**Real-Life Trials in Oncology Programme 2023**

**Proposal of Clinical Trial**

This form must be filled out entirely in English.

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

|  |  |
| --- | --- |
| FRENCH PRINCIPAL INVESTIGATOR  |  |
| FRENCH INSTITUTION |  |
| PI INFORMATION (PHONE /E-MAIL) |  |

|  |  |
| --- | --- |
| SPANISH PRINCIPAL INVESTIGATOR  |  |
| SPANISH INSTITUTION |  |
| PI INFORMATION (PHONE /E-MAIL) |  |

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

|  |  |
| --- | --- |
| TITLE |  |
| CODE / ACRONYM |  |
| KEYWORDS |  |
| DESIGN OF STUDY |  |
| STUDY PHASE |  |
| PATIENT POPULATION |  |
| NUMBER OF STUDY SITES / COUNTRIES |  |
| STUDY DRUGS (COMMERCIAL / NON-COMMERCIAL) |  |
| STUDY CALENDAR |  |

1. **Rationale and hypothesis**
* Background information of the trial and 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 (maximum 1.500.000€)** (not computed for max number of pages)
* Resources available and other needed for Study development
* Estimated Budget and other funding sources (if any)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Concept** | **YEAR 1** | **YEAR 2** | **YEAR 3** | **TOTAL COST (€)** |
| Personnel salary |  |  |  |  |
| Study Design and Approval process cost |  |  |  |  |
| Monitoring and clinical operations |  |  |  |  |
| Insurance |  |  |  |  |
| Outsourcing of services (central lab, pharmacy) |  |  |  |  |
| Data management and Statistics |  |  |  |  |
| Study grant: Patient´s fee and clinical servicesStudy specific clinical procedures (above and beyond SOC):Blood tests, imaging, clinical visits, biopsies, molecular markers… as well as any treatment costs |  |  |  |  |
| Passthrough costs |  |  |  |  |
| Other project direct costs (courier, consumables, etc.) |  |  |  |  |
| Audit cost |  |  |  |  |
| Other costs |  |  |  |  |
| **Subtotal – study direct costs** |  |  |  |  |
| Indirect costs (2%) |  |  |  |  |
| **Total study cost** |  |  |  |  |

\* Differentiate the budget between both host institutions

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)

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**GENERAL INSTRUCTIONS**

* Maximum Trial Proposal length is 2 pages (item 3 to 10)
* Proposal should be completed in English language.
* Din A4
* Please complete in Calibri, Times New Roman, Arial or Helvetica 11-12 size and single space.
* Once finished the Proposal form, please convert the document to PDF format (no more than 4 Mb) and send it to the following e-mail addresses:
	+ RLtrials@gustaveroussy.fr
	+ clinicaltrials@criscancer.org