ATTRACT

Accelerate Together Rare Cancer Treatment

Joint International Call

for research proposals on

Rare Cancer Drug Development

Pre-Proposal Application Form

Version 01
21 November 22

Pre-Proposal
Application Form

Instructions

1. Please fill out this application form, following the instructions below and in accordance with the 'Guidelines for Applicants'.
2. The project application consists of two parts: the part for the scientific expert review, and the part for the Patient Advocacy Committee (PAC) review. The project application is only accepted if both parts are fully and correctly completed.
3. Please fill out the project leader name and the project number in the footer of all pages of the proposal. The project number will be generated automatically upon opening of the application in GMS.
4. Please respect the following formatting constraints: Verdana font size 9, single line spacing, 2.5 cm margins.
5. Please respect the maximum word count constraints provided at each section as applicable. Applications should be submitted as one single PDF-file, formatted in DIN-A4, via the GMS-application system.
6. Allowed annexes are specified in section 6 and should be included within this PDF, with the exception of References which may be submitted as separate file (template available in GMS).
7. Proposals that do not meet the completion and formatting instructions will be declined.

Project title

Project acronym

1. Parties of the project

Sponsor/Promotor of the Study

Project leader

Name	
Position/Expertise	
Institute	
Department	
Address	
Country	
Phone	
E-mail address	

Project manager*

Name	
Position/Expertise	
Institute/Organization	
Address	
Country	
Phone	
E-mail address	
Management expertise/experience	

* Complete details if this person is already identified. If he/she will be recruited after funding, details can be provided later.

Regulatory officer*

Name	
Position/Expertise	
Institute/Organization	
Address	
Country	
Phone	
E-mail address	
Regulatory expertise/ experience	

* Complete details if this person is already identified. If he/she will be recruited after funding, details can be provided later.

Research Consortium Parties

(Work package leaders exclusively located in Belgium, France, Spain or the Netherlands)

	Country	Name of research partner (principal investigator)	Institution & Department	Phone	Email address
1					
2					
3					
4					
5					
6					
…	*Add rows as needed*				

Other participating parties

Type	Institutes/Organizations	Country
Co-funders	*Specify if a private party is involved and if public-private requirements are met*	
External Inclusion centres	*Outside Belgium, France, the Netherlands or Spain. Optional in pre-proposal phase; insert if already known*	
Service providers		
Other		

Collaboration
(maximum 150 words)

Briefly describe the nature and experience of the research consortium partners and participating parties, including the added value of any proposed multidisciplinary or public-private collaboration.

2. Project Description

Adherence to scope, aim and topic of this call
(maximum 150 words total)

Select if criterion has been met. Proposals need to cover **all four criteria** to be eligible for application.

☐ Tumour-type under investigation is a rare cancer according to the RARECARE-definition (incidence of less than 6 per 100,000 persons per year)

Please elaborate.

☐ Phase II/III clinical trial with a primary endpoint aiming for improvement of treatment of rare cancer

Please elaborate.

☐ International collaboration of at least 2 consortium partners from Belgium France, Spain or the Netherlands.

Please elaborate.

☐ Limited commercial interest and therefore need for non-commercial international funding

Please elaborate.

Background and Relevance
(maximum 350 words)

- Scientific background, previous research and evidence supporting the objective of the trial (i.e. state of the art),
- Unmet medical need; based on the target population, current standard of care, current life expectancy and potential impact on survival and/or quality of life of patients
- References may be added as appendix (separated document, template available via GMS).

Study design
(maximum 1000 words)

- Describe the trial design (including statistics, methodology)
- A schematic representation of the design and treatment arms, a flowchart and/or visit overview may be included as appendix

Study Synopsis	
Study phase/type	
Objective	
Primary endpoint	
Secondary endpoints	
Study design	*Methodology, set up, arms, # visits, procedures.* *A study flowchart/visit overview may be included as annex.*
Sample size	*Sample size and sample size calculation*
Number of sites, countries	
Statistical Analysis Plan	
Study population/Enrolment criteria	*For the preproposal application, a description of the population suffices*

3. Workplan

Milestones
A Gantt chart may be added as appendix (to be included in this PDF).

Milestone	**Duration (# months)**
EC/CA submissions	
EC/CA approvals	
Clinical Trial Agreements signed	
First Patient Enrolled	
Last Patient Enrolled	
Last Patient Last Visit	
Data collection Complete	
Analysis & Reporting	

Total project duration for funding	

Recruitment plan
(maximum 150 words)

- Describe the estimated number of enrolled patients per country (or site). Please provide the exact actual number of eligible patients treated per year per country (or site). Numbers may be derived directly from the clinic/national registry/etc.
- An enrolment projection graph may be included as appendix (to be included in this pdf)

Work packages & Responsible parties
(maximum 300 words)

- Describe the work packages needed to execute the trial, including Responsible parties and success indicators.

4. Development strategy*

*It is not obliged to have these regulatory steps completed at time of the application; applicants may describe the current status and future plans on these topics. However, the better elaborated and the further in progress, the higher the developmental potential.

