ATTRACT

Accelerate Together Rare Cancer Treatment

Pre-proposal application form

Disclaimer
This document is aimed at informing potential applicants for the ATTRACT 2025 call. The actual pre-proposal application form, provided in the Fondation ARC online submission system, might differ from this example.

APPLICATION FORM

PROJECT OVERVIEW

Identification

Project title	
Title	255cc max
Publishable project title	255cc max
Acronym	255cc max
I am informed that in case of funding, the "Publishable project title" and "Acronym" may be used by the ATTRACT partners in actions aimed at the general public, donors, subscribers to the various communication media and I expressly agree to this use.	☑

Project summary

Study population	
Choose one or several	◦ Pediatric (0-14) ◦ Adolescent (15-17) ◦ Young adult (18-30) ◦ Adult ◦ Elderly/Geriatric ◦ Not relevant

Cancer location(s) of interest*
Specific(s) location(s): To select from a list or enter manually

General information

How many countries and centres are involved?	300cc max

SCIENTIFIC ABSTRACT

Keywords

List of keywords
- KEYWORD 1
- KEYWORD 2
- KEYWORD 3
- KEYWORD 4
- KEYWORD 5

Abstract

Scientific abstract

Please provide a scientific abstract of the project.	2000cc max

PROJECT LEADER

Profile information

Contact information

Civility	-
Title	-
Last name	-
First name	-
Birth name	-
Birthdate	-
Nationality	-
Second nationality	-
ORCID iD	-
Other phone number	-
Other E-mail	-
Contact email	-
Contact phone	-

Institution

Research structure	Institution name (Managed by First name LAST NAME) Address Postcode CITY - **COUNTRY**
Laboratory Name :	-
Team :	-
Address :	-
Administrative affiliation	*Mandatory information if laboratory in France. To select from a list of choices (CNRS/ INSERM units, University...)*

Research expertise

Please describe briefly your research expertise demonstrating the competence to carry out this project.	800cc max

NATIONAL COORDINATORS

Instructions

Please provide information about national coordinators, exclusively located in Belgium, France, Spain or the Netherlands For each partnering country, one national coordinator should be appointed. If the project is selected, he/she will be the national contact point for the project follow-up and will be responsible for the funds granted at his/her national level.

Participation commitment	Declaration of commitment (template to be provided online) - PDF format

NATIONAL COORDINATOR 1

Profile information

Reference country	To select from the list: Belgium/France/Netherlands/Spain
Contact information	
Civility	-
Title	-
Last name	-
First name	-
Birth name	-
Birth date	-
Nationality	-
Second nationality	-
ORCID iD	-
Contact phone number	-
Contact E-mail	-
Second E-mail	-

Institution

Research structure	Institution name (Managed by First name LAST NAME) Address
Laboratory Name :	-
Team :	-
Address :	Address Postcode CITY - **COUNTRY**
Administrative affiliation	*Mandatory information if laboratory in France. To select from the list of choices (CNRS/ INSERM units, University...)*

Laboratory Manager

Civility :	-
Last name :	-
First name :	-

Research expertise

Please describe briefly his/her research expertise demonstrating the competence to carry out this project.	800cc max

NATIONAL COORDINATOR 2

Profile information

Reference country	To select from the list: Belgium/France/Netherlands/Spain

Contact information

Civility	-
Title	-
Last name	-
First name	-
Birth name	-
Birth date	-
Nationality	-
Second nationality	-
ORCID iD	-
Contact phone number	-
Contact E-mail	-
Second E-mail	-

Institution

Research structure	Institution name (Managed by First name LAST NAME) Address

Laboratory Name :	-
Team :	-
Address :	-
Administrative affiliation	*Mandatory information if laboratory in France. To select from a list of choices (CNRS/ INSERM units, University...)*

Research expertise

Please describe briefly his/her research expertise demonstrating the competence to carry out this project.	800cc max

NATIONAL COORDINATOR 3

Profile information

Reference country	To select from the list: Belgium/France/Netherlands/Spain
Contact information	
Civility	-
Title	-
Last name	-
First name	-
Birth name	-
Birth date	-
Nationality	-
Second nationality	-
ORCID iD	-
Contact phone number	-
Contact E-mail	-
Second E-mail	-

Institution

Research structure	Institution name (Managed by First name LAST NAME) Address Postcode CITY - **COUNTRY**
Laboratory Name :	-
Team :	-
Address :	-
Administrative affiliation	*Mandatory information if laboratory in France. To select from a list of choices (CNRS/ INSERM units, University...)*

Research expertise

Please describe briefly his/her research expertise demonstrating the competence to carry out this project.	800cc max

PARTIES OF THE PROJECT

Sponsor/Promotor of the study

Name	255cc max

Patient organisations

Please describe the patient organisations involved and elaborate on their role. If not applicable, write N/A.	1000cc max
If patient organisations are involved in the project, please provide a letter of commitment. Otherwise, load a blank page.	Letter of commitment / Blank page - PDF format

Other participating parties

Are external inclusion centres (i.e. centres from outside Belgium, France, the Netherlands or Spain) involved in the project ?	1000cc max; *If applicable, please elaborate. If not applicable, write N/A.*

Industrial parties

Please describe the for-profit parties involved and elaborate on the role and relation with the company. If not applicable, write N/A.

