**GRF-CRIS Real-Life Trials in Oncology Programme.**

**Call for Applicantions 2025.**

**Proposal of Clinical Trial form**

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| **GENERAL INSTRUCTIONS**   * Maximum Trial Proposal length is **2 pages** (item 3 to 10) * Proposal should be completed in **English**. * Din A4 * In Nunito, Calibri, Times New Roman, Arial or Helvetica, 11-12 size and single space. * Once finished, please convert the document to PDF format and send it, together with the budget and the CVs of the PIs, to the following e-mail addresses: * [RLtrials@gustaveroussy.fr](mailto:RLtrials@gustaveroussy.fr) * [clinicaltrials@criscancer.org](mailto:clinicaltrials@criscancer.org) |

1. **Administrative information of the proposal** (not computed for max number of pages)

|  |  |
| --- | --- |
| **France - Institution** |  |
| **France - PI name** |  |
| **France - PI Position** |  |
| **France - PI email** |  |
| **France - PI phone** |  |

|  |  |
| --- | --- |
| **Spain - Institution** |  |
| **Spain - PI name** |  |
| **Spain - PI Position** |  |
| **Spain - PI email** |  |
| **Spain - PI phone** |  |

1. **General information of the trial** (not computed for max number of pages)

|  |  |
| --- | --- |
| **Title** |  |
| **Code / Acronym** |  |
| **Keyword** |  |
| **Design of study** |  |
| **Study Phase** |  |
| **Patient Population** |  |
| **Number of sites / countries** |  |
| **Study Drugs (commercial / non-commercial)** |  |
| **Study calendar** |  |

1. **Rationale and hypothesis**

* Background information of the trial.
* State of the art of the research.
* Hypothesis.

1. **Objectives and endpoints**

* Primary and secondary objectives.
* Endpoints.

1. **Design / methodology**

* Population, variables, etc.
* Key inclusion/exclusion criteria.

1. **Treatment arms and follow-up**

* Description of the treatment arms.
* Treatment description, duration, and follow-up.

1. **Type of samples**

* Description of the biological samples (if any) and schedule.
* Biomarker analysis (if any).

1. **Data management and statistics**

* Sample size calculation.
* Data collection.
* Brief description of statistics and interim analysis (if any).

1. **Trial schedule**

* Flow chart of the Clinical Trial / Project
* Trial timelines: 1st Pt in, last Pt enrolled, 1° endpoint read-out, trial duration, …

1. **Study impact**

* Foreseen impact for patient outcome
* Was input from a patient group obtained?
* Why is this project strategic for cancer patients and society?

1. **Project/Trial resources and cost** (not computed for max number of pages)

* Resources available and other needed for Study development
* Estimated Budget (Use the budget template)
* Other funding sources (if any)



* Proposal of the payment schedule by study **milestones**

1. **Bibliography** (not computed for max number of pages)

* List of publications with reference number

1. **Figures** **and graphics** (not computed for max number of pages)