investments in combatting infectious diseases, particularly HIV over the past two decades. These investments have boosted capacity in healthcare personnel, medical records, healthcare systems, medical laboratories, medical research and supply chain management. They have revolutionized HIV prevention and care and changed the trajectory of the pandemic across Africa. Though these investments have at time pulled

In the face of the power imbalance, there is a need to empower patients, caretakers, SSA scientists and institutions to become leaders in research and to actively participate in and lead the framing and prioritizing of the research agenda in SSA; there is an opportunity to address some historical injustices; meaningful and sustained linkages between researchers, clinicians, institutions, and policy makers must be developed.

Cancer in sub-Saharan Africa: a Lancet Oncology Commission. Lancet Oncol. 2022. (Jun;23(6):e251-e312) attention and resources away from non-communicable diseases, they have also resulted in expanded capacity that can be leveraged to address cancer.

In many high-income countries, cancer research focuses on the latest cutting-edge advancements like cellular therapies while in sub-Saharan Africa, many patients are diagnosed at advanced stages with limited access to even basic treatment and care. There is an urgent need to enhance cancer detection, early interventions, palliative care and accessible/affordable approaches to treatment and care.

This grants program, focused on Uganda and Kenya, will serve as a pilot initiative to advance clinical cancer research for rapid impact on patient outcomes in sub-Saharan Africa; and to enhance capacity in order to empower applicants from these countries to effectively compete as leading investigators for global research opportunities in the future. Once success with this pilot initiative can be demonstrated in Kenya and Uganda, RTFCCR will draw on lessons learned to expand this program in subsequent years to additional sub-Saharan African countries.

Supported Research Approaches, and Permissible Technical Foci:

Areas of cancer intervention that will be supported under this program include early detection and diagnosis, treatment, delivery of care, and palliative care.

Applications focused on breast, colorectal, esophageal, or hematological cancers are strongly encouraged. Applications focused on cancers largely supported under global infectious disease investments (such as cervical or Kaposi Sarcoma) should NOT be submitted.

RTFCCR is particularly interested in research that can lead to better patient outcomes in the near-term, including quality of life; with an emphasis on outcomes identified in partnership with patients.

Implementation research, as well as clinical trials, both bio-medical and behavioral, will be supported under this RFP. Proposals for basic and/or translational research are NOT invited and will NOT be reviewed.

RTFCCR has a particular interest in drug-repurposing, therapy de-escalation, and palliative care, as well as application of technology to expand capacity in-country for detection and/or treatment. Regardless of the specific focus or approach, applicants must include Patients as Partners in their efforts to be eligible for funding under this RFP.

Patient as Partners – Required Component:

RTFCCR defines Patient Engagement as meaningful engagement of patients in the development of therapeutic, detection or prevention approaches. It encompasses the active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process,

where research decision making is guided by patients' contributions as partners, recognizing their specific experiences, values, and expertise.

It is important for purposes of this RFP that applicants understand and distinguish between Patient as Partners and Research Participants or Subjects. Partners are members of the research team and involved in the planning, conducting and dissemination of the research, whereas trial participants are those individuals actually enrolled into the study.

Applicants for this RFP will be required to submit a preliminary "Patient Engagement Plan" for Stage I and a much more detailed plan with defined roles throughout the grant period for Patient Engagement in Stage II applications.

Grants Program Structure: Two Stages

This is a two-staged grants program, in which only applicants who have successfully completed Stage I (Needs Assessment and Planning Grants) with quality will be invited to apply for Stage II (Research Implementation Grants).

Stage I of the grants program will provide successful applicants with a USD\$20,000 planning grant to be used over a 10-month period of performance to inform and plan out the research approach. In Stage I, Institutional Review Board (IRB) approval is not anticipated, but an IRB waiver might be required. Stage I applicants should include, but are not limited to, the following efforts in their applications:

- Identifying patients, patient advocates and/or patient organizations that have a vested interest in the research question, and developing plans and agreements for their engagement throughout the entire research process.
- Defining, with the patient population, the research questions(s) to be asked, interventions tested, and/or meaningful scientific aims sought to improve patient outcomes, including quality of life.
- Identifying and engaging appropriate multi-sectoral stakeholders (i.e. policy makers, health care administrators, community leaders, etc.) to ensure the research question being advanced aligns with local contexts and can truly impact cancer care in the near term.
- Assessment of importance and/or impact of research question upon clinical cancer care first within host country, but secondarily for potential replication within other sub-Saharan African countries.
- Identifying, as needed, external partners that may assist in the research approach through provision of technical assistance and/or capacity building from throughout the global cancer research field.

Stage II grants, building off results of Stage I, will provide successful applicants with up to \$250,000 to implement clinical cancer research in partnership with patients over a two to three-year period. Eligible Applicants:

Applications require both a named Principal Investigator and sponsoring research or medical institution.

Principal Investigators must meet the following requirements:

- Has completed an advanced degree related to cancer care and/or research;
- Is a citizen of Kenya or Uganda, currently living in either country and formally connected to a Uganda and/or Kenyan-based organization; and
- Has worked as a funded co-investigator (or played a significant funded role) on an IRB-approved research project in the past;

Research of medical institutions must be registered and governed within either Kenya or Uganda and meet the following requirements:

- The organization has implemented IRB-approved research in the past with a portion of the research funding provided by a multi-national donor/funder/government body; and
- The organization has access to the patient (or at risk) population and can document that in their application.

