Priority Program ‘Translational Oncology’
Applicants’ Guidelines
Letter of Intent / Project Outlines

Introduction

The major goal of German Cancer Aid’s funding program for the development of ‘Interdisciplinary Oncology Centers of Excellence’ (‘Onkologische Spitzenzentren’) in Germany is to continuously improve the treatment and care of cancer patients. Conducting interdisciplinary research programs that encompass both basic science as well as the essential translation of scientific findings into clinical practice is therefore an essential task of ‘Interdisciplinary Oncology Centers of Excellence’. Patients can then rapidly benefit from new scientific progress. The following program for ‘Translational Oncology’ is another step in reaching this goal.

With the goal of further supporting collaborative translational cancer research projects at ‘Interdisciplinary Oncology Centers of Excellence’ and Comprehensive Cancer Centers, the German Cancer Aid has decided to launch a fourth call for applications within the funding program ‘Translational Oncology’. Projects may be collaborative scientific projects (‘Verbundprojekte’) or innovative clinical trials, which must be performed at more than two sites and necessitate close collaboration between several research groups. The maximal budget for this fourth call is 7 million Euros.

At least one research group must be located at an ‘Interdisciplinary Oncology Center of Excellence’ funded by the German Cancer Aid.

Research groups that are not based at an ‘Interdisciplinary Oncology Center of Excellence’ or a Comprehensive Cancer Center may act as co-applicants.

General Comments/Procedure:

We wish to point out that applications are not accepted from members of profit-making organizations or from persons not permitted to publish results in a generally accessible form.

The application and evaluation procedure takes place in three steps: Applicants must inform the German Cancer Aid by December 20, 2016, 13:00 that they plan to submit an application (Letter of Intent). Project outlines must be submitted no later than February 14, 2017, 13:00. If the preliminary evaluation is favorable, full applications must be submitted by September 05, 2017, 13:00. Please submit all required printed documents by post/courier (not by e-mail or fax) to the offices of the German Cancer Aid. Please note: only the date and time of receipt in our offices (receipt stamp) is valid and not the postmark.
The project outlines and applications submitted will be evaluated by an international committee of experts. For this reason, all project outlines and applications must be in English. The requirements for project outlines are described in detail in the following sections.

Please submit all required documents in writing by post to the office of the Deutsche Krebshilfe:

Deutsche Krebshilfe e. V.
Abteilung Förderung
Buschstraße 32
53113 Bonn

Letters of intent, project outlines and full applications **may not be sent by e-mail or fax.**

Within two weeks of receipt of the letters of intent, project outlines and full applications by the Deutsche Krebshilfe Office, the applicant or coordinator will receive a written confirmation of receipt, together with a reference number. If you fail to receive confirmation of receipt, please send an email to the Funding Department of the Deutsche Krebshilfe (foerderung@krebshilfe.de), giving the full project title and your telephone number. If you have any questions, please contact:
Dr. Matthias Serwe, 0228 / 729 90-223, email: serwe@krebshilfe.de
Dr. Laura Planko, 0228 / 729 90-224, email: planko@krebshilfe.de

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### A. Guideline for Letter of Intent

1. **Applicants**
The following information is needed for all applicants. Please give the name of the principal investigator, who is responsible for all co-applicants and for correspondence with the Deutsche Krebshilfe first:

- First name, surname, degree
- Full name of the institution at which the coordinator works
- List of all participating centers/research groups including the names of co-applicants

2. **Project title**

3. **Type of application.** Please state whether this is a collaborative scientific project or a Phase I/II trial.

**The letter of intent must be signed by the principal investigator.**
B. Guideline for Project Outlines

Please submit ten copies of the project outline (one original and 9 copies of this) to the office of the Deutsche Krebshilfe. Also send a Word document (filename extension docx) of the project outline by email (foerderung@krebshilfe.de).

The project outlines must be written in English.

Please use the section numbers as below, with the corresponding titles.

The project outline must be signed by all applicants.

