

**Joint call for International Clinical Trial on
Rare Cancer Drug Development**



ATTRACT

Accelerate Together Rare Cancer Treatment



Fondation
pour la recherche
sur le cancer



fundación científica
asociación española
contra el cáncer



RISING TIDE.
Foundation for Clinical
Cancer Research

Guidelines for Budget Request

Version 2, 31 July 2024

BUDGET

The estimated total budget for the ATTRACT-call is up to 12.4 million euro, provided by the 6 collaborating funding organisations: Spanish Association against Cancer Scientific Foundation, Anticancer Fund, Fondation ARC, Kom Op Tegen Kanker, KWF Dutch Cancer Society and Rising Tide Foundation for Clinical Cancer Research.

No estimated budget per trial is foreseen at the moment as the amount depends on the scientific and medical needs and should be justified in the requested budget. Therefore, no estimation on the number of trials to be funded can be made. However, it is highly recommended to respect the available budget mentioned in Appendix 1.

FUNDING CONDITIONS

Project Leaders and National Coordinators are the funding recipients of the ATTRACT grant. Consequently, they should take note of individual national rules/funding conditions (see Appendix 1) while constructing their budget request and contact their national contact person for specific questions. Project Leader and National Coordinators will have to co-sign a declaration of commitment letter (template will be provided online), ensuring they have all reviewed and agreed with the whole submitted application, including the budget request.

Applicants with external inclusions centres outside Belgium, France, Spain or the Netherlands should also consult the funding terms for external inclusion centres (see Appendix 2).

The project duration i.e. the funding period cannot exceed 10 years.

ELIGIBLE TYPE OF FEES

The global financial plan must be filled online. Details of the budget request for the Project Leader and the National Coordinators will have to be provided within the application form.

The categories of fee types available are as follows:

- Personnel costs
Personnel involved on the project for whom all or part of the salary will be covered by the grant, proportional to the extent to which they are employed on the project. Please indicate their status and their implication (FTE).
- Operational costs
Direct operating costs.
- Service providers
*External or internal service providers, Insurance, EC/CA fees. Describe here the total costs per internal inclusion site based on the number of patients*patient fee, including costs for drug/compound, study procedures and assessments.*
- Travel expenses
Costs related to meeting attendance.
- Other
Please list and justify other direct costs.

Detail of eligible and ineligible costs falling into the previous categories is dependent on individual national rules/funding conditions as described in the Appendix 1. Please consult the Appendix 1 carefully.

Overhead costs and indirect costs are not eligible for funding.

BUDGET REQUEST FOR EXTERNAL INCLUSION CENTERS

The budget request for external inclusion centres should not exceed 20% of the total requested budget, with a maximum of 1 million euros. This budget will be provided by the Anticancer Fund and/or Rising Tide Foundation for Clinical Cancer Research and/or KWF Dutch Cancer Society (if a Dutch applicant is involved). Please refer to Appendix 1 and Appendix 2 to consult the funding terms.

Budget for external inclusion centres will be indicated aside from the national budgets. For each site to be involved in the project, the total cost will be automatically calculated based on the per-patient fee and site-specific enrolment target. Specification about how the per-patient fee is established, listing a cost-specification of services that are included in the per-patient fee, is mandatory.

If the list of external inclusion sites is not precisely defined at the time of the pre-proposal submission, please indicate the countries you are prospecting in to estimate a total country budget, rather than a site budget. Please note that the precise list of external centres involved in the project will have to be provided at the full-proposal stage.

CONTACTS

Appendices 1 and 2 refer to national contact person(s) for specific questions.

For any general or technical question, the Call Secretariat can be contacted at attract@fondation-arc.org.

