RISING TIDE®
Foundation for Clinical
Cancer Research

krebsforschung schweiz
recherche suisse contre le cancer
ricerca svizzera contro il cancro
swiss cancer research

REQUEST FOR APPLICATIONS

PATIENT DIRECTED

CLINICAL TRIALS

JUBILEE AWARD

FUNDING GUIDELINES

PLEASE READ ALL INSTRUCTIONS CAREFULLY

For any questions, email us at grants@risingtide.ch

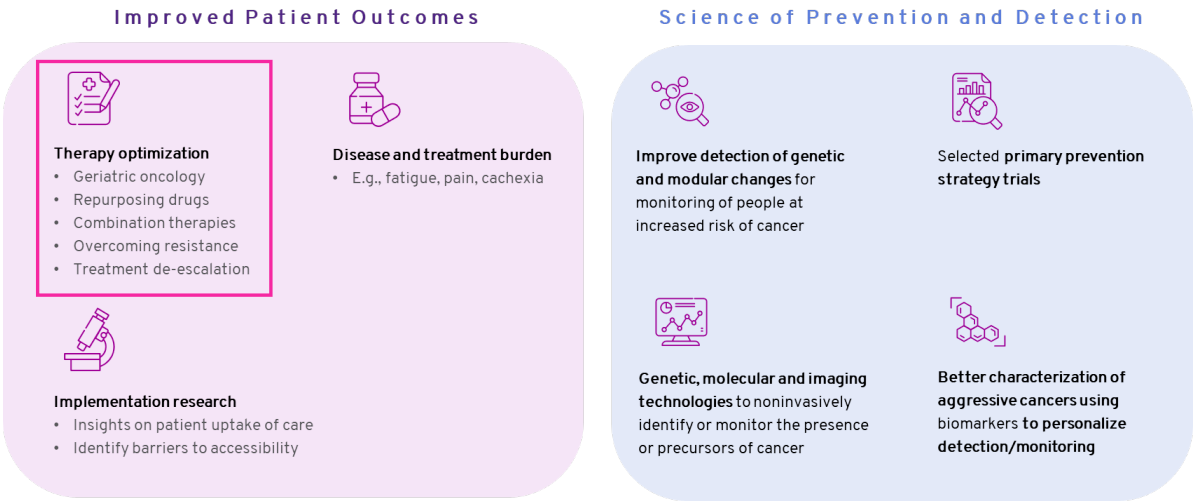
About the Rising Tide Foundation for Clinical Cancer Research

Rising Tide Foundation for Clinical Cancer Research (RTFCCR) is a charitable, non-profit organization established in 2010 and is located in Schaffhausen, Switzerland. Our mission is to promote freedom to improve quality of life everywhere. Using a patient-centred approach, we support research grants that enable patients to better understand their treatment options and to have a voice in trial design, thereby empowering them to be active agents in enhancing their quality of life.

RTFCCR's primary consideration in granting support is given to truly innovative, unique, patient-centred clinical research. The long-term ambition of the foundation is to optimize partnerships and attract the best in Phase I to Phase III clinical trials that aim to bring maximum patient benefit in the shortest time possible. With patients at the core of the mission, the foundation strives to support clinical trials resulting in the creation of less toxic therapeutic approaches, better disease burden management, earlier cancer detection, and innovative prevention strategies that will lead to increased quality of life and survival.

RTFCCR provides funding for research that directly benefits patients in the short term. We do not provide funding for basic research. We seek to provide support for clinical research topics that would not likely be funded by the pharma industry or other for-profit sources. Funding can be provided to any relevant institution in any country where meaningful grant oversight is possible.

RTFCCR Strategic Focus Areas



Further information can be found on our website - https://www.risingtide-foundation.org/clinical-cancer-research

About the Swiss Cancer Research Foundation

The Swiss Cancer Research foundation (SCR) is a non-profit organization located in Bern, Switzerland. It has been funding research projects in all areas of oncology (basic research, health services research, clinical, epidemiological, and psychosocial research) since 1991. Particular attention is paid to supporting patient-oriented research, the results of which benefit patients and their loved ones as directly as possible.

Next to national project grants, the SCR also awards international training fellowships to motivated and talented early-career clinicians, enabling the opportunity to gain research experience abroad, receive training and for further education.