Project Outline for Collaborative Projects:

1. General Information
   1.1 Project title (not more than 160 characters)
   1.2 Lead applicant (Coordinator):
       • First name, surname, degree
       • Full name of the institution at which the coordinator works
       • Postal address
       • Telephone and fax number, email address
   1.3 Short summary and description of the planned collaborative project
       (not more than 1 page)
       Description of the overall concept and the main focal points of the project
   1.4 Translational aspects of the proposed study
       (not more than 0.5 pages)
       What are the expected translational aspects of the project? How will scientific findings be translated into clinical practice?
   1.5 Long-term research objective(s) of the planned collaborative project
       (not more than 0.5 pages)
       What are the special potential innovation and the long-term perspective for the project (bearing in mind the current status of the research)?
   1.6 Status of the planned collaboration in national and international competition
       (not more than 2 pages)
       • What are the important national and international developments (or lack of developments) in this area of research?
       • How does the planned collaboration fit into the present research landscape? To what extent does it go beyond the current status of this research?
       • How does it differ from present research collaborations working on similar themes?
2. **Tabular overview of subprojects**
   For each subproject, please give the following:
   - Title of the subproject
   - For each applicant:
     - First name, surname, degree
     - Full name of the institution at which the applicant works
   - Third party funding - current and applied for - of all applicants, giving for each the project title, the (potential) source of funds, the duration and the amount of the financial support

3. **Subprojects of the collaborative project**
   Please give the following for each subprojects:
   (not more than 3 pages)
   - Title of the subproject
   - For each applicant:
     - Name, institute address
     - Summary and description of the subproject
     - Scientific question to be answered
     - Own previous studies, possibly with reference to publications on this subject
     - Research status with literature citations
     - Objectives, working program and methods
     - Role in the planned collaboration (contribution of the subproject to the collaborative project, significance of the collaborative project for the subproject, cooperation with other research groups in the collaborative project)
   - Cooperation with research groups outside the collaborative project

4. **Selection of research groups and subprojects**
   (not more than 2 pages)
   - Which criteria were used to select the subprojects?
   - Do the participating research groups already collaborate (e.g. documented by common publications)?
   - What are the specific strengths of the individual research groups?
   - How do the research groups complement and support each other ('synergy effect')?
   - Why can the scientific problem only be solved by close collaboration between the research groups participating in the collaboration (necessity for collaboration between the research groups)?

5. **Financial plan**
   Tabular overview of the estimated annual amount of funding for each subproject (broken down into the usual expenses positions: personnel expenses, investments, expenses for consumables, expenses for purchasing and keeping of animals, travelling expenses, other expenses).

6. **Appendix: CVs and publication lists for all applicants**
   For each applicant:
   - Current tabular CV (not more than 2 pages)
   - Publication list of the 5 most important publications from the last 5 years
Project Outline for clinical studies (Phase I/II)

Note: The description of the study should not exceed 20 pages max.

An application can be made to the Deutsche Krebshilfe for a research grant for performing non-commercial science-driven cancer therapy studies ('Investigator Initiated Trials'). But please note the following fundamental comments:

- If a study is supported by the Deutsche Krebshilfe, the only permissible form of support from industrial partners is the free provision of the test substance. The project management must disclose financial support for the study to the Deutsche Krebshilfe in the application and at any time during the course of the study. Written agreements with industrial partners must be attached to the application documents. The project management must have exclusive ownership of all data. The design, conduct, recording and reporting of the clinical trial has to be under the control of the project management.

- Outlines and applications for funding study projects cannot be included in the evaluation procedure if recruitment has started before application, or is to be started during the application procedure.

- The outlines should be written according to the following template:

1. Study Synopsis
Give a synopsis of your planned study, using this tabular form:

<table>
<thead>
<tr>
<th>Applicant/coordinating investigator</th>
<th>Name, address, telephone, fax, email</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If there are multiple applicants, the principal investigator/coordinating investigator of the trial will assume responsibility for conducting the clinical trial and should be listed first.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Title of study</th>
<th>(maximum 160 characters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition</td>
<td>The medical condition being studied</td>
</tr>
<tr>
<td>Objective(s)/Hypotheses</td>
<td>Which principal research questions are to be addressed? Clearly specify the primary hypotheses of the trial that determine sample size calculation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention(s)</th>
<th>Description of the experimental and the control treatments or interventions, as well as dose and mode of application. For diagnostic tests or procedures, the index test and the reference procedure (gold standard) should be described.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Experimental intervention / index test:</td>
</tr>
<tr>
<td></td>
<td>Control intervention / reference test:</td>
</tr>
<tr>
<td></td>
<td>Follow-up per patient:</td>
</tr>
<tr>
<td></td>
<td>Duration of intervention per patient:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Key inclusion and exclusion criteria</th>
<th>Key inclusion criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Key exclusion criteria:</td>
</tr>
</tbody>
</table>
### Outcome(s)
- Primary efficacy endpoint:
- Key secondary endpoint(s):
- Assessment of safety:

### Study type
- e. g. randomized/non-randomized, type of masking (single, double, observer blind), type of controls (active/placebo), parallel group/crossover, prognostic, diagnostic

### Statistical analysis
- Efficacy / test accuracy:
  - Description of the primary efficacy / test accuracy analysis and population:
  - Safety:
  - Secondary endpoints:

### Sample size
- To be assessed for eligibility (n = ...)
- To be allocated to trial (n = ...)
- To be analyzed (n = ...)

### Trial duration
- Duration of the entire trial (first patient in to last patient out, recruitment period).

### Participating centers
- How many centers will be involved? (n= ...)

1.1 Intervention scheme / trial flow
Describe the intervention scheme and give a schematic diagram (flow chart) of design, procedures and stages.

1.2 Frequency and scope of study visits
What is the proposed frequency and scope of study visits and, if applicable, the duration of post-trial follow-up? Please also give a table with time points of visits and procedures per time-point. Specify items to be recorded CRF per procedure.

2. The medical problem
- Which medical problem is to be addressed?
- What is the novel aspect of the proposed trial?
- Which principal research questions are to be addressed? Bring them into order indicating major and minor motivations / starting hypotheses of the investigation planned.

2.1 Evidence
Set your trial into perspective. This section should give the detailed background of the starting hypotheses and the feasibility of the trial.
- Which trials have been conducted either by you or by others? What is the relevance of their results? Give references to any relevant systematic review(s) and/or (your own) pilot studies, feasibility studies, relevant previous/ongoing trials, case reports/series. State what your study adds to the overall evidence, in the context of previous work. Include a description of how you searched for evidence (databases, search terms, limits) and how you assessed its quality - i.e., how you selected and how you combined the evidence. If any relevant evidence is not included, the project will not be funded.
2.2 The need for a trial

- How significant is the trial in terms of its potential impact on relieving the burden of disease and/or improving human health?
- What impact will the results have on clinical practice?
- How will the individual patient benefit from the trial? Describe any potential commercial interest of a company in the results of the trial or explain why no such interest exists. If a company has direct commercial interest in the results of the trial, the project will not be funded.

3. Justification of design aspects

Please provide justifications and do not only list the respective information.

3.1 Control(s)/comparator(s)

- Justify the choice of control(s)/comparison(s): Is placebo acceptable?
- Which trials establish the efficacy and safety of the chosen control regimen?
- For diagnostic trials: What is the rationale for the units, cut off and/or categories?

3.2 Inclusion/exclusion criteria

Justify the population to be studied, include consideration of generalizability and representativeness.

3.3 Outcome measures

Justify the endpoints chosen:

- Are there other trials that have utilized this endpoint?
- Are there any guidelines that propose this endpoint/these endpoints? Discuss the clinical relevance of the outcome measures for the target population.
- Have the measures been validated?

3.4 Methods to reduce bias

- Is randomization feasible?
- Which prognostic factors need to be considered in the randomization scheme and the analysis?
- What are the proposed practical arrangements for allocating participants to trial groups?
- Is blinding possible? If blinding is not possible, please explain why not and give details of alternative methods to avoid biased assessment of results (e.g. blinded assessment of outcome).
- For diagnostic trials: What is the training and expertise of persons performing and reading the index tests and the reference standards?
3.5 Proposed sample size/power calculations
What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include a comprehensible, checkable description of the power calculations and sample sizes, with details of the outcome measures on which these have been based for both control and experimental groups; give event rates, means and medians, the software used for sample size calculation etc., as appropriate. Justify the size of the difference that the trial is powered to detect, or in the case of a non-inferiority or equivalence study, the size of the difference that the trial is powered to exclude. It is important that the sample size calculations should take into account the anticipated rates of non-compliance and losses to follow up.

