Regulations clinical studies Kom op tegen Kanker 2024

1. The theme of the call

To be eligible for funding within the call for clinical trials, the project must meet the following 7 conditions:

1. The clinical study is being conducted in cancer patients and former cancer patients.
2. This is a prospective clinical study (interventional or registry-based) investigating patient-relevant outcomes, either focused on the treatment of cancer or focused on the side effect(s) of cancer/ cancer treatment. An intervention in this context could be a (new) therapy, surgical technique, diagnostic test, lifestyle intervention or a comparison of different treatments (not limited to these examples).
3. The study is qualitative in terms of evidence, safety and feasibility.
4. The study must be conducted at any time as a function of maximising added value for patients/ former patients. In this regard, the study is characterised by the following aspects:
    - Primary outcomes that represent a concrete need of patients/ former patients and are based on direct input from patients/ former patients.
    - Primary outcomes that are patient-relevant and therefore correlate with a demonstrable improvement in quality of life and/or a demonstrable improvement in life expectancy while maintaining quality of life.
    - A multidisciplinary approach that pays sufficient attention to the physical, psychological and social functioning of patients/ former patients.
    - The safety of patients/ former patients is a priority at all times.
    - The accessibility and affordability of medical intervention are taken into consideration.
5. At every point in the study, patients/ former patients are central and active patient participation is an integral part of the study, in which respect the study will strive to achieve co-creation between patients/ former patients and researchers.
6. Collaboration, including at the international level, with academic and non-academic centres is strongly encouraged to, among other things, increase feasibility of the study (recruitment) and support for valorisation and implementation.

7. Research results must be maximally valorised and/or implemented to realise the maximum added value for cancer patients in practice as soon as possible.

Kom op tegen Kanker underlines the complementary nature of its funding, awarding grants only for clinical cancer research with a potentially high patient benefit but for which no or insufficient funding is being made available by government, industry and/or other funders.

Applications for funding cannot be made for translational research within the call for clinical research projects.

The way the project applications are assessed, the follow-up and the financial management of the supported projects guarantee a good and efficient expenditure of the funds of Kom op tegen Kanker. Key words in that approach are patient-centredness, scientific excellence, independent assessment, collaboration, transparency and communication.

2. Application

2.1. Who can apply?

Kom op tegen Kanker awards grants to Belgian research and healthcare institutions to coordinate or participate in clinical studies (including at the international level), provided that the research is conducted with no direct commercial purposes. The terms research and healthcare institutions refer to non-profit R&D actors, including universities, hospitals, healthcare organisations and others. To be eligible for funding, recruitment of patients of Flemish institutions and accessibility of study-based treatment for patients in Flanders must be guaranteed.

If a collaboration between different research institutions can add value to the achievement of the objectives, it is expected that a collaboration will be set up. Clinical research in the context of a public-private partnership may be eligible if it is necessary for the execution of the project, the complementarity of funding from Kom op tegen Kanker remains guaranteed, appropriate agreements regarding intellectual property are in place and if guarantees can be given on accessibility and fair price setting[1] after the research is completed. Commercial/industrial actors (for-profit) cannot apply for funding themselves under any circumstances.

To submit a project application as a project promoter / co-promoter, the researcher must hold at least the academic degree of doctor (PhD). A researcher can submit only one project application as project promoter per call. Each project can have only 1 project promoter. The

[1]A 'fair price' is justified, predictable and cost-effective within the goals and priorities of the healthcare system and the available budget. 'Justified' means a price that reflects the documented and clinically relevant benefit of the drug, and a reasonable relationship between the cost of bringing the product to market (including R&D, manufacturing, marketing, public funding) and the price.

project promoter has a coordinating role for the entire project. Moreover, a researcher can be appointed as co-promoter on a project application only once per call.

Kom op tegen Kanker wants to encourage young researchers to also submit projects as project promoter. On the application form, it is possible to indicate that the project promoter has less than 10 years of post-doctoral experience (taking into account career breaks) so that the clinical expert committee can take this into account when assessing the project.

2.2. For what period of time can funding be applied for?

The term of a project is envisaged at a maximum of 6 years. An application can be submitted for a longer term, if this is necessary for the proper implementation of this project. However, this must be adequately justified. The start and end dates will be determined in consultation between the Research, Care and Prevention Funding Department of Kom op tegen Kanker and the project promoter. Projects are started within a year of approval, in principle.

