











CALL TEXT











Five European cancer charities are joining forces to accelerate international clinical research on innovative local treatments for rare and hard-to-treat cancers. Through the INTER-LOCAL Call, this joint funding initiative aims to stimulate cross-border phase 2 and 3 clinical trials, advancing the development of more effective local treatment strategies and improving outcomes for patients facing these challenging cancer types.

RARE AND HARD TO TREAT CANCERS

Survival rate for many cancers has doubled over the past 40 years, with 70% of patients surviving to 10 years or longer. However, progress has not advanced equally for all types of cancer. Survival for some types of cancer is lagging behind, due to the lack of successful treatment. For hard-to-treat cancers, the 5-year survival rate is still below 25% and little or no improvement has occurred in the past decades. Also, for rare cancers, there are hardly any specific new successful therapies available, leaving patients with limited or no treatment options, especially when they have metastases. The causes of therapeutic failure for hard-to-treat and rare cancers can be multiple, such as absence of appropriate targeted approaches, tumour heterogeneity, acquired drug resistance, problems with drug penetration and problematic drug development due to the rarity of some tumour types. Moreover, hard-to-treat cancers often present significant challenges for patients, leading to a high burden on their quality of life. The aggressive nature of these cancers, limited treatment options, severe side effects of therapies and the emotional impact of dealing with a severe diagnosis all contribute to a reduced quality of life for patients. While development of anticancer drugs has significantly improved cancer treatment outcomes, they may not always be effective against certain types of cancer or in advanced stages. Therefore, the development of highly effective alternative treatment modalities is crucial, especially when cancer drug development falls short as seen in rare cancers in particular. The local treatment of cancer, for example by surgery or radiotherapy, has long been established as a highly effective treatment option, played pivotal roles in treating various types of cancer and contributed largely to improving outcomes. These local therapies have developed over the years in more minimally invasive techniques that spare healthy tissue and precisely target the tumour, which significantly improves the quality of life after treatment.

The potential for significant financial returns in drug development, where pharmaceutical companies can patent and sell drugs to wide patient populations, make drugs attractive to private investors. However, limited financial interest in the development of effective and innovative local treatment has hampered the progress in this field.

SCOPE

In order to close the gap in resources, to promote the international development of effective local treatments, and to increase survival and quality of life of patients with hard-to-treat and rare cancers, we would like to take the initiative to set up a call to stimulate international clinical research for local treatment options for these cancer types. Through this call, the consortium partners aim to stimulate international collaboration in clinical research between the respective funding countries, and by extension across the entire European region.











GLOSSARY

1. PARTICIPATING PARTIES

PROJECT LEADER –The Project Leader is the international project coordinator, in charge of submitting the application on the behalf of the whole research consortium. He/she will be the main contact point for the project submission and follow-up, as he/she oversees all activities related to the project. Project Leaders are funding recipients of the INTER-LOCAL grant. He/she may be responsible for research and financial activities related to the external inclusion centres, in addition to the activities at his/her national level.

NATIONAL COORDINATOR – Eligible research consortia are composed of minimal 3 National Coordinators, among who one Project Leader will be nominated. National coordinators, as well as the Project Leader, must be located in Belgium, Sweden, the Netherlands, Spain or Norway. Only one National Coordinator is to be nominated per country (Belgium, Sweden, the Netherlands, Spain or Norway). National Coordinator are funding recipients of the INTER-LOCAL grant. Each National Coordinator is responsible for the research and financial activities at his/her national level.

INTERNAL INCLUSION CENTRES – Patient inclusion centres located in Belgium, Sweden, the Netherlands, Spain and Norway. Activities and budget for these centres will be managed by the National Coordinator from the same country.

EXTERNAL INCLUSION CENTRES – Patient inclusion centres located outside of Belgium, Sweden, the Netherlands, Spain and Norway. External inclusion centres are located within geographical Europe. Specific funding conditions apply for these centres, as described in the Guidelines for Budget request.

2. CALL IMPLEMENTATION BODIES

SCIENTIFIC EVALUATION COMMITTEE – The SEC is a panel of internationally recognised scientific experts in charge of the evaluation of submitted pre- and full proposals. Their evaluation is based on the evaluation criteria described in this document. Reviewers are not allowed to submit or participate in proposals within this call and must sign declarations on conflict of interest and confidentiality.

PATIENT ADVOCACY COMMITTEE – The PAC is a panel of patients or caregivers in charge of the evaluation of submitted pre- and full proposals. Their evaluation is based on the evaluation criteria described in this document. Reviewers are not allowed to submit or participate in proposals within this call and must sign declarations on conflict of interest and confidentiality.

