

Guidelines for Letter of Intent and Project Outline Priority Programme 'Physical Exercise and Cancer Patients'

Introduction

Physical exercise has shown positive effects in the prevention of various cancers and in the rehabilitation of cancer patients after primary treatment. In patients with advanced cancer, physical exercise is considered to have supportive and synergistic effects with palliative treatments. These benefits of physical exercise may be due to somatic as well as psychooncologic effects.

However, systematic physical exercise is not yet fully integrated into standard oncological therapeutic regimes until today. This is true for clinical pathways as well as patient awareness.

This initiative of Deutsche Krebshilfe aims at supporting the development of routine treatment pathways that reflect the potential benefits of organized physical exercise for cancer patients. In order to enhance the acceptance of physical exercise by medical staff and patients, its details and effects should be analyzed for a better understanding of the underlying mechanisms of action as well as its prospective outcome.

Please notice that the focus of this programme is restricted to physical exercise during treatment.

General Procedure

The procedure for application and evaluation consists of three steps. Prospective applicants must submit a letter of intent to German Cancer Aid by **29 Jul 2011**, 13:00. Project outlines in English must be submitted not later than **22 Aug 2011**, 13:00. If the preliminary evaluation is favourable, full applications must be submitted by **12 Apr 2012**, 13:00 to German Cancer Aid.

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 within the following chapters.

Please submit all required documents in writing by post to the office of German Cancer Aid:

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

Letter of intents, outlines and applications may not be sent by e-mail or fax.

Within two weeks of receipt of the application by the Cancer Aid Office, the applicant/ coordinator will receive a written confirmation of receipt, together with a reference number. If you fail to receive confirmation of receipt, please send an e-mail to the Funding Department of German Cancer Aid (foerderung@krebshilfe.de), giving the full project title and your telephone number.

If you have any questions, please contact:

Annika Thiel, 0228 / 72990-220, e-mail: annika.thiel@krebshilfe.de

Eva Grierson, 0228 / 72990-228, e-mail: grierson@krebshilfe.de

Guideline for Letter of Intent

You are requested to notify German Cancer Aid of your intent to submit an application. This notification has to be provided by letter no later than **29 Jul 2011, 13:00** (e-mail and faxes are NOT accepted). German Cancer Aid office acknowledges receipt of every Letter of Intent by letter within two weeks.

The Letter of Intent must include:

- the full name, address, phone, fax and e-mail contact information of the principal applicant
- the project title in English and German

Please note that this Letter of Intent is a **prerequisite for submission of an application**, i. e. project outlines will only be accepted from applicants who submitted a Letter of Intent earlier.

Guideline for Project Outline

Please submit **8 copies** of the project outline (one unbound version with original signatures and seven bound copies) as well as a CD-ROM with a pdf-Version of the complete project outline not later than **22 Aug 2011**, 13:00 to the office of German Cancer Aid (e-mails and faxes are NOT accepted). Bound copies are intended to be sent to the experts of the evaluation team. Please note that bound copies are NOT checked for completeness by Cancer Aid Office.

We ask you to arrange the project outline as follows, using the given reference numbers:

1. General Information

1.1 Study Synopsis

Give a synopsis of your planned study, using this tabular form:

Applicant(s)/Coordinating Investigator	<p>We wish to point out that applications are not accepted from members of profit-making organisations or from persons not permitted to publish results in a generally accessible form.</p> <p>All applicants are expected to provide the following information:</p> <ul style="list-style-type: none"> • First name, surname, academic degree, date of birth • Full name of the institution/organisation • Postal address • Telephone and fax numbers, e-mail address • Reference numbers of all previous applications to German Cancer Aid for project funding <p>If your application is submitted by several applicants or by an interdisciplinary consortium, please indicate the person assigned for corresponding with German Cancer Aid as the coordinator on behalf of all applicants or the consortium.</p> <p>Please inform us at once if you change your address.</p>
Project title (in English)	(maximum 160 characters)
Project title (in German)	(maximum 160 characters)
Objective(s)/Hypotheses	Which principal research questions are to be addressed? Specify clearly the primary hypotheses of the trial that determine sample size calculation.
Intervention(s)	<p>Description of the experimental and the control treatments or interventions as well as dose and mode application.</p> <ul style="list-style-type: none"> • Experimental intervention • Control intervention • Duration of intervention per patient