APPENDIX 1. National rules/funding conditions

COUNTRY	BELGIUM
Funding organisation	Kom op tegen Kanker
National contact persons	<p>Robrecht Lembrechts Robrecht.Lembrechts@komoptegenkanker.be +32 2 486 21 17</p> <p>Erwin Lauwers Erwin.lauwers@komoptegenkanker.be +32 2 225 83 17</p>
Funding commitment	€ 2M
Maximum funding per grant awarded to a project partner	There is no maximum funding per grant; the amount depends on the scientific and medical needs and should be justified in the requested budget. However, it is highly recommended to respect the available budget of each funding organization.
Eligibility of projects	<p>Please refer to the call text.</p> <p>To apply for funding as Project Leader from Belgium, a research consortium must be established with at least one partner (non-profit R&D actor) from the Flemish Community and one partner from the (Belgian) French-speaking community. This condition does not apply if the Project Leader is from one of the other participating countries.</p>
Eligibility of a partner as a beneficiary institution	Non-profit R&D actors in Belgium: universities, hospitals and research institutions. Research institutions are eligible for funding provided that the research is to be conducted in Belgium without direct commercial purposes.
Eligibility of project leader or national coordinator	The project manager/PI should hold a doctoral degree or have corresponding qualifications and is experienced in the field related to the project. The PI must be employed in an eligible institution.
Eligibility of costs, types, and their caps	<p>- Staffing costs: the salary of both scientific and technical staff, proportional to the extent to which they are employed on the project, can be included. The salary of staff members (ZAP) is excluded. The following salary scales apply: PhD student: max. €57,000/year (1 FTE) Technical /administrative staff (ATP), data nurse: max. €70,000/year (1 FTE) Scientific staff / researcher: max €88,000/year (1 FTE) Postdoctoral researcher: max. €112,000/year (1 FTE, max. 0.5 FTE/ project year)</p> <p>Divergence from these scales is possible, where this is sufficiently substantiated and where it can clearly be shown that this is necessary for the project.</p>

- **Operating costs:** the operating costs eligible are those directly attributable to the project. It must be possible to trace back these costs in the accounting records and via invoices. In all cases, only the costs proportional to the use in the project can be included.

For the part of the funding depending on the number of patients that will be included at each site, it is requested that the budget is expressed as much as possible in the form of a 'start-up fee' (costs necessary to start the clinical trial within the institution) and/or a 'fee-per-patient' (costs necessary for the follow-up and treatment of a patient in the context of the study). Both fees in this context may include both personnel and operating costs.

- **Publication costs** can be included up to a maximum of €2,000 per project year. Publication costs can only be contributed for publication of scientific articles that have undergone peer review and are (also) available in an open access.

- Under no circumstances may **overhead costs (indirect costs) and avoidable VAT** be included.

- The **cost of purchase of medication is not eligible for inclusion as an operating cost**. As an exception, approval may be given to include the cost of off-patent medication, if the scientific expert committee concludes that the availability of the medication cannot be guaranteed in any other way and that the cost is essential for the execution of the research project.

- **Travel costs:** only for project management meetings. The total amount of travel expenses should not exceed 10.000 euro per project. **Conference costs** are excluded.

- In exceptional cases, **equipment costs** may be included in the project budget. The conditions for this are:

- The equipment/items in question must be clearly attributable to the execution of the project. It must be possible to demonstrate a clear relationship between the equipment and the project goal.
- The subsidised cost is the depreciation over the course of the project, commensurate with the use of the equipment/items for the project. The depreciation rules applied must correspond with the accounting practice within the relevant research institution.

Equipment rental costs are also eligible for inclusion. For rental costs, the same conditions apply as described above.

Further guidance

Please contact one of the National contact persons listed if you have questions regarding the above.

COUNTRY	FRANCE
Funding organisation	Fondation ARC pour la recherche sur le cancer
National contact persons	<p>Charlotte Audoynaud Project manager, Translational Research & Innovation 9 rue Guy Môquet 94803 Villejuif Cedex, France attract@fondation-arc.org +33 (0)1 45 59 58 45</p>
Funding commitment	€ 3M
Maximum funding per grant awarded to a project partner	There is no maximum funding per grant; the amount depends on the scientific and medical needs and should be justified in the requested budget. However, it is highly recommended to respect the available budget of each funding organization.
Eligibility of projects	Please refer to the call text.
Eligibility of a partner as a beneficiary institution	<ul style="list-style-type: none"> - Public research institutions (university, EPST, EPIC, etc.) - Non-profit organizations (associations, foundations, etc.) - Hospitals or other health care providers (CHU, CRLCC, etc.)
Eligibility of project leader or national coordinator	<ul style="list-style-type: none"> - Public research institutions (university, EPST, EPIC, etc.) - Non-profit organisations (associations, foundations, etc.) - Hospitals or other health care providers (CHU, CRLCC, etc.)
Eligibility of costs, types, and their caps	<ul style="list-style-type: none"> - <u>Staffing costs:</u> <ul style="list-style-type: none"> • Recruitment of non-permanent staff (post-doctoral researchers, engineers, technicians, data manager or other) for a period not exceeding the grant period • Salary costs for permanent staff may be included in the budget except for civil servants • Not eligible: salaries of PhD students; traineeship grants for students; salaries of clinical personnel employed as individual contractors ("vacataires") - <u>Operating costs:</u> <ul style="list-style-type: none"> • Consumables • Software licenses and fees • Computers hardware can be covered by the funding only if mentioned in the provisional budget • Acquisition work in the field (<i>i.e.</i>, travel costs involved in investigations, etc.) • Publication costs • Not eligible: office supplies; subscription to scientific society and/or membership fees, equipment maintenance costs - <u>Service provisions:</u> Service provisions are allowed. However, private sector service companies (start-up, biotech, etc.) should not claim any intellectual property rights in relation to the results that may arise from the project.