CALL STEERING COMMITTEE – The CSC is composed of representative(s) from each funding organisation participating in INTER-LOCAL. The CSC will supervise the preparation and the implementation of the call and will take all decisions concerning the call. Based on the ranking list established by the SEC, the CSC will take the final decision on the proposals to be funded. Members of the CSC are not allowed to submit proposals to this call.











REQUIREMENTS

APPLICATION REQUIREMENTS		GUIDANCE
Research consortium partners	Hospital or institute based in Belgium, Sweden, the Netherlands, Spain or Norway	 Each National Coordinator (including the Project Leader) gets a funding contract/letter of grant from the respective national funding organisation. They should, in accordance with the national funding conditions, fall within the following categories: Academic research groups (from universities or other higher education or research institutions); or Clinical/public health sector research groups (from hospitals/public health and/or other health care settings and health organisations). Young researchers are welcome to apply; taking into account that the right expertise and experience should be available within the consortium and that the project should be led by the best suitable candidate.
Transnational research consortium	Multicentre, collaborative, internationally organised (> 3 participating countries)	 The Project Leader as well as National Coordinators should be located in Belgium, Sweden, the Netherlands, Spain or Norway with a minimum participation of 3 countries. Participation of all 5 countries is highly encouraged. Inclusion centres and other participating parties located in other countries are allowed (see below).
Patient Involvement	It is required to actively involve patients throughout the entire project lifecycle	 Active involvement of patients is mandatory throughout the entire project lifecycle (project set-up and execution, communication of results etc). See Guidelines for Patient Centricity and Patient Involvement for further guidance.
Other participating parties (not mandatory)	External inclusion centres	- External inclusion centres outside of Belgium, Sweden, the Netherlands, Spain and Norway are allowed, in order to support swift enrolment of study patients in clinical trials. The external inclusion centres are located within geographical Europe, in order to encourage and enhance European collaboration. Requested funding for external inclusion centres must not exceed 20% of the total requested budget, with a maximum of 500.000 euros. Funding conditions for external inclusion centres are described in the Guidelines for Budget request.
	Industrial partners	 Public/Private collaborations are accepted if needed for the execution of the project, and as long as co-funding as well as appropriate agreements on intellectual property and fair pricing are in place. Commercial partners cannot be a Project Leader or National Coordinator and may only be involved if collaborating with Academic or Clinical/public health research groups. Commercial parties will not receive funding directly and are required to provide in-kind contribution to the project. This contribution should be of an extent appropriate for the type and size of the project. In case of financial contribution, and why the remaining budget cannot be foreseen by the commercial party and why non-profit funding would be needed to execute the project. Intellectual Property (IP): the background owned by any applicant will remain the sole property of the applicant (or his/her affiliated research structure (i.e. institutes, research centres and investigators). In addition, all data and results that are generated during the project remain the property of the applicants or his/her affiliated research structure (i.e. institutes, research centres and investigators)) for the duration of the project. Projects with IP of study results exclusively owned by commercial parties are not eligible for this call.











		Commercial parties are requested to express their commitment
		and guarantee their maximal and reasonable efforts to accommodate further development, implementation, and access for patients after the end of the project. Clear agreements between industry partners and researchers should be in place prior to the trial, assuring independent research and publishing. Agreements between applicants and commercial parties as well as letters of intent should be provided for review as part of the full proposal application process.
Study Sponsor	The sponsor of the trial must be an academic or non-profit research party	The sponsor of a study is the party who has overall responsibility for the initiation and management of a clinical trial. Industry sponsored trials are not accepted.
Research type	Multinational multicentre clinical trial	Under no circumstances can funding be requested for translational research activities. The aim of this call is to accelerate clinical research towards implementation in clinical practice and is therefore not meant for translational research.
Research phase	Phase II and/or phase III clinical trial, or comparable (including single arm phase II trial)	Confirmatory or pivotal trials. Trials that are close to patient impact, implementation, registration, market authorisation and/or change of treatment guidelines.
Scientific Rationale	A strong scientific rationale that supports the hypothesis and objective of the trial is required.	
Trial design	Prospective, well-controlled studies, using the best-fitting trial design	 Including but not limited to randomised trials, innovative trial designs, designs that use methodologies to enhance patient inclusion, designs that leverage existing patient registries, etc. Designs that make use of validated clinically relevant endpoints or validated surrogate endpoints are both allowed. Including real world data (for example as control arm) may be considered. Design should include the best suitable and most representative study population, with respect to the studied disease. Depending on the context and feasibility, the most appropriate study design should be used in order to successfully achieve the primary objective of the trial Trial designs that use validated biomarkers (e.g. genetic mutations or molecular markers typical for rare cancers) to identify and/or stratify eligible patients or subgroups to one or multiple treatment arms, are allowed as long as the primary endpoint of the trial is clinically relevant (survival, QoL) and not biomarker validation.
Cancer type	Rare and/or hard to treat cancer	 Rare cancers: the cancer type must be rare, defined as having an annual incidence (number of initial diagnoses) of fewer than 6 cases per 100,000 individuals in the European region, based on the most recent and reliable epidemiological data or registry sources. This classification is based solely on the cancer type itself and is independent of the stage at initial diagnosis. Rare cancer in both adult and paediatric populations is accepted. Hard-to-treat cancers: the cancer type must be classified as hard-to-treat by a 5-year survival rate below 25% (from the time of initial diagnosis and independent from the stage at the time of initial diagnosis), based on peer-reviewed scientific evidence published in high-impact journals.











