

## Real-Life Trials in Oncology Programme: A joint call between Gustave Roussy Foundation and CRIS Cancer Foundation. Call for Applications 2022

### 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 US dollars per patient. At the other extreme, trials testing strategies without novel drugs 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, 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.

## 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 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-CCF Committee will evaluate to confirm or deny the extension.

The call for applications opens on **1<sup>st</sup> February 2022** and closes on **30<sup>th</sup> April 2022** at midnight (Central European Time - CET).

Beneficiaries must accept their place on the programme between **1<sup>st</sup> July and 31<sup>st</sup> December 2022**. 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.

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.
  - Consumables for any trial related testing.
  - 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.

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

Gustave Roussy Foundation will sign an agreement with the French host hospital and CRIS Cancer Foundation 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 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 French or Spanish hospitals.

## 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 a French institution)

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 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 Hospitals in France and/or 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 <https://www.gustaveroussy.fr/en/clinical-research> and at [www.criscancer.org/programascris](http://www.criscancer.org/programascris). All applications must be submitted by e-mail to [RLtrials@gustaveroussy.fr](mailto:RLtrials@gustaveroussy.fr) and [clinicaltrials@criscancer.org](mailto:clinicaltrials@criscancer.org) during the application submission period for the 2021 programme.

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

The Clinical Trial **proposal form**, available at the website <https://www.gustaveroussy.fr/en/clinical-research> and at [www.criscancer.org/programascris](http://www.criscancer.org/programascris), includes the following elements:

- a. **General information about the candidates and institutions**
  - i. Spanish PI: First and last name, institution, and contact details
  - ii. French PI: First and last name, institution, and contact details
  
- b. **Information of the Clinical Trial**
  - i. General information of the trial: Title, code/acronym, keywords, design of the Clinical Trial...
  - ii. Background, hypothesis, objectives, endpoints, methodology, project description, duration, and work plan
  - iii. Project resources and budget detailing foreseen annual costs and payment schedule by study milestones
  - iv. Expected impact of the proposed research.
  - v. Project schedule.

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.

- a. Spanish PI's abbreviated CV (maximum 5 pages)
- b. 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 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.

*About the Clinical Trial Proposal form: The template provided must be used, and the report must not exceed 2 pages, excluding administrative information of the proposal, general information of the trial, budget, bibliography, graphs, and figures. The format of the text should be as follows:*

- *Din A4.*
- *Calibri, Times New Roman, Arial or Helvetica.*
- *Font size 11 or 12.*
- *Single line spacing.*
- *Margins: 2 cm on either side.*

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 case the candidates or their institutions have any questions about the **Real-Life Trials in Oncology Programme**, they can visit the webpage of the call for applications at <https://www.gustaveroussy.fr/en/clinical-research> and at [www.criscancer.org/programascris](http://www.criscancer.org/programascris) or e-mail to [RLtrials@gustaveroussy.fr](mailto:RLtrials@gustaveroussy.fr) and [clinicaltrials@criscancer.org](mailto:clinicaltrials@criscancer.org).

## 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.

### 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. Administrative Evaluation:

When evaluating eligibility, 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 a panel of experts**. Each proposal shall be reviewed by two different evaluators. The higher scored candidates will go through to the final evaluation stage.

Candidacies shall be evaluated in accordance with the criteria specified below in the section on **General evaluation criteria**.

### 3. Final Discussion and interview:

The **GRF-CRIS Evaluation Committee** will be in charge of the final phase of the evaluation process and 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.

The evaluation committee shall review and discuss all the finalist applications, which shall be evaluated in accordance with the criteria specified below in the section on General evaluation criteria.

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 centre a suitable place to develop the research project?
- b. To what extent is the investigator able to develop the trial at his/her hospital?

### 3.2 French Institution: 5 points

- a. To what extent is the centre a suitable place to develop the research project?
- b. To what extent is the investigator able to develop the trial at his/her hospital?

## 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](mailto:RLtrials@gustaveroussy.fr) and [clinicaltrials@criscancer.org](mailto: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 July 2022.

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 **31<sup>st</sup> December 2022 at 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 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](mailto:RLtrials@gustaveroussy.fr) or [clinicaltrials@criscancer.org](mailto: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 afore mentioned 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.

The host institutions shall deduct 2% of the budget for indirect costs and management expenses from the total funding awarded.