FAQs - Frequently Asked Questions
Real-Life Trials in Oncology Programme
Call for applications 2023

Who runs the Real-Life Trials in Oncology Programme?
The *Real-Life Trials in Oncology Programme* is run and co-funded by Gustave Roussy Foundation and CRIS Cancer Foundation.

What is the aim of the Real-Life Trials in Oncology Programme?
The *Real-Life Trials in Oncology Programme* aims to support the development of practice-changing clinical trials in France and Spain.

When is the call published and resolved?
The 2023 call of the *Real-Life Trials in Oncology Programme* opens for applications on **8th May 2023** and ends on **7th July 2023** at 24:00 Central European Time (CET).
The final resolution of the Programme will be announced by December 2023, on our websites:

- https://criscancer.org/es/convocatorias-real-life-trial-in-oncology-2023/
- https://www.gustaveroussy.fr/en/real-life-trials-oncology-programme

How many trials will be awarded?
The number of awardees will depend on the individual budget submitted by the top-ranked trials as the maximum amount to be funded per call is 1.5 M in 3 years.

What is the profile of the eligible candidate?
Real-Life Trials in Oncology Programme is open to clinical researchers of **any nationality** working at French or Spanish hospitals.
Candidates must be **specialist clinicians developing their trials in France or Spain** with clinical research experience and with the potential to develop transformative clinical trials.

Is it necessary to have a PhD degree to apply for the call?
A medical researcher can participate with or without a PhD if they meet the rest of the eligibility requirements.

How should the documentation be submitted to participate in the call for applications?
During the opening period of the calls (from 8th May 2023 till 7th July 2023) the applicant must send the documentation (Proposal Clinical Trial Form, and (Abbreviated) Curriculum Vitae of the Principal Investigator) by email to RLtrials@gustaveroussy.fr and clinicaltrials@criscancer.org.

Which are the eligible beneficiary centres?
- Public health entities with clinical-healthcare activity.
- Private not-for-profit health entities with clinical-healthcare activity linked or affiliated to the INSERM or SNS

* INSERM - France: Institut national de la santé et de la recherche médicale / National Institute of Health and Medical Research)
* SNS - Spain: Sistema Nacional de Salud / Spanish National Health System.

Can more than one investigator submit an application from the same host institution?
There is no limitation in the number of applications submitted from the same institution.

What are the requirements for the investigators?
Investigators must be **specialist clinicians developing their trials at French and Spanish hospitals** with clinical research experience. There should be two principal investigators, one in France and one in Spain for each trial proposal.

What is the duration of the research project?
The trials of the *Real-Life Trials in Oncology Programme* should run for a maximum of 3 years. In case of justifiable delay of the project, the principal investigator may ask for an extended period and the GRF-CRIS Cancer Committee will evaluate it, to confirm or deny the extension.

Can the duration of the research project be less than 3 years?
Support could be granted for a trial of less than 3 years, provided that the budget is adapted to the maximum attributable to each year.

In which languages can the documents be submitted?
All the documentation must be submitted in English.

Which institution should be listed as the host institution?
The host institutions are the ones where the two principal investigators (French and Spanish PIs) practice their clinical activities and the agreements with the candidates are formalized. Those institutions will be the recipients of the funding for the programme.

Who can be the sponsor of the trial?
The clinical trial sponsor is decided by the PIs. It must be a Spanish or French institution: hospital, research foundation, etc. Gustave Roussy Foundation and CRIS Cancer Foundation may also act as clinical trial sponsors.

Can the trial be multicenter?
There must be at least 2 institutions involved in the trial (the Spanish and the French host institutions) but the number of participating sites is not limited.

How is the number of pages in the "Proposal Clinical Trial Form" computed?
It is compulsory to use the template for the "Proposal Clinical Trial Form", that can be downloaded from the website or both Foundations (https://criscancer.org/es/convocatorias-real-life-trial-in-oncology-2023/ and https://www.gustaveroussy.fr/en/real-life-trials-oncology-programme)
Sections 1 ("Administrative information of the proposal"), 2 ("General information of the trial"), 12 ("Bibliography") and 13 ("Figures and graphics") are "not computed for

max number of pages". Therefore, the maximum of 2 pages only takes into account sections 3 to 11.

Does the budget have to be within the maximum established by the call? Can I apply for less money?

In no case the budget must exceed the maximum established in the call (500,000€/year), and may be equal to or less than this amount.

What type of expenses does the grant cover?

The financial envelope of the call includes both direct and indirect costs:

- Salary/Intensification of the investigator, nurse or study coordinator
- Recruitment of personnel
- Acquisition and maintenance of scientific equipment and fungible material.
- Travel and subsistence expenses
- Costs for the management of industrial and intellectual property rights related to the project
- Patent costs
- External audit costs
- Other expenses related to the development of the trial:
  - 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.
- Indirect costs (2% of the total budget)

How should the indirect costs/expenses be calculated?

From the total amount (maximum €1,500,000), a maximum of 2% is deducted for indirect costs of the receiving institution.

The indirect costs correspond to the total 2% of the trial, including the candidate's contract, the final audit, and the rest of the items.

Is there an obligation to carry out an external financial audit?

Yes, at least one external audit must be carried out at the end of the trial.

Gustave Roussy Foundation and CRIS Cancer Foundation reserve the right to request, if deemed necessary, any additional external audit. If so, the investigator will be expressly notified for such an audit.

Would it be possible to include the costs of external audits in the budget?

These costs can be included in the budget as a justifiable and chargeable cost for the project.

If the amount earmarked for external audit(s) is less than the amount originally budgeted for that purpose, the remaining funds could be allocated, upon request, to some other budgeted item.

Are there any modifications to the budget submitted once the project has been awarded?

The budget referred to the salary can be modified, within the limits established in the call and the limits established by the beneficiary entity.

The modification of this budget must be notified to the Gustave Roussy Foundation and CRIS Cancer Foundation during the monitoring of the trial and may in no case exceed the limit established in the terms and conditions of the call.

Once the grant has been awarded, who signs the agreement?

Gustave Roussy Foundation and CRIS Cancer Foundation sign an agreement with the host institutions.

Who manages the grant, the researcher or the institution?

The host institutions are the recipients of the funds, and are responsible for their justification. The management of the funds will depend on the procedures of the institutions.

How are the payments made?

For the *Real-Life Trials in Oncology Programme*, the first payment of the grant, referring to 50% of the total, will be made at the beginning of the execution of the trial (estimated for the middle of the year), and the rest at the end of the annuity.

Will financial evaluations of the grant be carried out?

The host institutions and Principal Investigators will submit economic justifications annually to Gustave Roussy Foundation and CRIS Cancer Foundation. They must include both the completed template and the list of expenses attributable to the trial and the attached documentation (invoices and forms) supporting each expense.

Will scientific evaluations of the trial be carried out?

Annually, a template for the scientific report provided by the Gustave Roussy Foundation and CRIS Cancer Foundation to the investigator must be filled in.

The scientific report for the final year may be submitted up to 2 months after the end of the agreement.

Are physician-researchers working in the hospital eligible for this support?

Yes.