For all applicants – the following non-discrimination policy will be required. If applicants know they will be unable to sign such policy, they should not apply for this grant opportunity:

"The inclusion of patient and patient advocates in funded research shall not be limited based on any of the following: race, colour, sex, language, religion, political or other opinion, nationality, ethnic or social origin, disability, pregnancy, mental status or HIV status, sexual identity or gender identity."

Application Format and Submission:

All materials must be submitted in English; in either word or excel. Please ensure 1-inch margins on all documents, clear page numbering, use of font no smaller than 11-point and single spacing.

Application must include a completed Cover-Page & Submission Checklist (template provided here); as well as all of the following:

- **Grant Abstract** Not to exceed 1 page.
- **Grant Narrative** Not to exceed 5 pages. Grant Narrative should utilize the following headings/sections at a minimum (though may add others):
 - Research Team Information on Principal Investigator(s), any co-investigator(s) and other key
 personnel. Please include name, title(s), affiliation(s) and educational background along with
 information on relevant research and/or clinical work history.
 - Organization/Institution Organization or research entity responsible for receipt of funds, administering the research project (including payment of Principal Investigator(s)), and financial and compliance reporting. Please provide no more than one page of background on the

organization including relevant history, number of employees, experience and linkage to the relevant patient (or at-risk) population, and experience administering IRB-approved research, with particular focus on that funded by external donors.

- Research Focus / Project Description Proposed focus as it relates to patient population, intervention (diagnosis, treatment, access, palliative care, etc....), type of research (i.e. clinical (bio or behavioral), implementation), and cancer being addressed (i.e. breast, colorectal, esophageal, etc....). Information on potential impact of research within local communities and potential for future replication.
- Patient Engagement Plan- Has documented clear and measurable plans for patient engagement throughout grant performance period which may include any or all of the following methods: focus groups, surveys, consultation, advisory bodies and more. Has identified specific patient group, patient advisors or advisory councils ready to engage on grant activities and includes at least two letters of support in that regard.
- Budget Please use budget template bundled with this RFP. Note budgeting should be done in local schillings and not exceed the equivalent of USD\$20,000 at prevailing exchange rate at time of submission. Indirect rates for applicants is capped at 5%. In addition to completed excel template, include a word or pdf document providing details/justification on what has been included in travel, supplies and subcontracts.

- Required Appendices:

- At least two letters from patient organizations, patient body, or individual patient consultant/advocate.
- Key Personnel Template & bio sketch for Principal Investigator and any Key Personnel essential for program success
- Most recent Audit and/or Annual Report with financials included

To be eligible for consideration, complete applications are to be submitted to rtfccrteam@risingtide.ch no later than 24:00 East Africa Time on Friday Dec. 1, 2024

Evaluation Criteria for Stage I Planning & Needs Assessment Grants:

Complete grant applications meeting eligibility requirements will be reviewed through a peer-review process including both patients and researchers from within Kenya and Uganda. Grants will be reviewed based on the following criteria:

• 20% - Principal Investigator — Capacity, relevant experience and qualifications as it relates to the proposed research.

- 20% Research of Medical Institution Capacity, relevant experience, infrastructure relevant to clinical cancer research and past experience administering IRB-approved research supported through external funding sources.
- 20% Patient Engagement Plan Provides a clear and detailed plan that will result in meaningful engagement of patients and patient advocates through the research process.
- 20% Potential Impact of Research information showing need for such research or interventions along with description on how that research can be used to advance care in local communities. Potential replicability and utility of research for patients
- 20% Project Description. Provides a clear and detailed plan for grant implementation.

About Rising Tide Foundation for Clinical Cancer Research (RTFCCR):

RTFCCR is a charitable, non-profit organization established in 2010 and located in Schaffhausen, Switzerland.

The foundation seeks to establish a new norm in clinical cancer research, where patients are treated as partners, from the creation of the research questions to the dissemination of results.

RTFCCR's primary consideration in granting support is given to innovative, patient-centered clinical research. The long-term ambition of the foundation is to bring the maximum benefit in the shortest time possible to those impacted by cancer. The foundation works towards this objective by fostering partnerships and striving to attract and support the best in Phase I to Phase III clinical trials.

The foundation s supports the creation of less toxic therapeutic approaches, better disease burden management, earlier cancer detection, and innovative intervention strategies that will lead to increased quality of life and survival for patients.

RTFCCR Contact Information

For questions regarding RTFCCR, or this RFP – you may contact the following:

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¹ Davies L, Milner DA Jr, Shulman LN, Kyokunda L, Bedada A, Vuylsteke P, Masalu N, Jackson P, Jennings N, Odunlami A, Mtshali P, Dugan U. Analysis of Cancer Research Projects in Sub-Saharan Africa: A Quantitative Perspective on Unmet Needs and Opportunities. JCO Glob Oncol. 2023 Jun;9:e2200203. doi: 10.1200/GO.22.00203. PMID: 37290022.

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