Cris contra el cáncer

INVESTIGACIÓN PARA OTRA OPORTUNIDAD

GUSTAVE ROUSSY CANCER CAMPUS GRAND PARIS FONDATION

REAL-LIFE TRIALS IN ONCOLOGY PROGRAMME

A joint call between Gustave Roussy Foundation and CRIS Cancer Foundation

Call for Applications 2025

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Introduction

Clinical research represents the tool to explore and, more importantly, to validate the utility of medical strategies. Clinical trials include very different designs and require very different levels of infrastructure depending on the question they address. As an example, trials testing new drugs or new devices usually require a high level of infrastructure and, therefore, present a high cost per patient. These trials usually require a cost of around $20,000 per patient. At the other extreme, trials testing strategies without novel drug innovation require a lower level of infrastructure and data collection.

These trials could be called **« real life trials »** as they ask questions related to daily practice in oncology, do not require specific infrastructure, require a minimal amount of data collection, and have the potential to impact millions of patients worldwide. As an example, the lungRT trial sponsored by Gustave Roussy Foundation recently tested the impact of radiation therapy in resected stage III NSCLC. Getting an answer to this question is now translating into better practice for around 400,000 patients per year worldwide.

While these trials were abundant in the 90's, their number is decreasing. This is partly due to the preference of centres to run trials investigating therapeutic approaches implicating a high level of innovation and mostly driven by pharmaceutical companies. But their number is also decreasing because investigators do not find funding to run such pragmatic trials. This latter reason is a paradox because these trials should theoretically have a very low cost. Investigators and clinical research operators often generate high budgets because they overload the trials with data acquisition, data management and clinical operations that are not necessary. As an example, most of the trials require extensive clinical exams or blood tests that are not helpful in addressing the primary endpoint and generate extra-costs.

This introduction therefore generates a rationale to develop a new generation of practice-changing or practice-informing trials that will require low-level infrastructure, minimal data acquisition and therefore minimal cost.

The Gustave Roussy Foundation and CRIS Cancer Foundation are calling for applications to their Real-Life Trials in Oncology Programme to support the development of practice-changing clinical trials in France and Spain.

Candidates must be specialist clinicians currently working in France and/or Spain with clinical research experience and with the potential to develop transformative clinical trials. The participation of patient associations in the development of the project will be valued.

The aim of the Real-Life Trials in Oncology Programme is to provide competitive funding conditions to clinical researchers to develop their trials in France and Spain.

Definition of a Real-Life Trial (Pragmatic Trial)

A Real-Life Trial, also known as a **Pragmatic Trial**, is a type of clinical study designed to evaluate new treatment approaches under real world conditions that can be implemented in routine clinical practice across diverse healthcare settings.

Key characteristics include:

- **simplicity**
- **affordability**
- **feasibility** by utilizing minimal infrastructure and data collection.
- **broad applicability**, have the potential to change or inform practice across clinical settings and geography
- **Broad Inclusion Criteria**, include diverse patient populations to reflect real-world practice.
- straightforward inclusion and exclusion criteria
- endpoints that are directly relevant to patients
- the primary aim is to generate evidence that informs or changes cancer therapy or prevention practices on a large scale, ensuring practical utility and accessibility for widespread adoption.
- Cannot have any component of innovation.

Real-life trials avoid excessive complexity and focus on strategies that are cost-effective and impactful, addressing significant gaps in patient care without requiring high levels of technological innovation or resources.

Call for Applications

Every year, the Gustave Roussy Foundation and CRIS Cancer Foundation run a programme to **Award Clinical Trial Proposals**, as part of the Real-Life Trials in Oncology Programme. The purpose is to fund trials led by a pair of principal investigators (one in France (at Gustave Roussy Institute) and one in Spain).

The number of proposals to be funded will be decided after selection, depending on ranking and individual budget submitted. The maximum amount to be funded per call is **1.5 M; 500.000€ annually for 3 years.**

The programme invites applications from all specialist physicians who have a transformative clinical trial proposal and look for co-investigators in France or Spain to develop the trial.

The trial should run for a maximum of 3 years. In case of justifiable delay of the project, the principal investigators may ask for an extended period and the GRF-CRIS Committee will evaluate to confirm or deny the extension.

