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)	

2. 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	

3. Rationale and hypothesis

- Background information of the trial and state of the art of the research
- Hypothesis

4. Objectives and endpoints

- Primary and secondary objectives
- Endpoints

5. Design/methodology

- population, variables, etc.
- Key inclusion/exclusion criteria

6. Treatment arms and follow-up

- Description of the treatment arms

- Treatment description, duration, and follow-up

7. Type of samples

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

8. Data management and statistics

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

9. Trial schedule

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

10. Study impact

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

11. 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 services Study 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

12. Bibliography (not computed for max number of pages)

- List of publications with reference number

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

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