2.3 What budget can be applied for?

Kom op tegen Kanker only funds biomedical cancer research in cases for which no or insufficient funding is made available by government, industry and/or other funders.

No maximum budget is defined per research project. The amount must be justified very comprehensively (per research institution). The requested budget must be sufficient to implement the project. The research budget can be used to cover:

- **Personnel costs**: the use of personnel must be thoroughly justified as a function of the execution of the research project. The salary cost of both scientific staff and technical staff (ATP) can be included. The following scales of pay apply:

- PhD student: max. €57.000/year (1 FTE)
- Technical staff (ATP), data manager or data nurse: max €70.000/year (1 FTE)
- Researcher (scientific co-worker): max. €88.000/year (1 FTE)
- Postdoctoral researcher: max €112.000 /year (1 FTE)

The above scales must be used to calculate the budget for personnel costs in the full project proposal. At the end of the research project, settlement of personnel costs will be based on actual salary costs. The part of the budget provided for salary costs per employee that was not used must be made available to Kom op tegen Kanker again.

Exceptions to pay scales are possible if it can be shown that it is necessary for the project and sufficiently justified. Salary costs for staff members or independent academic staff (ZAP) cannot be included.

In the case of a doctoral student, salary costs will only be reimbursable on project funding from Kom op tegen Kanker in a full-time position, and the subject of his/her doctorate must be in line with the subject of the research project funded by Kom op tegen Kanker. For the

deployment of a postdoctoral researcher on the research project, application can be made for staff costs for up to 0.5 FTE per project year.

- **Operating costs**: the operating costs directly attributable to the project are eligible. These costs must be traceable in the accounting records and must be substantiated with internal or external invoices. In all cases, costs can only be included in proportion to their use for the project.

- Costs for purchasing **medication** do not qualify as operating costs. Exceptionally, approval may be given to include the cost of off-patent medication if the clinical expert committee considers that availability cannot be guaranteed in any other way and that the cost is necessary to carry out the research project.

- In the case of participation in a clinical trial (including at the international level), in which context all or part of the funding of one or more institutions depends on the number of patients that will be included, it is requested that the budget be 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, with a maximum of €2.000 per project year. Publication costs can only be included for publication of scientific articles that have undergone peer review and are (also) available in an 'open access' journal or database.

- Equipment costs can be included in the project in exceptional cases. The conditions are:

- The equipment/goods involved must be unambiguously attributable to the implementation 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 cost over the duration of the project and proportional to the use of the equipment/goods for the project. The depreciation regime must be in line with the accounting practice at the institution in question.
- Equipment rental fees are also eligible. Rentals are subject to the same conditions as above.

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

- **Travel, accommodation and conference costs** are **not eligible.**

2.4. When can applications be made?

The project grant can be applied for as soon as the call has appeared on the Kom op tegen Kanker website until the submission limit date mentioned on the website. In case of any doubt, the date and time the application was finalised through the website for submission of applications to Kom op tegen Kanker will apply.

2.5. How to apply?

Applications are made via the website using standard application forms made available on the Kom op tegen Kanker website: http://expro.komoptegenkanker.be.

3. Evaluation procedure

The application process is in two stages. In the first stage, an abstract is submitted with a brief description of the project according to the standard forms offered. If the abstract is evaluated positively, a full project proposal may be submitted according to the standard forms offered.

3.1 Evaluation of abstracts

The application is first assessed for eligibility by a staff member of the department for Research, Care and Prevention Funding of Kom op tegen Kanker. This involves verifying that the project was submitted on time, the file is complete and the applicant meets the eligibility criteria.

All members of the clinical expert committee review the submitted abstracts based on the conditions of the call and potential patient impact.

When there is a call for clinical studies, abstracts are also evaluated by the biomedical patient committee. A separate application form must be submitted for this. All members of the biomedical patient committee review the submitted abstracts on the basis of the following criteria:

- **Added value** of the study, incorporating:
    - The *needs* of the patient population covered by the study
    - The *solution* proposed in the project
    - The *patient centredness* of the solution
    - The *impact* of the solution/benefits on the life expectancy and quality of life of these patients
- **Patient participation** in the study

For each abstract, the biomedical patient committee formulates concrete feedback and comments for the applicant to enable it to adjust its research in terms of patient added value and patient participation if applicable.