Regulatory Strategy
(maximum 300 words)

Describe the foreseen regulatory strategy (either academic or commercial) to bring the product to clinical practice. This may include the following topics:

- market-authorization

- valorisation
- reimbursement
- implementation
- Business Development plan
- Intellectual Property strategy

Regulatory advice & Consultations
(maximum 300 words total)

If available, describe results/recommendations of previous consultations. If not available, please describe any future plans and envisioned next steps.

Orphan Designation	
(early) HTA advice	
National Competent Authority and/or EMA advice	

Regulatory Workplan
(maximum 300 words)

Describe in general which parties are, or need to be, involved to accomplish the strategy described above.

Application form continues on next page

5. Project Budget

Global financial plan

- Please describe the requested budget only.
- Please note that eligibility of costs is subject to national funding conditions. Overhead costs are not eligible for funding.

	Main Applicant		**Partner 1**		**Partner 2**		**Partner 3**		**Partner 4[2]**		**Total**	
Name (Principal Investigator)												
Institute												
Country (B, ESP, F, NL)												
Personnel	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:
- Project Manager	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:
- Regulatory-Officer	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:
- Scientist	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:
- PhD-Student	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:
- Technician	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:
- Other	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:	FTE:	€:
Materials	€		€		€		€		€		€	
Specify posts as applicable	€		€		€		€		€		€	
Service Providers	€		€		€		€		€		€	
- Patient costs (total)[1]	€		€		€		€		€		€	
- External Inclusion Centers (outside B, ESP, F, NL)	€		-		-		-		-		-	
- Insurance	€		€		€		€		€		€	
- EC and CA fees	€		€		€		€		€		€	
- Other	€		€		€		€		€		€	

Other direct costs	€	€	€	€	€	€
Total requested budget	€	€	€	€	€	€

[1] Total costs per institute based on number of patients x patient fee, including costs for drug/compound, study procedures and assessments. Provide specification below.
[2] Add and copy column in case of more than 4 consortium partners

Specification Per-Patient costs
Please specify how the per-patient fee is established, listing a cost-specification of services that are included in the per-patient-fee.

Specification External Inclusion Centers
For External Inclusion Centers outside Belgium, France, the Netherlands or Spain, please list the requested budget per inclusion center, based on the per-patient-fee and site-specific enrolment target.

Site (Name/Country)	**Per-patient fee** (as specified above)	**Enrolment target/# patients**	**Site budget**
… (insert rows as needed)			

Overall budget
Please provide an indication of the overall project budget

	Amount (€)	**Comment/justification**
Requested Budget (as above)		
Own Contribution		
Co-funding (if applicable)		

Total		

6. Annexes
(to be included in this pdf)

The following annexes are allowed:
- Diagrams and Figures
- Study flowchart/visit overview
- GANTT chart
- Enrollment projection graph
- Statements/Letters of Intent, if available

References can be submitted as separate document; template available in GMS.

Application form continues on next page

Pre-Proposal
Patient Advocacy Committee
Application Form

1. This section of the pre-proposal application must be completed in layman's language, so that non-scientists, people without scientific/medical background, can read and assess the preproposal. Using layman's language not only ensures that the patient advocacy committee (PAC) gets a clear and structured representation of your project, but also gives the PAC an idea of the way the researcher communicates with patients.
2. When writing a project application, it is important that all evaluation criteria are filled in and interpreted correctly. If certain criteria require additional clarification, please do not hesitate to contact us.
3. The concrete guidelines for drawing up a patient-oriented project (application), which meets the requirements of the PAC, can be found in the Guidelines for Applicants (Page 10, Guidelines on Patient Centricity & Patient Involvement).
4. If you would like more information about this application and/or the PAC, you can always contact the contact person of your local funding organization).

1 | General Information about the project
Project title
Project leader
Research institution of the project leader
Duration for the project
Requested budget
Participating countries and centers

2 | Glossary

Please clarify important terms/words and abbreviations mentioned in the application form here:

-
-
-

3 | Summary of the project (in layman's language)

(max. ½ page)

4 | Patient relevance

(max. ½ page)

Who are the patients and what type(s) of cancer are involved? What is the current situation for these patients (in terms of diagnosis, treatment, side effects, …)*? What are the needs of the patients that this project wants to address?

*When using numbers, please state the source

What is the aim of the project? How are you going to achieve this?
What will be the (potential) impact of the results of the trial on the lives of these patients?

5 | Patient burden (max. ½ page)
Which interventions will the participating patients receive in this project? What are the possible risks and side effects? Explain why the benefits of this drug outweigh the possible risks and side effects.
What actions will be taken to minimize the burden (travel burden, number of visits, side effects, …) for the participating patients?

6 | Patient participation (max. ½ page) For more information and background on patient participation, as well as how to achieve it, please consult the 'Guidelines patient centricity and involvement' (page 10 of the Guidelines for

Applicants)
To what extent will patients have added value within your research project? Please note that we do not refer to the participation of patients in the clinical trial.
Specify the actions that have already been and will be taken to actively involve patients in the preparation of the project.
Specify the actions that will be taken to actively involve patients during the conduction of the project.
Patient dissemination: specify how the results of this project will be communicated to cancer patients and the cancer community

Application form completed