The call for applications opens on **2nd April 2025** and closes on **16th June 2025** at midnight (Central European Time - CET).

Beneficiaries must accept their place on the programme between **1st January and 30th June 2026.** The start date must be communicated to the Gustave Roussy Foundation and CRIS Cancer Foundation prior to that date.

Programme resources

The maximum amount awarded will be €1.500.000, which will be divided among the awarded proposals and spread over three annual instalments according to the budget calendar description, which must detail the annual breakdown of the budget, not exceeding €500.000 per year summing up all the proposals awarded. If the awarded trial has a lower budget than the maximum grant offered in the Call, the evaluation panel will select the top-scored trials up to reach the maximum grant awarded by this Call.

Annual instalments may include:

a. Salary: to cover labour costs corresponding to the intensification in the working hours of sub-investigators, nursing, or study coordinators. This cost includes Social Security contributions and any other amounts payable by the institution, as well as the gross remuneration of the beneficiary.

b. Costs associated to the clinical trial including:

- Fee per patient included to cover all the site costs: clinical practice, extraordinary tests, other services costs, and hospital overhead. (NOTE: Standard of Care procedures cannot be included).
- Consumables for any trial related testing. (NOTE: (NOTE: Translational research will not be funded).
- Outsourcing of services related to the management of the trial, CRO, central pharmacy, central lab, database management, etc.
- Other expenses related to the clinical trial as the insurance policy, regulatory agencies taxes, couriers, publication costs, etc.

Please note that the **allocated funds must be relatively balanced between the two participating institutions/countries**. Applications, where the trial in one country is already funded and funds are only requested to cover the costs of the other country, will not be considered.

These amounts will be subject to the corresponding legal tax retention.

Gustave Roussy Foundation will sign an agreement with the Gustave Roussy Institute and CRIS Cancer Foundation will sign an agreement with the Spanish host hospital, which will receive the programme allowance directly and must cover all expenses specified at the programme budget at each hosting hospital.

The contractual relationship between the investigators and their hospital shall comply with the provisions of the legislation in force at any given time.

The principal investigators are the named recipients of the funding and must be employees by the host institutions. The principal investigators must declare any other funding sources for the project.

Requirements for applicants

Training

Applications will be admitted from specialist physicians in France (at Gustave Roussy Institute) or Spain, who have proven experience on developing and managing independent clinical trials.

Nationality

Real-Life Trials in Oncology Programme is open to clinical researchers of any nationality working at Gustave Roussy Institute or any Spanish hospital.

Clinical Trial

Candidates must provide a proposal of the clinical trial associated with the call for applications and which will be the object of funding. The clinical trial shall demonstrate a high level of methodology and scientific quality. The trial must be **practice-changing or practice-informing** and must have a measurable impact on patient outcome and patient management, whether the primary endpoint is met or not.

Principal Investigator (PI)

There will be two Principal Investigators, a Spanish PI (working at a Spanish institution) and a French PI (working at Gustave Roussy Institute)

Information about their background must be provided along with the application.

Both investigators shall show an active role in the development of the clinical trial.

Restrictions

The following restrictions apply to the submission of applications:

- A researcher cannot submit several proposals to the same call for proposals.
- A researcher may only be a beneficiary of one Real-Life Trials in Oncology Programme at the same time. They may only re-apply following completion of the previous programme.
- Only Gustave Roussy Institute and Hospitals in Spain can be the beneficiary of the Real-Life Trials in Oncology Programme.
- Members of the scientific evaluation board will not be able to apply for these programmes.

If an applicant has been rejected previously due to a lack of scientific integrity, they may not reapply.

Documentation required for the application

Candidates or their institutions can access the Real-Life Trials in Oncology Programme call for applications, at:

- Gustave Roussy website:

  https://www.gustaveroussy.fr/en/clinical-research

- CRIS cancer website:

  https://criscancer.org/es/gustaveroussy/

All applications must be submitted by filling the form https://forms.gle/GQd7HegBah6SXeHw5 during the application submission period for the 2025 programme.

All the templates needed are available at the Gustave Roussy website (https://www.gustaveroussy.fr/en/clinical-research) and at the CRIS cancer website (https://criscancer.org/es/gustaveroussy/),

All applications must provide two blocks of documentation, which **must be completed entirely in English**.