Biomedical patient committee abstract scores are combined with clinical expert committee fit-to-call scores in a 30/70 ratio.

Based on the overall score, the abstracts are ranked and discussed for further evaluation. If the abstract receives a final positive evaluation, a full project proposal may be submitted according to the standard forms offered.

The clinical expert and biomedical patient committee formulate concrete feedback for the selected abstracts, if applicable, in terms of research plan, feasibility, valorisation, budget, patient added value and patient participation.

3.2. Evaluation of the full project proposal

In the second round of evaluation, the comprehensive project proposals are reviewed by three parties, namely the clinical expert committee, external reviewers and the biomedical patient committee. Whereas the clinical expert committee and external reviewers assess the researcher, the research team and the scientific content of the project, the biomedical patient committee assesses the patient-centredness and patient participation of the study in detail.

3.2.1 The biomedical patient committee

When submitting the full project proposal, the applicant must submit a separate document describing the purpose and patient-centredness of the project proposal in layman's terms.

All members of the biomedical patient committee assess whether the project proposals are patient-oriented, meet a major need within biomedical research from the point of view of the cancer patient and in what way patients are actively involved in the development of the research project. The biomedical patient committee scores all projects based on the following criteria:

- **Concrete need:** does the project respond to a concrete need of patients?
- **Added value:** The intended results of this study could lead to great added value for patients.
- **Patient burden:** The burden on patients participating in the clinical trial must be minimised.
- **Patient participation:** patients must be actively involved in the study.

3.2.2 External reviewers

If an application is selected for the second round of evaluation, international experts specialised in the research field of the application must be contacted to evaluate the project based on the same evaluation criteria as the clinical expert committee (see 3.3.3).

Only academics who have not co-authored a publication in the last 3 years by the project promoter, co-promoter(s) and collaborators associated with the project are eligible for this external review.

The comments of the external reviewers are made available to the project promoter of the project application. The project promoter is given a minimum of 1 week to submit written comments on the external reviewers' evaluation. If a report from an external reviewer reaches us too late, this response period may be shortened to less than one week.

3.2.3 The clinical expert committee

The assessment of the external reviewers, along with any comments on the reports of the external reviewers from the project promoter, are made available to all members of the clinical expert committee. Committee members assess applications using the same criteria as the external reviewers:

- **Added value for the patient**, taking into account the following aspects:
  - Potential impact on QOL and survival
  - Need for the study
  - Relevance
- **Project execution**, taking into account the following aspects:
  - Research competence
  - Feasibility
  - Patient-relevant outcomes
  - Collaboration/stakeholder participation
- **Valorisation/knowledge utilisation**, taking into account the following aspects:
  - Valorisation
  - Scope/stakeholder participation

Based on the scores of the clinical expert committee and the biomedical patient committee, a ranking of the project proposals is made. Biomedical patient committee scores count for 30% in the project's final score, and clinical expert committee scores for 70%. After establishing a ranking based on the joint final scores, the clinical expert committee discusses the applications according to the available budget and the complementary nature of the funding of the project applications.

3.3. Final decision

The clinical expert committee submits the best-scored research proposals qualified for funding to the Governing Body for approval.

3.4. Feedback

Four feedback moments are provided during the procedure:

- If the abstract is declared not formally eligible, the project promoter will be informed immediately, stating the reason for ineligibility.

- After the evaluation of the abstracts, the project promoter will be informed in writing whether a full project proposal may be submitted. Project promoters who are eligible to submit a comprehensive project proposal will be invited to consult with a staff member of the Research, Care and Prevention Funding Department of Kom op tegen Kanker at which the evaluation and feedback from the clinical expert and biomedical patient committee will be explained.

- Before the final deliberation of the clinical expert committee, the project promoter is given access to the reports of the external reviewers and given the opportunity to submit written comments.

- After the Governing Body of Kom op tegen Kanker makes its final decision, the project promoter will be informed of the decision. The Research, Care and Prevention Funding Department can always be contacted for further information on the evaluation.