1000cc max; *If applicable:*

- Describe if there is commitment from the company to support the study, and what kind of support (e.g. in-kind, financial, supply of study drugs)

- Is there commitment (yes/no) from the company to support further development in case of positive study results (provide further information in Section Development strategy)

- Are IP agreements already been made (provide further information in Section Development strategy)

If industrial/for-profit parties are involved in the project, please provide a letter of commitment. Otherwise, load a blank page.	Letter of commitment / Blank page - PDF format

Co-funders

Please list the co-funders involved. If not applicable, write N/A.	1000cc max; *Please indicate :* *- If they are non-profit or for-profit organizations* *- The type and amount of their contribution* *- In case of industrial partners, provide additional information in the dedicated section*

If co-funders are involved in the project, please provide a letter of commitment. Otherwise, load a blank page.	Letter of commitment / Blank page - PDF format

Other parties

Please describe the name and role of other parties involved, if applicable.	1000cc max
Please provide a letter of commitment	Letter of commitment / Blank page - PDF format

■ Collaboration

Briefly describe the nature and experience of collaboration between the Project Leader, the National Coordinators and the participating parties, including the added value of any proposed multidisciplinary or public-private collaboration.	1000cc max

■ Project manager

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

Name	-
Position/Expertise	-
Institute/Organization	-
Address	Address Postcode CITY - **COUNTRY**
Phone	-
E-mail address	-

PROJECT DESCRIPTION

■ Adherence to scope, aim and topic of this call

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	800cc max
Phase II/III clinical trial with a patient-relevant primary endpoint (f.e. improvement of quality-of-life and/or survival while at least maintaining quality of life)	☑
Please elaborate	800cc max
International collaboration of at least 3 consortium partners from Belgium, France, Spain or the Netherlands.	☑
Please elaborate	800cc max
Limited commercial interest and therefore need for non-commercial international funding	☑
Please elaborate	800cc max

Background and Relevance

Please elaborate on the study background and relevance	6000cc max - *Please describe:* *- 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

10 references max.

The reference list is to be entered online. Publication available on Pubmed can be automatically found with the corresponding PMID. Any publication that is not available or cannot be found automatically may be entered manually.

Study synopsis

Study phase/type	Phase x
Patient population with main eligibility criteria	800cc max
Investigational medicinal product(s)	800cc max
Objective	800cc max
Primary and secondary endpoints	800cc max
Study design	800cc max; *Methodology, set up, arms, # visits, procedures.*
Sample size and calculation	800cc max
Number of sites, countries	800cc max
Statistical analysis plan	800cc max
Please provide a schematic representation of the study design and treatment arms	Schematic - PDF format

Workplan

Milestones

	Estimated timeline	Duration (months)
EC/CA submissions	Text box - ex: Q2 YYYY	0.0
EC/CA approvals	Text box - ex: Q2 YYYY	0.0
Clinical Trial Agreements signed	Text box - ex: Q2 YYYY	0.0
First Patient Enrolled	Text box - ex: Q2 YYYY	0.0
Last Patient Enrolled	Text box - ex: Q2 YYYY	0.0
Last Patient Last Visit	Text box - ex: Q2 YYYY	0.0
Data collection Complete	Text box - ex: Q2 YYYY	0.0
Analysis & Reporting	Text box - ex: Q2 YYYY	0.0

Please upload a GANTT chart	GANTT Chart - PDF format

Recruitment plan

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.	1000cc max
Please provide a realistic enrolment projection graph	Enrolment projection graph - PDF format

Global workplan

Describe the work packages needed to execute the trial, including responsible parties and success indicators.	2000cc max

DEVELOPMENT STRATEGY

Product description

Please provide information about the study drug(s): what is the active substance? Is it repurposing (on-patent or off-patent) or a novel product?	1000cc max

Consultation with regulatory authorities

I am informed that in case of selection to the full proposal stage, my application could be transferred to and evaluated by competent regulatory authorities.	☑
If available, describe results/recommendations of previous consultations. If not available, please describe any future plans and envisioned next steps.	2000cc max