- **Travel costs:** attending symposiums, conferences, project management meetings. Except for a particular situation (evidence must be provided), the total amount of travel expenses must not exceed a **maximum of 4%** of the total requested budget for the partner.

- **Indirect costs/overheads are not eligible**

Except for the travel costs, there are no restrictions on how the budget is allocated, particularly how much is dedicated to staffing costs.

Further guidance

Please contact the national contact person listed if you have questions regarding the above.

COUNTRY	SPAIN
Funding organisation	Spanish Association against Cancer Scientific Foundation (FC AECC)
National contact persons	Marina Reguero Simón International Projects Manager C/Teniente Coronel Noreña, 30 28045 Madrid Marina.reguero@contraelcancer.es
Funding commitment	€ 1M
Maximum funding per grant awarded to a project partner	FCAECC does not have a maximum funding per grant; the amount depends on the scientific and medical needs and should be justified in the requested budget. However, it is highly recommended to respect the available budget and anticipated number of fundable research groups mentioned above.
Eligibility of projects	Please refer to the Call Text
Eligibility of a partner as a beneficiary institution	<ul style="list-style-type: none"> - Hospitals attached to the patronage law 49.2002 - Research Centres attached to the patronage law 49.2002 - Universities
Eligibility of project leader or national coordinator	<p><i>Reminder: Each transnational consortium must nominate a coordinator from one of the ATTRACT-call countries/regions. The coordinator will be responsible for the internal scientific management and for the external representation towards the Call Secretary and the CSC. Each consortium partner will be represented by one principal investigator, who will be the contact person for the respective national/regional funding organisation.</i></p> <ul style="list-style-type: none"> - Hospitals attached to the patronage law 49.2002 - Research Centres attached to the patronage law 49.2002 - Universities
Eligibility of costs, types, and their caps	<p>For the research project:</p> <ul style="list-style-type: none"> - Services: Technical services and Outsourcing, no more than 25% of the budget can be allocated to this category - Personnel costs: no more than 40% of the budget can be allocated to personnel costs - Travel and accommodation: Travel, diets and congresses must not exceed 5% of the total budget. Only for the partner team members and for project management meetings; Include: Travel and subsistence expenses, registration and attendance at conferences and meetings, brief stays of researchers. - Indirect costs/overheads: not eligible. <p>For more details, a further guideline document can be shared upon request.</p>

Further guidance

Please contact the national contact person listed if you have questions regarding the above.

COUNTRY	THE NETHERLANDS
Funding organisation	KWF Dutch Cancer Society
National contact person	Tessa Nauta Science Liaison Drug Development tnauta@kwf.nl +31205700437
Funding commitment	€ 5M, including € 0.5M for external inclusion centres
Maximum funding per grant awarded to a project partner	There is no maximum funding per grant; the amount depends on the scientific and medical needs and should be justified in the requested budget. However, it is highly recommended to respect the available budget of each funding organization.
Eligibility of projects	Please refer to the Call Text.
Eligibility of a partner as a beneficiary institution	<p>Eligible:</p> <ul style="list-style-type: none"> - University - Medical centre - Research institute, for example: <ul style="list-style-type: none"> o An NWO institute o A KNAW institute o Netherlands Cancer Institute o Princess Máxima Centre <p>Upon approval:</p> <ul style="list-style-type: none"> - Peripheral hospitals, including: <ul style="list-style-type: none"> o hospitals affiliated with the Association of Top Clinical Teaching Hospitals (in Dutch: Samenwerkende Topklinische Ziekenhuizen, STZ) - Organisations, for example: <ul style="list-style-type: none"> o Universities of applied sciences o So-called Public Benefit Organisations (in Dutch: Algemeen Nut Beogende Instelling, or ANBI) o Data management centres <p>Not eligible:</p> <ul style="list-style-type: none"> - Organisations*, for example: <ul style="list-style-type: none"> o SMEs (small to medium enterprise) o Large companies - Foreign organisations (with the exception from external inclusion centres, as described in Appendix 2) <p>For details and the full requirements, please refer to Guidelines KWF Kankerbestrijding Appendix 1 (KWF Website)</p>
Eligibility of project leader or national coordinator	<p>Project Leader:</p> <p>The researcher who leads the Dutch part of the proposal on behalf of the Dutch Lead Institute, holds a PhD at the starting date of the Project, has final responsibility for execution and quality of the Dutch Project, the Dissemination and</p>