Objections regarding the evaluation of projects by Kom op tegen Kanker must be submitted in writing to the Research, Care and Prevention Funding department of Kom op tegen Kanker at financiering@komoptegenkanker.be. No appeal or request for review can be made regarding the decision on eligibility of an application and an interim or final decision of the clinical expert committee.

However, Kom op tegen Kanker will formally take note of any objections and consider them with a view to the continuous professional functioning of the committees. Under no circumstances may information about the meeting be given to third parties. If committee members receive questions about the meeting, they must always pass them on to the Research, Care and Prevention Funding Officer of Kom op tegen Kanker.

4. Progress and evaluation of the research project

4.1. Agreement

Once the grant has been awarded, an agreement is concluded between Kom op tegen Kanker, the project promoters and the applicant institution(s).

The project budget is disbursed in monthly payments over the entire duration of the research project. The final instalment, consisting of 10% of the total project grant, is paid after approval by Kom op tegen Kanker of the final content and financial report of the research project.

In the case of participation in a clinical study (including at the international level) using a start-up fee and a per-patient fee, a payment in monthly instalments is waived. In such cases, the institution will be funded by Kom op tegen Kanker on an annual basis, and the grant will be paid after written approval of the annual interim progress report.

4.2. Evaluating the progress of the research project

The agreement provides for an annual application for continuation of the research project by the project promoter. This annual continuation request must always include a report on the project's progress in terms of content and finance, and a schedule for the coming period with the necessary explanations.

The content-related section must present an overview of the research activities already carried out, their results and a concrete schedule for the research activities yet to be carried out. If applicable, the number of patients included in the clinical research project by institution must also be included in this report. The progress of the project must be checked against the predetermined objectives and schedule in this context, as included in the original project application and added as an annex to the agreement. This report must be signed by the project promoter. Costs incurred by the project promoter after the deadline for submission of the interim application can only be covered by Kom op tegen Kanker after written approval of the

interim report. An extension must be requested no later than 3 months before the original end date of the research project.

The financial section of the interim report must consist of an overview by the institution's finance department, and include all costs incurred within the project up to the time of the interim report. Only costs that are project-specific and can be demonstrated by means of pay slips or internal/external invoices can be included. The project promoter is required to proactively communicate the names of staff whose salary costs are reimbursed through project funding from Kom op tegen Kanker.

This report must be signed by the relevant file manager of the finance department. However, the final approval of expenditures under the research project by Kom op tegen Kanker always takes place after the research project has been completed, based on the final financial report.

The project promoter shall submit the final report no later than three months after the end of the project term. The final report must always include comprehensive sections on project content and finance. In principle, no amendments can be made to the final financial report after final submission. It is the responsibility of the project promoter and the institution to provide the necessary internal controls so that spending is project-specific and in accordance with these regulations, and is accounted for. Only costs that are specific to the project and can be demonstrated by means of pay slips or internal/external invoices can be approved by Kom op tegen Kanker. Following a positive assessment of this final report, the final payment of the total project grant will be done, if applicable. In the case of a clinical multicentre research project, this rule may be waived with the written approval of Kom op tegen Kanker.

The annual application for continuation of the research project as well as the final reporting is done via the website using the templates for the interim report and the final report made available on the Kom op tegen Kanker website: http://expro.komoptegenkanker.be.

In addition to the annual progress and financial report, the project promoter must always keep Kom op tegen Kanker informed of any significant changes, bottlenecks or problems in the context of the research project. If alternative funding for the project is obtained during the project, the project promoter must immediately inform Kom op tegen Kanker in writing.

4.3. Communication in the context of the research project.

The project promoter must always inform Kom op tegen Kanker in writing in advance about planned public communications and publications about the research project, and must explicitly mention the support of Kom op tegen Kanker in all public communications and publications about the research project. Unless otherwise previously agreed in writing, the following statement must be used in this context: "research project realised with the support of Kom op tegen Kanker". In the context of an international publication, the following wording must be used: "research project funded by Kom op tegen Kanker, the Flemish cancer society".

The applicant must always provide Kom op tegen Kanker with an electronic copy of the accepted publication(s) in the context of the research project during the research project and after its completion.

The project promoter must be willing to cooperate with initiatives set up by Kom op tegen Kanker to raise awareness of Kom op tegen Kanker research funding among the general public or potential donors, and with initiatives to inform existing donors about the ongoing research project.