		 Molecular subtypes may be considered eligible only if the experimental intervention under investigation necessitates a specific therapeutic approach tailored to that subtype. Proposals may address any stage of cancer (as long as cancer type at time of initial diagnosis fulfils the Rare or hard-to-treat criteria above), including locally advanced, recurrent, or metastatic disease, taking into account the relevance of a local/locoregional therapeutic option within the proposed study context.
Intervention type	Radiotherapy and surgery	 Radiation therapy (e.g. proton therapy, photon therapy, carbon ion therapy, image-guided radiation therapy, brachytherapy) Surgical interventions (e.g. minimally Invasive surgery, precision/image-guided surgery) The intervention under investigation itself must not involve the use of drugs, tracers or other active substances. Trials with local/locoregional drug delivery as therapeutic intervention, taking into account the efficacy of the drug, are not eligible. Combination therapy with other treatment modalities (e.g. systemic therapies, immunotherapies, or other local/locoregional therapies), is allowed but only if the experimental intervention
		includes local/locoregional therapy (radiotherapy or surgery) and the independent therapeutic contribution of the local/locoregional treatment can be unambiguously demonstrated. If the experimental intervention is combined with a medicinal product, that product must be part of the current standard of care.
Project Manager	A Project manager must be allocated to the project	 A project manager is obligated to be allocated to the project, to coordinate and manage the international clinical trial. The allocated Project manager preferably has strong international clinical trial management and regulatory (EC/CA) experience.
Ethical and regulatory requirements		- The trial must be conducted in full compliance with Good Clinical Practice (GCP) guidelines, applicable EU regulations, and national regulatory requirements in all participating countries.
Go-to- patient/clinical implementatio n strategies		 Applicants have to provide a clear and realistic plan for the implementation of the trial results into routine clinical practice across multiple European countries, assuming the trial demonstrates positive outcomes. Applicants should demonstrate awareness of the regulatory and implementation landscape relevant to their intervention and describe how they will ensure alignment with these requirements throughout the project lifecycle. It is strongly encouraged to have obtained (early) HTA and /or regulatory advice at the applicable authorities (i.e. National Competent Authorities, Notified Bodies,), as applicable.
Dissemination plan		A plan to disseminate project data and results is required. Projects are expected to contribute to reproducible science and have a plan to disseminate their data and results, in particular: - Sharing of results in public databases, particularly after initial publication; - Publication of data in addition to the results adhering to FAIR principles (https://www.gofair.org/); - Publication of results in open-access journals.

SUBMISSION PROCEDURE

This call is a two-stage submission procedure, i.e. a pre- and full proposals stage. Both pre- and full proposals must be written in English and submitted by the Project Leader through the electronic submission system hosted by Swedish Cancer Society exclusively. **Please note that registration in the system is required prior to submitting your application**.











The pre- and full proposals must be submitted to the electronic submission system no later than the exact deadline of **22 January 2026; 12pm (noon) (CET)** for the pre-proposal and **18 June 2026; 12pm (noon) (CEST)** for the full application (see detailed Timeline section below). Please note that full proposals are only accepted from Project Leaders who are explicitly invited by the call secretariat to submit them.