	Exploitation. The Project Leader is during the duration of the Project linked to the Dutch Lead Institute, through an employment contract, which includes sufficient hours to be able to perform the work as a Project Leader. Other research members: Please refer to the KWF Finance conditions at the KWF website (in Dutch) (KWF Website)
Eligibility of costs, types and their caps	Costs that are not eligible for funding are infrastructural costs at company level and costs for materials and personnel that are not related to the project. Overhead costs are not eligible for funding. For details and other requirements, please refer to Guidelines KWF Kankerbestrijding Section 10.11 (KWF Website)
Further guidance	For detailed guidance and conditions, please refer to the KWF Finance Conditions and the KWF Guidelines at the KWF Website (KWF Website)

IN CASE KWF PROVIDES FUNDING FOR THE EXTERNAL INCLUSION CENTRES, KWF WILL PROVIDE THIS BUDGET TO THE DUTCH NATIONAL COORDINATOR, AND THE DUTCH NATIONAL COORDINATOR IS RESPONSIBLE FOR DISTRIBUTION OF THE BUDGET AMONG THE EXTERNAL INCLUSION CENTRES.

External inclusion centre (recruitment site outside Belgium, France, Spain or the Netherlands – preferably located within geographical Europe)	<ul style="list-style-type: none"> - The centre only includes patients for the clinical trial and has no active research role in the project. - The centre is preferably located within Europe. If the applicant wishes to include inclusion centres outside of Europe, it should be limited, and a strong rationale and justification should be provided on the need, feasibility, and prior existence (if any) of the intercontinental collaboration. - This centre has no right to the overall project results and analyses. An exception to this may be that an external inclusion centre retains the right on its own generated data, information, samples, knowledge and inventions. These agreements are specified in the project specific clinical trial agreement.
Budget for the external inclusion centres	<ul style="list-style-type: none"> - KWF provides a total budget of €0,5M for external inclusion centres. KWF will only provide funding for the external inclusion centres if a Dutch applicant is involved. - The budget should be listed in the dedicated section “External Inclusion Centres”. - The budget should be based on a per-patient-fee and estimated enrolment numbers. - The structure/build-up of the per-patient-fee should be specified and substantiated with a cost-specification of services that are included in the per-patient-fee. Start-up fee for support in the approval and reporting process of the Ethics Committee, or other applicable authorities, and monitoring of the external inclusion centres should be included in the per-patient-fee calculation. - The structure/build-up of the per-patient-fee may include both personnel and operating costs that is linked to the external inclusion centre. - The requested budget should be listed as amount per inclusion centre, based on the per-patient-fee and site-specific enrolment target (i.e. estimated enrolment number per site, as specified in the Clinical Trial Agreement). - For each site, the requested budget should be substantiated with a quotation (including taxes, if applicable), or appendix of the Clinical Trial Agreement describing financial agreements.
Accountability of the external inclusion centre	<ul style="list-style-type: none"> - Financial accountability will be the responsibility of the Dutch national coordinator. - Actual realised expenditures on the inclusion centres should be reported in the financial end report of the project by the Dutch national coordinator and be accounted for by substantiated invoices of each centre. The financial end report needs to be approved by an external accountant and will be shared with KWF.

Coordination of the external inclusion centre

- In case major discrepancies between the estimated budget and actual expenditures arise, or other issues with the financial accountability of the external inclusion centre-costs occur, the Dutch national coordinator and/or the Dutch national coordinators funding organisation immediately will inform KWF, as well as the JCS, so appropriate corrective actions can be taken.
 - Expenses and quality will be further monitored by the Dutch national coordinators funding organisation, in accordance with the Dutch national coordinators funding organisation conditions.
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- Funding provided by KWF for external inclusion centres will be documented in a letter of grant, provided by KWF, as applicable, to the Dutch national coordinator.
 - The letter of grant will specify at least the following information for each supported project: Project title, amount of provided budget; specified per inclusion centre and per-patient-fee; estimated project start- and end-date.
 - Funding provided by KWF for external inclusion centres will be provided to the Dutch national coordinator, by means of quarterly payments at the end of every quarter.
 - At the end of the supported project, KWF, as applicable, will receive a report or justification on the realised costs for the external inclusion centres from the Dutch national coordinators funding organisation or from the Dutch national coordinator directly. This may include a (copy of the) financial end report including quotes, expenditures, and corresponding invoices. In case any budget meant for external inclusion centres remains at the end of the project, this will be returned to KWF.