The SCR is also committed to the continuing education and networking of scientists in the field of oncology by providing financial support for the organization of scientific conferences.

The foundation is independent of the pharmaceutical industry.

FUNDING GUIDELINES

INTRODUCTION

This year RTFCCR is celebrating its 10-year anniversary. In parallel, Swiss Cancer Research (SCR) is having a 30-year celebration. To mark these milestones, we would like to have a joint call for proposals to fund a jubilee award. This award seeks to provide funding to support the creation of a patient-initiated protocol for a clinical trial on a topic that aligns with the focus areas of RTFCCR and the mission of both organizations. We define 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.

PURPOSE

The purpose of the award is to increase the awareness and show the benefits of having patients involved at an early stage in clinical trial design, with the goal of making a significant difference to cancer patients. Priority will be given to trials proposed by an active patient group, where they have a clinical research question, they would like to take forward to clinical trial.

ELIGIBILITY CRITERIA

Clinical trials are eligible if they meet all the following criteria:

- Clinical trials need to be an interventional trial
- Clinical trials are open to all cancer types.
- If applicants wish to apply for immunotherapy or cell-based therapies, applications are asked to contact the RTFCCR team to discuss eligibility.
- Open for early stage first in human clinical trials to late-stage clinical trials (Phase 1, 2 and 3) where creation of a patient-initiated protocol is possible.
- Clinical trials should serve patients interests with primary endpoints that seek to provide clinical benefit. Trials should not have biological or translational primary endpoints, but applicants may include secondary non-clinical endpoints

DETAILS

- Geographical location: Switzerland
- The budget must be realistic and limited to the core activity of conducting the clinical trial.
    - Total Budget – CHF 800,000 (CHF 400,000 SCR and CHF 400,000 RTFCCR)
    - Co-funding is welcome. If the total cost of the trial exceeds CHF 800,000 applicants must disclose the plan to secure the remainder of the funding to ensure the trial can be completed
- No. of grants: 1
- Duration – up to 4 years

GUIDANCE FOR PLANNING YOUR PATIENT ENGAGEMENT IN RESEARCH

Early involvement of Patient Partners, based on co-design principles allows a better formulation of relevant research questions, more credibility of the knowledge produced, identifying, and solving potential challenges faced during the trial, and better application of outcomes to specific contexts.

Here is a checklist to help you plan Patient Engagement and complete our Patient Engagement Plan table required to be submitted as part of the Letter of Intent. It encompasses points that should be considered for the application phase, during the implementation of the project, and beyond the project.

Before the project starts

- Patient Engagement is planned across the entire project lifecycle
- The most appropriate Patient Engagement model is selected
- The appropriate Patient Partners are involved early in formulating the concept, hypothesis
- Appropriate budget for patient engagement activities and compensation of Patient Partners is reflected in the Patient Engagement Plan and the overall grant budget request

During the project

- Assessment of needs of trial participants by Patient Partners is included
- Adaptation of trial and procedures where necessary to meet trial participants' needs
- Assessment of the impact of patient engagement in your project at mid-term and at the end of the project is considered

Beyond the project

- Communication and dissemination of study outcomes with patient / public partners is planned after project end
- Collaboration with patient community on trial outcomes is planned

For more information, please refer to: http://synapse.pfmd.org/resources/considerations-guide-to-implementing-patient-centric-initiatives-in-health-care-product-development/download

CHOICE OF MODEL OF PATIENT ENGAGEMENT IN RESEARCH PROJECTS

Research teams should think carefully about the activities across the whole project lifecycle that the Patient Partners could undertake. Short term activities are easy to define upfront, but it is more challenging to think about sustained involvement across the entire project.