Applicants should also take note of individual national rules/funding conditions (see Guidelines for budget request) and contact their national contact persons for specific questions prior the proposal submission. In addition, applicants should agree that all information and documents that will be submitted in either the pre- or full proposal stage and as part of monitoring, are to be shared between all funding organisations in the context of the eligibility check, the project evaluation and monitoring.

ELIGIBILITY CHECK

All pre-proposals and full proposals will be checked in terms of eligibility by the call secretariat and the Call Steering Committee.

All pre-proposals are examined to ensure that they meet all criteria specified in the Requirements section (see above), date of submission, and inclusion of all necessary information in English. The relevant national funding organisations also perform a formal check of compliance with their respective regulations/funding conditions. Pre-proposals not considered eligible are rejected without further review. The Project Leaders of the non-eligible pre-proposals are informed accordingly. There will be no possibility to object to this decision. Moreover, the information provided in the pre-proposal application is binding for the entire application process.

An eligibility check of the full proposals is performed to ensure that they meet the formal criteria of the call and have not changed substantially from the respective pre-proposals. A full proposal may be excluded from further review, if criteria are not met or if the proposal objectives or the composition of the consortium deviate substantially from the previously submitted pre-proposal. Any substantial changes between the pre-proposal and the full proposal must be communicated in advance to the call secretariat with a detailed justification and will only be accepted under exceptional circumstances.

EVALUATION CRITERIA

Because of the two-stage application procedure, there will be a two-stage evaluation procedure. Proposals will be reviewed at both stages by scientific experts and by a Patient Advocacy Committee (PAC), with distinct evaluation criteria. Consequently, both pre-proposal and full proposal application forms will be composed of two distinct parts: a scientific application part and a specific patient-friendly application section should be completed by the applicants as part of the application form (see Guidelines for Patient Centricity and Patient Involvement). Of note, scientific experts will not review the application part dedicated to PAC review; and reciprocally, the PAC will not review the application part dedicated to review by scientific expert.

Evaluation criteria for each committee are presented below.

Scientific evaluation criteria

Pre- and full proposals are assessed according to the criteria specified in the Requirements and Recommendations sections (see tables above) and in addition, the scientific review will focus on the following criteria:











1. Scientific quality

- a. Relevance in relation to the topic of this call (fit-to-call): primary endpoint aiming for improvement of treatment of cancer, limited commercial interest/need for international funding, international collaboration.
- b. Sound trial design (i.e. statistics, methodology, compliance to quality standards and norms for good research practices and good clinical practices) and scientific background, previous research and evidence supporting the objective of the trial (i.e. state of the art).

2. Feasibility of the workplan

Including feasible workplan and recruitment plan considering potential competitive trials (within the call and beyond), good quality consortium, appropriateness of the project management and of the budget request.

3. Developmental potential

The project must demonstrate a strong regulatory/go-to patient/registration/implementation strategy, tailored to the context of the trial. This strategy can be approached in various ways, either academic or commercial, such as early dialogue/advice from National Competent Authorities (NCAs), early HTA, a reimbursement strategy and/or guarantees for a sustainable patient accessibility. Additionally, assigning a regulatory lead can significantly enhance the effectiveness of the regulatory strategy.

While these criteria do not need to be fully met at the time of application, a detailed description of the current status and future plans regarding these factors can enhance the perceived developmental potential of the project. The more advanced and well-elaborated these aspects are, the higher the project's developmental potential.

4. Patient Impact potential

- a. Targeting an unmet patient need
- b. Potential impact on survival and/or quality of life (appropriate burden/benefit assessment) of patients.

PAC evaluation criteria

The PAC will assess whether the project proposals are patient-centric and whether, from the perspective of the cancer patient, they address a pressing need; they will also assess the way in which patient participation forms part of the research project, including burden for participants in the clinical trial. PAC evaluation will be done by taking into account the following criteria:

1. Concrete need

The project must address one or several concrete need(s) among patients that is/are clearly and comprehensively described.

2. Added value

The proposed solution seemed adequate and of added value for the patients in needs. The solution must demonstrate patient-friendliness and have a significative impact on the life expectancy and/or quality of life.

3. Patient burden

Patient burden must be adequately monitored and assessed throughout the clinical trial, ensuring that it is sufficiently taken into consideration when the intervention becomes available in the clinic afterwards. Efforts must be made to ensure that the burden on the patient is minimized and that the burden/benefit ratio is appropriately balanced.

4. Active patient participation

Appropriate involvement of patients throughout the entire project lifecycle (from the project's











design, set-up and execution to the dissemination aspects). Projects that include a patient association as a collaborative partner in the trial must provide a signed letter of intention or a letter of commitment.