APPENDIX 2. Conditions of external inclusion centres

FUNDING FOR EXTERNAL INCLUSION CENTRES, I.E. CENTRES LOCATED OUTSIDE BELGIUM, FRANCE, SPAIN AND THE NETHERLANDS, WILL BE PROVIDED BY THE ANTICANCER FUND (ACF) OR RISING TIDE FOUNDATION FOR CANCER CLINICAL RESEARCH (RTFCCR) OR THE DUTCH CANCER SOCIETY (KWF).

ACF AND RTFCCR WILL PROVIDE THIS BUDGET TO THE PROJECT LEADER, AND THE PROJECT LEADER IS RESPONSIBLE FOR DISTRIBUTION OF THE BUDGET AMONG THE EXTERNAL INCLUSION CENTRES.

KWF WILL PROVIDE THIS BUDGET TO THE DUTCH NATIONAL COORDINATOR, AND THE DUTCH NATIONAL COORDINATOR IS RESPONSIBLE FOR DISTRIBUTION OF THE BUDGET AMONG THE EXTERNAL INCLUSION CENTRES. FOR KWF SPECIFIC FUNDING CONDITIONS SEE APPENDIX 1.

<p>External inclusion centre</p> <p>(recruitment site outside Belgium, France, Spain or the Netherlands – preferably located within geographical Europe)</p>	<ul style="list-style-type: none"> - The centre only includes patients for the clinical trial and has no active research role in the project. - The centre is preferably located within Europe. If the applicant wishes to include inclusion centres outside of Europe, it should be limited, and a strong rationale and justification should be provided on the need, feasibility, and prior existence (if any) of the intercontinental collaboration.
<p>Budget</p>	<ul style="list-style-type: none"> - The budget should be listed in the dedicated section “External Inclusion Centres”. - The budget should be based on a per-patient-fee and estimated enrolment numbers. - The structure/build-up of the per-patient-fee should be specified and substantiated with a cost-specification of services that are included in the per-patient-fee. Start-up fee for support in the approval and reporting process of the Ethics Committee, or other applicable authorities, and monitoring of the external inclusion centres should be included in the per-patient-fee calculation. - The structure/build-up of the per-patient-fee may include both personnel and operating costs that is linked to the external inclusion centre. - The requested budget should be listed as amount per inclusion centre, based on the per-patient-fee and site-specific enrolment target (i.e. estimated enrolment number per site, as specified in the Clinical Trial Agreement).
<p>Accountability</p>	<ul style="list-style-type: none"> - Financial accountability will be the responsibility of the Project Leader. - Actual realized expenditures on the inclusion centres should be reported in the financial end report of the project by the Project Leader and be accounted for by substantiated invoices of each centre. The financial end report will be shared with the applicable funding organisation (ACF or RTFCCR). - In case major discrepancies between the estimated budget and actual expenditures arise, or other issues with the financial accountability of the external inclusion centre-costs occur, the Project Leader will inform the applicable funding organisation (ACF or RTFCCR), as well as the JCS, so appropriate corrective actions can be taken.
<p>Coordination</p>	<ul style="list-style-type: none"> - Funding provided by ACF or RTFCCR for external inclusion centres will be documented in a collaboration agreement, provided by ACF or RTFCCR, as applicable, to the Project Leader. This agreement will specify at least the following information for each supported project: Project title, amount of provided budget; specified per inclusion centre and per-patient-fee; estimated project start- and end-date.

- Funding provided by ACF or RTFCCR for external inclusion centres will be provided to the Project Leader, by means of milestone-based payments. Milestones will be identified per project and documented in the collaboration agreement prior to the start of the project.
- At the end of the supported project, ACF or RTFCCR, as applicable, will receive a final study report and a justification on the realized costs for the external inclusion centres from the Project Leader directly. In case any budget meant for external inclusion centres remains at the end of the project, this will be returned to the applicable funding organisation (ACF or RTFCCR).

Further guidance

Please contact one of the contact persons listed below if you have questions regarding the above.

Contact person

Anticancer Fund (ACF)

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