Therefore, depending on the research project, it is important to think about the most applicable role of a Patient Partner for contributing in a clinical research project:

Patient role	Examples	Engagement level
Consultant role	• Patients provide a priori and continuous consultation on outcomes of importance, study design, etc. • Patients are paid investigators or consultants • Patients have a governance role – "a seat at the table"	High
Advisor role	• Patients serve as advisory committee members or provide a priori consultation on outcomes of importance and study design, but have no leadership role or governance authority	Moderate
Reactor role	• Patient input is collected distally through surveys, focus groups or interviews, but patients are not consulted directly or a priori on such things as study design and outcomes of importance • Patients are asked to react to what has been put before them rather than being the origin of the concepts of interest	Low

PATIENT ENGAGEMENT PLAN

We require you to submit a "Patient Engagement Plan" as part of your LOI and Full Application. The plan should describe Patient Engagement processes during the generation of the project application as well as during the implementation of your project. It describes engagement e.g., how you engaged with the patient community when your research question was defined, while the proposal is written, when it is being submitted and resubmitted, and which patient engagement model you chose for the implementation of your project.
When developing your project budget, please make sure that adequate and realistic resources for Patient Engagement are reflected in the Patient Engagement Plan and the overall grant budget request. This could include e.g. appropriate budget for work time (staff or contractors in patient organizations) as well as project-related pass-through costs (e.g. travel expenses and meeting venue costs).

Different phases of research will need different activities to ensure patient engagement is implemented in the way defined in this document, *for example Phase I first in human studies may require a different approach than other studies.*

We accept different formats of patient engagement plan, as long as:

- Activities proposed are listed and properly described
- Activities proposed are designed for patients and with patients
- The results of these activities are implementable in the clinical trial design or execution to ensure patient needs are met

Be very clear at the outset about what you expect to achieve and what metrics – both quantitative and qualitative – you will use to measure progress against and achievement of both overall research goals and specific patient-centricity goals.

SUBMISSION PROCESS

- This is a 2-step request for proposals (RFP)
    - Step 1: applicants are requested to submit a Letter of Intent (LOI) through proposalCENTRAL.
    - Step 2: LOIs will be screened by the RTFCCR team, the RTFCCR advisory board members and the SCR team, which includes a member of the SCR scientific advisory committee. A video call will be held between RTFCCR and SCR to finalize selection of applicants to invite for full application.
    - Applicants will be requested to submit a full application, to include a draft trial protocol, a detailed budget, a rebuttal letter on feedback about the LOI and a detailed patient engagement plan. Support will be provided by the RTFCCR team to help coach patient-researcher groups to develop their ideas
- Full application evaluation process
    - Full applications will be reviewed using an international grant review committee (GRC). The GRC will include patient expert, biostatistician, and subject matter experts, in addition to RTF and SCR staff and scientific advisory board members. The RTFCCR and SCR teams will select the GRC members and organize a GRC telephone call to discuss the strengths, weakness and provide a final score. After the GRC call, RTFCCR will collate the reviewer's comments and create a score table. Applications scoring higher than 6 will be recommended to both Boards for approval.

DETAILS

Tasks	Dates
Launch	September 27, 2021
Submission period LOI	September 27, 2021 - December 31, 2021
Deadline LOI	December 31, 2021
Evaluation period LOI	January 03, 2022 - January 14, 2022
Sent out Invitation for full applications	January 17, 2022
Submission period for full applications	January 17, 2022 – March 20, 2022
Board update SCR	March 04 2022
Deadline Full Applications	March 20, 2022
GRC Evaluation Period	March 21, 2021 - April 11, 2022
Joint Grant Review Committee Call	April 11, 2022
RTFCCR Board Approval	May 11, 2022
SCR Board Approval	June 17, 2022

GRANT AGREEMENTS

- Upon approval of the successful applications by the SCR and RTFCCR Boards of Directors, SCR and RTFCCR would each issue a separate funding award agreement that would cover 50% of the total awarded budget.

PAYMENTS AND FUNDS USE

- For RTFCCR, RTFCCR manages an initial and final payment, with the remaining payments being deliverable based for the duration of the grant
- SCR funding is paid in six to eight installments over the duration of the grant.

ROYALTIES AND INTELLECTUAL PROPERTY (IP)

- The processes and approaches may differ between the foundations, and as such, each funder will have the rights to use the standard terms they typically use within their executed awards with the collaboratively funded project.
- While RTFCCR seeks to share in any commercialization, SCR has no claim to IP in the grant agreement but asks the recipient to inform SCR if protected rights in conjunction with the funded research have been acquired.

PROGRESS REPORTS

- The RTFCCR team will monitor progress of the study using a milestone-based reporting process, where three written reports are required per annum detailing progress towards achieving milestones.
- SCR requests financial and scientific progress reports in the middle of the grant period and after completion of the project.