3.6 Feasibility of recruitment
What is the evidence that the intended recruitment rate is attainable (e.g. pilot study)? Describe the data you used to assess the potential for recruiting the required number of suitable subjects.

4. Statistical analysis
• What is the proposed strategy of statistical analysis?
• What is the strategy for analyzing the primary outcome? If interim analyses are planned, please specify.
• Are there any subgroup analyses?

5. Ethical considerations
Briefly discuss the acceptability of the risk incurred by the individual participant versus the potential benefit for the participant/population concerned.

6. Trial management
6.1 Major participants
Please indicate the persons responsible for the design, management and analysis of the trial.

<table>
<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>Affiliation</th>
<th>Responsibility/Role</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>principal/coordinating investigator</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>trial statistician</td>
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<td></td>
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<td>...</td>
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</tbody>
</table>

6.2 Professional expertise
Please indicate the professional expertise of all above-mentioned participants by citing relevant publications and/or specifying major roles in ongoing trial(s) (to be identified; max. 5 publications from the last 5 years per person). Ensure that the team of investigators has the necessary range of disciplines and expertise to carry out the study.

6.3 Facilities supporting the trial
Which trial-specific facilities and other resources are available for conducting the trial?
7. Financial summary
Please give a rough estimation of the costs expected for the total duration of the trial. Is the trial co-financed by a company?

<table>
<thead>
<tr>
<th>Item</th>
<th>Total funding period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical project management</td>
<td>€</td>
</tr>
<tr>
<td>Project management: (e.g. statistical planning, protocol, case report form (CRF), informed consent, CRF printing)</td>
<td>€</td>
</tr>
<tr>
<td>Documentation lump sum payment</td>
<td>€</td>
</tr>
<tr>
<td>Data management (e.g. database set-up and validation data entry, coding, query management)</td>
<td>€</td>
</tr>
<tr>
<td>Biostatistics</td>
<td>€</td>
</tr>
<tr>
<td>Quality assurance (e.g. on-site monitoring, data monitoring and safety committee)</td>
<td>€</td>
</tr>
<tr>
<td>Travel (e.g. trial committees, meetings)</td>
<td>€</td>
</tr>
<tr>
<td>Materials</td>
<td>€</td>
</tr>
<tr>
<td>Trial drug</td>
<td>€</td>
</tr>
<tr>
<td>Fees, insurance</td>
<td>€</td>
</tr>
<tr>
<td>Other</td>
<td>€</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>€</strong></td>
</tr>
</tbody>
</table>

8. Appendix: CVs and publication lists of all applicants
For each applicant:
- Current tabular CV
- Publication list of the 5 most important publications from the last 5 years

**Additional Comments**

- No legal claim for funding can be derived from the submission of an application. The applicant has no claim that a submitted application should be returned.
- The Deutsche Krebshilfe retains the right to check for duplicate funding by providing other external funding sources with the applicant's information (name, theme and objective of the project).
- The acceptance of a research grant obligates the funding recipient to comply with the rules of Good Scientific Practice. The rules of Good Scientific Practice are described in detail in the user guidelines for research funds from the German Research Foundation (DFG preprints 2.01 and 2.02). In the event of scientific misbehavior, sanctions can be concluded. In particular, scientific misbehavior is present when false information is provided deliberately or with gross negligence in a context of considerable scientific importance, or the intellectual property of others is violated or their research work is impaired. The circumstances of the individual case are always decisive.
Contact

Please contact the Project Funding Department of the Deutsche Krebshilfe before making an application. Your contacts are Dr. Matthias Serwe (Tel.: 0228/729 90-223, email: serwe@krebshilfe.de) and Dr. Laura Planko (Tel.: 0228 / 729 90-224, email: planko@krebshilfe.de).

Date 09/2016