1. The Clinical Trial proposal form.

Provided template must be used. Includes the following elements:

General information about the candidates and institutions

- Spanish PI: First and last name, institution, and contact details.
- French PI: First and last name, institution, and contact details.

Information of the Clinical Trial

- General information of the trial: Title, code/acronym, keywords, design of the Clinical Trial...
- Background, hypothesis, objectives, endpoints, methodology, project description, duration, and work plan
- Expected impact of the proposed research.
- Project schedule.

2. Budget.

Provided template must be used.

Project resources and budget detailing foreseen annual costs and payment schedule by study milestones.

Note that:

- Maximum of €1,500,000 in 3 annuities
- Standard of Care must not be included.
- The budget must be allocated around 50% to France and 50% to Spain.
- Overheads cannot exceed 10%.

3. Candidates should also include at the application their Curriculum Vitae, using a standardised summarised format (for example https:/cvn.fecyt.es/) following an abbreviated template of standard forms for public calls for applications (for example CVA). This document must be provided in English.

   i. Spanish PI's abbreviated CV (maximum 5 pages)

   ii. French PI's abbreviated CV (maximum 5 pages)

The requested documents must be submitted in PDF format (no more than 4Mb). These documents may be provided in the English language. Documents must be clear and legible. In addition, each page of the original document must correspond to a page of the PDF document.

In case the candidates or their institutions have any questions about the Real-Life Trials in Oncology Programme, they can e-mail to clinicaltrials@criscancer.org and RLtrials@gustaveroussy.fr or visit the webpages of the call for applications (https://criscancer.org/es/gustaveroussy/) or https://www.gustaveroussy.fr/en/clinical-research).

Selection process

The selection process is designed to identify outstanding candidates regardless of their origin, gender, nationality, or other aspects that could skew the selection. The goal is to ensure transparency, fairness, and impartiality throughout the process.

The members of the GRF-CRIS Evaluation Committee choose proposals, according to their own criteria, of clinical trials practice-changing or practice-informing which must have a measurable impact on patient outcome and patient management, and candidates that provide evidence of the greatest merits and abilities.

GRF-CRIS Evaluation Committee

The GRF-CRIS Evaluation Committee will be composed of scientists from various disciplines of the highest international scientific standard.

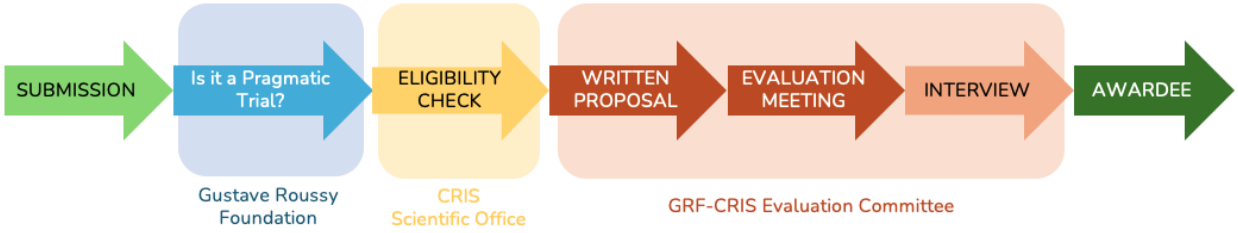
The evaluation committee shall consist of a Chairperson and five other members participating in the evaluation and a secretary lead of the committee.

The Secretary Lead, in addition to coordinating and monitoring the evaluation process, will perform the following tasks:

- Distribute the candidacies to the evaluators considering the expertise of each evaluator and the research area of the candidate.
- Ensure that each evaluator prepares a summary evaluation report for each application received.
- Ensure the evaluators who participate in the evaluation process do not present a conflict of interest with the candidates.
- Draw up a final report. The evaluation committee will meet at the end of the evaluation process and draw up a report listing the chosen candidates.

Stages of evaluation and expert panels

All applications that meet the necessary conditions will be evaluated by expert scientists.



There are three rounds of evaluation:

1. Eligibility check

   When evaluating eligibility, it will be checked:

   - if the proposal match with "Real-Life Trial" definition
   - if the proposal, PIs and institutions fix the requirements of the call

   All applications received will be evaluated, and those that do not meet the criteria set out in the terms and conditions of the call for applications will be rejected.