Regulatory strategy

Describe the foreseen regulatory strategy (either academic or commercial) to bring the product to clinical practice. This may include the following topics: - market-authorisation - valorisation - reimbursement - implementation - Business Development plan - Intellectual Property strategy.	2000cc max

BUDGET REQUEST

Global financial plan

Budget request	
Project duration (months)	-
Total requested budget	**0 €**
Additional resources	**0** €
Total project cost	0 €
Justification for additional resources	Additional resources obtained or to be obtained (co-funding, own contribution, other)

Overview

0 € Year 1	0 € Year 2	0 € Year 3	[…]	0 € Total

Detailed budgets

- Project Leader — 0 €

Personnel costs

- Year 1	- Year 2	- Year 3	[…]	0 € Total

Please elaborate - 3000cc max

Operational costs

- Year 1	- Year 2	- Year 3	[…]	0 € Total

Please elaborate - 3000cc max

Service providers

- Year 1	- Year 2	- Year 3	[…]	0 € Total

Please elaborate - 3000cc max

Travel expenses

- Year 1	- Year 2	- Year 3	[…]	0 € Total

Please elaborate - 3000cc max

Other

- Year 1	- Year 2	- Year 3	[…]	0 € Total

Please elaborate - 3000cc max

- National coordinator 1/2/3 — 0 €

As for the Project Leader, for each National Coordinator, a detailed budget (per type of fee / per year) should be provided.

External Inclusion Centres

Inclusion centres outside of Belgium, France, Spain or the Netherlands. Please detail the list of external inclusion centres, and for each, specify the estimated number of patients to be recruited and the per-patient fee. The total site budget will be calculated automatically.

Site (name/country)	Per-patient fee	Enrolment target	Site budget
Site name or Country	1,00	1,00	1,00
Site name or Country	1,00	1,00	1,00
Site name or Country	1,00	1,00	1,00
Total			**3,00**

If applicable, please specify in details how the per-patient fee is established for external inclusion centres, itemizing each cost that is included in the per-patient fee.	1000cc max

PAC EVALUATION SECTION

Instructions

This section of the application form must be completed inlayman's language, so that non-scientists, people without scientific/medical background, can read and assess the proposal. 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. **Please note that the PAC will only evaluate this section of the application form.** They do not have any insight into the previous scientific application form (except for the project overview - section 1), nor any appendices or references attached to the scientific application form.

Glossary

Please clarify important term/words and abbreviations mentioned in the application form here:	1500cc max
Figures and diagrams can be provided to support your text.	2 files max - Image or PDF format

Layman summary of the project

Summary	5000cc max

Patient relevance

Who are the patients and what type(s) of cancer are involved?	1500cc max; *Please describe what is the current situation for these patients (in terms of diagnosis, treatment, side effects, ...)* and 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?	1500cc max
What will be the (potential) impact of the results of the trial on the lives of these patients?	1500cc max

Patient burden

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.	2000cc max
What actions will be taken to minimize the burden (travel burden, number of visits, side effects, ...) for the participating patients?	2000cc max

Patient participation

To what extent will patients have added value within your research project?	1500cc max; *Please note that we do not refer to the participation of patients in the clinical trial.*

Patient Involvement Plan

Specify the actions that have already been and will be taken to actively involve patients in the preparation of the project (i.e. identification of research questions).	900cc max; *For each action: please describe the estimated start and end dates as well as the estimated contributors' time commitment, the expected benefit and outcome, and specify the method(s) or setting(s) used to reach these objectives (e.g. structured interviews, surveys, focus groups, advisory board meetings, or committee meetings).*
Specify the actions that have already been and will be taken to actively involve patients in the study design and the protocol development.	900cc max; *For each action: please describe the estimated start and end dates as well as the estimated contributors' time commitment, the expected benefit and outcome, and specify the method(s) or setting(s) used to reach these objectives (e.g. structured interviews, surveys, focus groups, advisory board meetings, or committee meetings).*
Specify the actions that will be taken to actively involve patients during the conduction of the project (e.g. actions from study management and process to data analysis and interpretation of results).	1800cc max; *For each action: please describe the estimated start and end dates as well as the estimated contributors' time commitment, the expected benefit and outcome, and specify the method(s) or setting(s) used to reach these objectives (e.g. structured interviews, surveys, focus groups, advisory board meetings, or committee meetings).*
Specify how the results of this project will be communicated and implemented to cancer patients and the cancer community.	900cc max; *For each action: please describe the estimated start and end dates as well as the estimated contributors' time commitment, the expected benefit and outcome, and specify the method(s) or setting(s) used to reach these objectives (e.g. structured interviews, surveys, focus groups, advisory board meetings, or committee meetings).*