REQUEST FOR APPLICATION
CLINICAL TRIALS IN
BRAIN METASTASES

- FUNDING GUIDELINES -

PLEASE READ ALL INSTRUCTIONS CAREFULLY

For any questions, please call (+32 2 268 48 16) or e-mail us (apply@anticancerfund.org)

About the Anticancer Fund

The Anticancer Fund (ACF) is a Belgian non-profit organisation with an international scope, dedicated to expanding the range of treatment options for cancer patients. The fund depends on donations and private funding to finance its work. With no commercial shareholders or interference from special interest groups or the pharma industry, it focuses exclusively on the evidence-based potential of new cancer treatments to respond to unmet patients' needs.

The ACF's vision

The ACF is committed to expanding the range of treatment options available to cancer patients, regardless of their commercial value. Its ultimate goal is to extend lives, increase quality of life and provide cures for cancer patients.

The ACF's mission

The ACF believes no promising treatment options should be left untapped and therefore works on commercially neglected therapies. It aims to complement the commercial drivers of cancer care with exclusive patient-first thinking. Hence, the ACF puts the focus on evidence-based development of high impact therapies for the benefit of cancer patients.

The ACF's work has three main pillars:

Research & Clinical trials

It promotes research, finances and/or coordinates clinical trials, investigating scientifically promising treatments that have the potential for significant positive impacts on patients lives but lack a market push for more research. If the effectiveness of a treatment is scientifically proven, it will further its access to patients.

Information & knowledge-sharing

It offers personalized, non-judgmental and evidence-based information about cancer treatments to patients who want to make informed decisions.

Policy-making

The ACF engages with stakeholders on both national and European levels to influence decision makers and eliminate barriers to rapid, affordable access to more cancer treatments.

Instructions for Applicants

Scope

This RFA seeks to increase clinical trial activities in patient diagnosed with **Brain Metastases (BM),** including Leptomeningeal metastases (LM). We are looking for innovative approaches that can improve survival rate in this specific patient population. The focus is on clinical trials assessing interventions that can increase survival or induce durable responses.

Despite of numerous registered trials and efforts in this patient population, there is still a high need of new and successful treatment options due to the rate of uncompleted and terminated trials. To limit trial execution failure, prioritisation will be given to applicants that have successfully conducted clinical trials in this patient population in the past and have a track record in conducting clinical trials in BM and/or LM.

We welcome applications from all over the world and do not have geographical restrictions.

As ACF seeks proposals in line with its vision and mission, the proposed intervention must be commercially neglected (as defined in detail in the eligibility criteria).

We encourage applicants to contact apply@anticancerfund.org for any question related to the RFA and to check eligibility of their proposal in case of doubt.

Eligibility criteria

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

1. The application needs to be an interventional trial in patients with brain metastases and/or leptomeningeal metastases.
2. The trial should serve patients' interest and be patient-centred.
3. The primary goal of the trial is to improve survival or induce durable response. Biological and translational endpoints are only accepted as secondary endpoints, not as primary endpoint.
4. All interventions (*i.e.* medicinal products, surgical techniques, radiation modalities or combination here of) are allowed, including intrathecal administration of approved medicinal products, **except**
    a. compounds (chemical/biological) that are still in drug development;
    b. medicinal products without marketing authorisation or approval from competent authorities (*i.e.* FDA, EMA, national) for any indication (cancer or not cancer related indication).
5. For on-patent medicinal products or medical devices with commercial owner: a written statement should be provided that the commercial owner is not willing to give funding for the conduct of the trial. On-patent medicinal products **should be donated** for the trial by the commercial owner (a written statement should be provided).
6. The leading clinical trial team has a track record of high-quality trials – preferentially investigator-driven trials – in the field of BM, LM or both. Applicants without expertise in this field should seek collaboration with investigators who have demonstrated expertise in BM/LM. A formal proof (letter) of collaboration should be provided.

7. There is no geographical restrictions. All nationalities and countries are permitted to submit their proposals. International collaboration is allowed and multicentre clinical trials over different countries are welcome.
8. There should be no trial competing for the same patient population in the participating centres and/or countries.

In case of doubt for any of these criteria, we recommend contacting us before working on the LOI to assess eligibility.

BUDGET

- The budget must be realistic and limited to the core activity of conducting the clinical trial.
- Applicants can request up to € 500K for their individual trial. We anticipate supporting 1 trial.
- Investigator fees and institutional overhead costs are not accepted.
- Budget for translational work should be limited.
- Co-funding is welcome. All applicants must disclose the funding already secured and all past and ongoing funding applications.

SUBMISSION AND SELECTION PROCESS

This is a **2-step RFA**

Step 1: Letter of Intent (LOI)

We ask all applicants to complete the LOI form which includes 2 main sections:

1. The **eligibility** section where applicants demonstrate that their proposal meets all the above-mentioned criteria.
2. The **trial information** section where applicants provide details on their proposal.

----- ----- Deadline for submission of the LOI is Sunday 1 May 2022, 23:59 CET ----- -----

The LOI template can be downloaded from our website.

Evaluation of the LOIs will include:

- checking the eligibility criteria;
- reviewing alignment with mission, focus areas and core belief of ACF;
- evaluating the scientific rationale and the possible existence of counterevidence;
- performing horizon scanning to assess competition.

Applicants will be notified whether their LOI has been selected for step 2 by **1 June 2022.**

Applications will be automatically rejected if the applicant omitted to disclose secured funding or ongoing funding applications for the same trial.

Step 2: Full Application

Step 2 starts with a virtual meeting between the ACF and the applicant. The goal of this meeting is to explain the process, go through the feedback on the LOI, perform a preliminary evaluation of the feasibility for running the trial, and assess whether any circumstances have changed since receipt of the LOI.

After the meeting, the applicants will be asked to submit a full application containing:

- **Protocol**: The applicants are asked to submit a protocol ready (or almost ready) to be submitted to the competent authorities and to the IRB/EC.
- **Budget**: The applicants are asked to submit a detailed breakdown of the requested budget.
- **Rebuttal**: The applicants are asked to elaborate on specific questions and/or concerns that arose during the evaluation of the LOI.

----- ----- Deadline for full application is Thursday 1 September 2022, 23:59 CET ----- -----

The evaluation of the full applications will be done by a grant review committee (GRC). The GRC together with the ACF review team will select the best applications for submission to the ACF Board for approval. The grant review committee will include patient experts, biostatisticians, and disease experts.

The final selection is expected to be communicated on **31 October 2022**. Selected applications will receive a conditional go. The final go and signing of the collaboration agreement will only be after a final assessment on the feasibility of running the trial and a site visit.

KEY DATES