   There will then be a period during which any outstanding documentation will be requested, or any corrections or clarifications should be made.

   All rejected applications will receive an email detailing the reason for rejection.

2. Individual Evaluation

   A second round will be screened by the GRF-CRIS Evaluation Committee.

   Each proposal shall be reviewed by two different evaluators. Candidacies shall be evaluated in accordance with the criteria specified below in the section on General evaluation criteria.

   The higher scored candidates will go through to the final evaluation stage.

3. Final Discussion (and interview)

   The GRF-CRIS Evaluation Committee will hold a virtual meeting and shall review and discuss all the finalist applications, in accordance with the criteria specified below in the section on General evaluation criteria.

   If the GRF-CRIS Evaluation Committee considers it necessary to interview the applicants for deciding the awardees, the top-scored candidates will be contacted by the committee for interview.

   The best candidate/s will be selected for the Real-Life Trials in Oncology Programme.

General evaluation criteria

In general, two main aspects will be taken into consideration to ensure the excellence of the proposal: the quality, innovation, and potential of the submitted proposal as well as the scientific track record, capacity, and potential of the principal investigators.

1. Clinical Trial Proposal: 60 points
    a. Is it an innovative and transformative project? Is it a proposal of practice-changing or practice-informing trial?
    b. To what extent does the scientific approach outlined consider the fact that the clinical trial is high risk/high reward?
    c. To what extent are the proposed methodology and operating system suitable for the achievement of the objectives set out?
    d. To what extent are the timescale, resources, and commitment of the candidate appropriate and justifiable?

2. Candidates - capability, experience, and creativity: 30 points

    2.1 Spanish Principal Investigator: 15 points
    a. To what extent has the candidate demonstrated sufficient capacity to conduct disruptive research?
    b. To what extent has the candidate provided evidence of independent creative thinking?
    c. Evaluation of previous publications in the relevant strand of research and new strands. Do they represent significant progress in their field?
    d. Experience in independent clinical trials and the capacity to train new researchers.

    2.2 French Principal Investigator: 15 points
    a. To what extent has the candidate demonstrated sufficient capacity to conduct disruptive research?
    b. To what extent has the candidate provided evidence of independent creative thinking?
    c. Evaluation of previous publications in the relevant strand of research and new strands. Do they represent significant progress in their field?
    d. Experience in independent clinical trials and the capacity to train new researchers.

3. Host institutions: 10 points

    3.1 Spanish Institution: 5 points
    a. To what extent is the investigator able to develop the trial at his/her hospital?
    b. To what extent is the centre a suitable place to develop the research project?
    3.2 French Institution: 5 points

Appeals

Following the publication of the provisional list of beneficiaries of Real-Life Trials in Oncology Programme there is a period of seven calendar days during which appeals may be submitted via emailing to RLtrials@gustaveroussy.fr and clinicaltrials@criscancer.org.

The appeals procedure will be strictly confidential and will not result in a scientific re-evaluation by the panel. The independence and objectivity of the assessment is guaranteed by the selection and evaluation process.

Any appeals submitted shall be resolved by an Appeals Committee, which shall notify the candidate of its findings by e-mail within 30 calendar days from the date the appeal is received.

Appointment

The list of Beneficiaries shall be published on the website of the Gustave Roussy Foundation and CRIS Cancer Foundation in the Real-Life Trials in Oncology Programme section by November 2025.

The candidates selected as beneficiaries shall be given a reasonable amount of time to confirm their interest in the institution they indicated as their first option. During this time, they will also be able to explore alternative possibilities that might be better suited to their personal project. However, they must inform the Gustave Roussy Foundation and the CRIS Cancer Foundation of these changes and obtain their agreement.

In the event that the chosen beneficiaries decide not to take part in the programme, the respective grant shall be awarded to the next highest-scoring candidate as ranked by the Evaluation Committee.

The Evaluation Committee, the Gustave Roussy Foundation and CRIS Cancer Foundation reserve the right to declare a post null and void if none of the highest-scoring candidates fulfils the requirements of the programme.