EVALUATION PROCESS

Evaluation of the pre-proposals

Pre-proposals passing the formal eligibility checks are reviewed:

- by the <u>Scientific Evaluation Committee (SEC)</u>. Each pre-proposal is allocated to members of the SEC, who will review the proposal in accordance with the criteria described above.
- by the <u>Patient Advocacy Committee (PAC)</u>. Selected pre-proposals will be evaluated by the PAC. Each selected pre-proposal will be provided to members of the PAC for review, resulting in a PAC Advise report. The pre-proposals will be evaluated by the PAC for patientcentricity of the research, taking into account the criteria described above.

Decision of the pre-proposal

The decision on the results of the pre-proposals and feedback will be communicated to all the applicants (successful and unsuccessful) by **the second half of April 2026**. There will be no possibility to object to this decision. Successful applicants will be invited to submit a full proposal. The invitation will include a summary of the evaluation and possible recommendations on the project from the SEC, the PAC, Regulatory Authorities, and the CSC for implementation in the full proposal.

Evaluation of the full proposals

Each full proposal is reviewed:

- by members of the SEC, possibly those who had reviewed the corresponding pre-proposal, and an additional methodology review by a SEC methodologist member.
- by external reviewers.
- by the PAC. For this purpose, the applicant must submit a specific patient-friendly application form as part of the full proposal application. In this form, the goal and the patient-centricity of the project is described in layman's terms, as well as an explanation whether of the prior comments listed in the PAC Advise report have been implemented. Review will result in a PAC Evaluation Report, including a PAC score.

As part of the review process of the full proposals, the SEC members and external reviewers will independently assess the full proposals according to the scientific evaluation criteria mentioned above.

The total score of the SEC and external reviewers will count for 70% of the total score for the project. The scores of the PAC account for 30% of the total score of each project proposal.

Rebuttal stage

Once the evaluation by the SEC members and the external reviewers completed, each Project Leader will have access to the anonymous evaluation reports (not to the assigned scores) by the SEC members and the external reviewers. Project Leaders are allowed to reply to reviewers' questions and to comment on factual errors or misunderstandings on the evaluations. However, issues which are not related with reviewers' comments or questions cannot be addressed and the work plan cannot be modified. The resubmission of the full proposal is not permitted in any case. This response to reviewers' comments must be submitted exclusively by the Project Leader through the electronic submission system, which only will be available during the Rebuttal Comment Window (7-10 days), as specified in the Timelines (see below). Please note that for the application to be admissible, the Project Leader will have to re-submit it online before the closing date of the rebuttal stage.











Decision of the Full proposal

Based on the total project scores and the optional responses in the rebuttal stage, a ranking list is established and discussed during the evaluation meeting with all members of the SEC, the PAC chair and delegate, and the Call Steering Committee (CSC) to reach a consensus on the proposal to be funded. The decision on the projects to be funded will be based on the ranking determined by the scores of the expert and patient committee, while also considering the available budget and the strategic priorities of the call. The decision on the results of the full proposals evaluation meeting will be communicated to all the Project Leaders (successful and unsuccessful) by the end of October 2026, as specified in the Timelines (see below). The Project Leaders will receive a conclusion of the evaluation. There will be no possibility to object to this decision.

TIMELINES

INTER-LOCAL Milestones	Provisional Timeline
Application Open Pre-proposal	01-12-2025
Application Deadline Pre-proposal	22-01-2026
Review process Pre-Proposal	09-02-2026
Application Open Full proposal	27-04-2026
Application Deadline Full proposal	18-06-2026
Review Process Full proposal	29-06-2026
Rebuttal week	07-09-2026
Funding Letters	27-10-2026

FUNDING CONDITIONS

Applicants should take note of individual national rules/funding conditions (see Guidelines for Budget request) and contact their national contact persons for specific questions.

Applicants with external inclusions centres outside Belgium, Spain, Sweden, Norway or the Netherlands should also consult the funding terms for external inclusion centres (see Guidelines for Budget request).

The project duration i.e. the funding period cannot exceed 6 years.

BUDGET

The estimated total budget for the INTER-LOCAL call is up to 8.5 million euro with a limit of 3 million euro per application, provided by the 5 collaborating funding organisations: Spanish Association against Cancer Scientific Foundation, Swedish Cancer Society, Norwegian Cancer Society, Kom Op Tegen Kanker and KWF Dutch Cancer Society. However, it is highly recommended to respect the available budget mentioned in Guidelines for Budget request.