Study population	<ul style="list-style-type: none"> • Key inclusion criteria • Key exclusion criteria
Outcome(s)	<ul style="list-style-type: none"> • Primary efficacy endpoint • Key secondary endpoint(s)
Duration of treatment and follow-up	<ul style="list-style-type: none"> • Duration of treatment per patient • Follow-up per patient
Study type	e. g. Randomized/non-randomized, parallel group/cross-over.
Statistical analysis	<ul style="list-style-type: none"> • Efficacy • Description of the primary efficacy analysis and population • Safety • Secondary endpoints
Sample size	<ul style="list-style-type: none"> • To be assessed for eligibility (n=) • To be allocated to trial (n=) • To be analysed (n=)
Trial Duration	Duration of the entire trial (First patient in to last patient out, Recruitment period).
Participating centres	How many centres will be involved? (n=)

1.2 Summary

Give a short summary of the main aspects of the project, e.g. goals, design, subjects, expected outcome of your project (max. 250 words).

2. Contents, Work Schedule, Methods

Give an evaluable presentation of your project (max. 5 pages), considering the following aspects:

2.1 Background (max. 1 page)

Give a brief summary of the relevant literature, from which the research question for the current application emerges. Which oncological 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.

2.2 Preliminary work (max. 1 page)

Evidence: Set your trial into perspective. 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 feasibility studies, relevant previous/ongoing trials.

2.3 Justification of Design Aspects (max. 3 pages)

Give some more detailed information on the following criteria:

- Study population
- Study design
- Interventions
- Data collection procedure
- Outcome measures
- Sample size calculation
- Statistical analyses
- Duration of the study/Milestones

3. Financial Summary

Please give a rough estimation of the costs expected for the recruiting and the follow up (e. g. Clinical Project Management, Trial Design and Preparation, Statistical Planning, Protocol, Case Report Form (CRF), Informed Consent, CRF printing, Data management, IT, Biometry, on-site Monitoring, Data Monitoring and Safety Committee, Travel costs for Trial Committees, Meetings, Reference Centres, Materials, Insurance).

If applicable, please indicate any co-financing of the trial by industry and/or other third parties.

4. Cooperation Partners

List all cooperation partners and add a 'letter of intent' (agreement to cooperate) from each of them (digital signatures are sufficient).

5. Curriculum Vitae and List of Publications

Please attach concise CVs for each applicant, including information about education, current position and previous grants (max. 1 page for each applicant).

Add a list with the 10 most relevant and recent publications for each applicant.

6. Signatures

Signatures of all applicants.

Sonstige Hinweise

- Aus der Vorlage eines Antrages kann kein Rechtsanspruch auf Förderung abgeleitet werden. Antragsteller/innen haben keinen Anspruch auf Rückgabe eines eingereichten Antrages.
- Die Deutsche Krebshilfe behält sich vor, den Namen des Antragstellers/der Antragstellerin, das Thema sowie die Zielsetzung des zur Förderung beantragten Projektes auch an andere Drittmittelgeber zur Überprüfung einer evtl. Doppelförderung zur Verfügung zu stellen.
- Die Annahme einer Sachbeihilfe verpflichtet den Förderempfänger, die Regeln guter wissenschaftlicher Praxis einzuhalten. Die Regeln guter wissenschaftlicher Praxis sind ausführlich wiedergegeben in den Verwendungsrichtlinien für Sachbeihilfen der Deutschen Forschungsgemeinschaft (DFG-Vordrucke 2.01 bzw. 2.02).

Im Falle wissenschaftlichen Fehlverhaltens können Sanktionen beschlossen werden. Wissenschaftliches Fehlverhalten liegt insbesondere vor, wenn in einem wissenschaftserheblichen Zusammenhang bewusst oder grob fahrlässig Falschangaben gemacht werden, geistiges Eigentum anderer verletzt oder deren Forschungstätigkeit beeinträchtigt wird. Entscheidend sind jeweils die Umstände des Einzelfalles.