The beneficiaries must submit the protocol to regulatory authorities by 30th June 2026, the latest. Under duly justified cases, if the proper documentation has been provided, this date can be delayed by up to 3 months. If this deadline is not respected, the funding will not be released for the programme.

Once the contract is in place, the candidates may transfer to another institution. A formal transfer request must be submitted along with all the documentation requested in the terms and conditions of the call for applications, in addition to an official acceptance from the new host centre. The Gustave Roussy Foundation and CRIS Cancer Foundation must evaluate the transfer request and issue its approval.

Incompatibilities

Candidates must carry out the research project in person, at the host research institution. Clinical practice and research must be carried out on a full-time basis at the host hospitals.

Any chosen candidates who decide not to take part in the programme may not reapply to subsequent programmes unless their reasons are duly justified and documented.

Any candidates who have been in contact with any member of the evaluation committee regarding issues related to the programme will be immediately excluded from the process and will not be able to reapply in the future.

Any breach of ethical considerations will lead to immediate termination of funding and said individuals will not be allowed to reapply to the programme.

Obligations

The beneficiary shall undertake to collaborate in communication activities and events organised by the Foundations related to these programmes.

The host institutions receiving the candidates will manage and administer the funds allocated annually by the Gustave Roussy Foundation and CRIS Cancer Foundation to this programme.

The Gustave Roussy Foundation and CRIS Cancer Foundation will request from the host institutions a detailed economic report breaking down the costs of activities carried out by the French and Spanish investigator. This report is required annually and at the end of the programme.

At any time, the Gustave Roussy Foundation and CRIS Cancer Foundation reserves the right to request accreditation, asking the investigators to provide the original documents or certified copies of any document indicated in the application or curriculum.

The investigators must submit annually a scientific-technical report in relation to the development of the project including the clinical trial approval from the Ethics Committee and Regulatory agencies.

At the end of the programme, investigators must submit the report of an external economic audit justifying the allocation of this funding. This amount can be included at the investigator´s budget.

Data protection and privacy

The Gustave Roussy Foundation and CRIS Cancer Foundation fully comply with current legislation on the protection of personal data.

The personal data of the researchers or any other individual listed in the application documents will be incorporated onto the Gustave Roussy Foundation and CRIS Cancer Foundation database and will only be used for the evaluation of proposals. By applying, the participant agrees for information about the Project to be incorporated onto these databases.

For the application and programme evaluation procedure to be conducted, anyone who applies will need to provide their personal data for incorporation onto our databases. The purpose of this is to send out notifications concerning the programme and application procedure.

To learn more about the transfer of data and how applicants may exercise their rights, you may request additional information by e-mailing RLtrials@gustaveroussy.fr or clinicaltrials@criscancer.org and you may also exercise your rights of access, correction, or erasure of your personal data, as well as limit or oppose the processing thereof.

Observations

The timeframes and times contained in these terms and conditions are understood to refer to mainland France and Spain (Central European Time - CET).

The submission of an application for this funding presupposes the candidate's express acceptance of these terms and conditions, as well as the criteria and decisions adopted by the Gustave Roussy Foundation and CRIS Cancer Foundation regarding any queries in the interpretation of the requirements and conditions set forth herein.

If any of the principal investigators of the proposal is found to have breached the terms and conditions set out herein, regardless of when this occurs or which stage of the application process or programme the candidate has reached, their candidacy shall be terminated, and any funding granted will be revoked. If any of the beneficiaries do not comply with the aforementioned commitments - or any others included in the conditions of the programme-, the Gustave Roussy Foundation and CRIS Cancer Foundation reserves the right to proceed as appropriate and even request that the beneficiaries repass any funding received.

The awarding of funding through this programme, as well as the amount awarded may be conditioned or modified in accordance with the actual resources available to the Gustave Roussy Foundation and CRIS Cancer Foundation at the time of the award.

In the event that results susceptible to economic exploitation are derived, the CRIS contra el Cáncer Foundation will have the right to receive a return of the amounts paid. In any case, the parties will sign the appropriate agreement in order to determine such participation.

Gustave Roussy Foundation is suggested to act as Sponsor of the French part of the Clinical Trial, and CRIS cancer can act as Sponsor of the Spanish part of the Trial