

Guidelines for Application Priority Programme Complementary Medicine in Oncology

Introduction

Complementary medicine is one of the most controversial topics in oncology. According to the NCCAM, the National Center for Complementary and Alternative Medicine of the NCI, it covers a wide range of different therapies within the categories 'natural products', 'mind-body medicine', and 'manipulative and body-based practices'.

The reason for the controversy is scarce evidence from clinical studies. Oncologists point to the danger of side effects and interactions with conventional therapies and lack of proper clinical trials assessing efficacy, toxicity and cost of complementary approaches. But even the strategy how to prove or disprove hypotheses within complementary approaches is not universally accepted. Proponents of complementary medicine consider randomized studies concentrating on a single intervention as not adequate because complementary methods mostly follow a holistic approach. Also, lack of financial support for research is an important problem preventing scientific evaluation of complementary approaches.

However, complementary methods are typically used before the academic community has approved of them and very often without communication of the patient towards 'conventional' caregivers. In spite of missing evidence, many cancer patients currently use 'non-conventional' methods during or after their active treatment. It is not known, who gives these patients advice, which qualification these advisors have, and how well they know the complementary approaches which they recommend. In Germany, complementary medicine is not part of the academic education of medical professionals, not in Medical School, and not in curricular postgraduate training of oncologists. Thus, patients who look for information often do not find it within conventional structures. Instead, providers of information and treatment come from diverse professions and their offers are heterogeneous. They are not submitted to any quality assessment. It does not even exist a system that allows to define, measure and ensure quality of these offers. Therefore, a thoroughly discussed and consented strategy of research is mandatory for the development of complementary approaches that take into account the patients' wish of participation while ensuring their safety and evaluating possible 'hard data' benefits of complementary approaches.

German Cancer Aid acknowledges that complementary medicine has a high priority in patients' view. To help with the establishment of an interdisciplinary network of competence in Germany, German Cancer Aid has set up this priority programme to increase transparency and objectivity in the area of 'non-conventional' treatments. The goal of this programme is to generate high-quality information on existing practices and evidence-based studies as well as to make this information easily accessible for health care professionals and advisors, researchers, patients and the general public.

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General Procedure

The procedure for application and evaluation consists of two steps. Prospective applicants must submit a letter of intent to German Cancer Aid by **01 Dec 2010**, 13:00. Full applications must be submitted by **17 Jan 2011**, 13:00 to German Cancer Aid.

The applications submitted will be evaluated by an international committee of experts. For this reason, all applications must be in English. The requirements for applications 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 and applications may not be sent by e-mail or fax.

If you have any questions, please contact:

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

Laura Planko, 0228/72990-224, e-mail: planko@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 **01 Dec 2010** 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 and his/her signature.
- The full name and address of all applicants which will be part of the consortium.
- The project title in English and German.

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

Guideline for Application

Application documents must contain the information and attachments as outlined below. Please use **all** reference numbers and corresponding titles as indicated in this guideline. If a chapter or point is not applicable, please designate it with 'not applicable', adding a brief explanation if necessary.

Please note that incomplete applications cannot be submitted to evaluation.

Applications will be evaluated by an international evaluation team of experts. **Please submit your application in English.** However, we ask you to submit the 'Project Title', the 'Summary' and the 'Summary of requested funding' **also** in German.

Please submit **8 copies** of the application (one unbound version with original signatures and seven bound copies) not later than **17 Jan 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 German Cancer Aid.

Please also include a CD-ROM with the following files:

- the complete application as a pdf-file, including signatures and attachments (maximum 8 MB)
- information on chapters 1 and 3 ('General Information' and 'Summary') as a Word- or RTF-document

1. General Information

1.1 Applicants

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.

We only accept applications of interdisciplinary consortia. The competence network should include experts in oncology, psychology, empirical social research, communication and education sciences.

All applicants are expected to provide the following information:

- 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

Please indicate the person assigned for corresponding with German Cancer Aid as the coordinator on behalf of the interdisciplinary consortium (principal investigator).

Please inform us at once if you change your address.

Within two weeks of receipt of the application by the Cancer Aid Office, the principal investigator 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.

1.2 Project title (in English)

(maximum 160 characters)

1.3 Project title (in German)

(maximum 160 characters)

1.4 Scheduled total duration of the project**1.5 Application period**

(the period for which funding is requested)

2. Table of contents with page numbers

Please indicate each chapter with the reference numbers.

3. Summary

3.1 Summary of the project (in English)

Please give a short description of the whole project, including the aims and objectives. The summary must not be longer than one DIN A4 page. It will be included in the submissions for the expert committee.

3.2 Summary of the project (in German)

(see 3.1)

4. Information on the proposed project

4.1 State of the art

The current state of the art should be presented briefly and precisely, together with the direct relevance to the specific project, as a justification for the project which is to be funded. Please also refer to the most relevant publications of other scientists. However, the text should be comprehensible without reading the cited articles.

4.2 Own preliminary work

Preliminary work of the applicants should be specified completely, including a description of expertise and capacities in managing collaborative studies.

You might also like to refer to the most important publications of the applicants which are specifically related to the subject or methods of the proposed project. However, a complete list of

the current publications of the applicants should be added as an attachment to your proposal (see chapter 10.2 of these guidelines).

4.3 Objectives and hypotheses

Please present a brief description (maximum 1 page) of the objectives and hypotheses of the planned project, considering points 1 to 3 mentioned within the call.

4.4 Work schedule

Please provide a detailed description of the planned project to be conducted during the application period. The approximate funding period will be three years.

Choose suitable methods and collaborations to reach each objective you have described. For analysis and evaluation purposes, professional statistical expertise should be involved. Make it clear if the methods are standard or if they still have to be developed, preferably by referring to relevant publications.

The quality of the work schedule is of critical importance in deciding whether the project deserves funding.

4.5 Time schedule and milestones

Please present a time-table of the work schedule including decisive milestones (maximum 1 page).

5. Requested Funding

5.1 Personnel

The following information is needed:

- Designation of the requested position (e.g. 'Scientific Assistant', 'Technician', 'Doctoral Student', 'Physician')
- The requested duration of employment (e.g. 'for 3 years')
- The salary grade according to the Wage Agreements for Public Employees (TV-L, TV-Ä; please do **not** give payments in Euros for staff members, Cancer Aid Office will calculate the necessary personnel funds)
- An exact description of the duties of each position requested (a reference to the work schedule is not sufficient)
- If the staff requested is already known to you, please indicate names

5.2 Funds for equipment/non-recurring investments

In particular, this includes scientific instrumentation. The following information is required:

- The name of the equipment or instrument
- Purchasing price in € including VAT, deducting discounts, together with a current tender or cost estimate from a possible supplier (copies of company catalogues or an Internet page are not accepted)
- A detailed explanation of why you need the requested instruments to perform the project, with reference to currently available equipment

Please bear in mind that German Cancer Aid does not in principle fund instruments which are part of the basic equipment of an institute or hospital.

5.3 Funds for consumables

Please describe the consumables (e.g. questionnaires), with the annual costs in € of each item requested.

5.4 Travel expenses

Funds can be requested for travel which is absolutely essential for the successful completion of the project (e.g. travel to cooperation partners). If you are applying for travel expenses, please state the amount on each position and justify the necessity.

5.5 Other costs

These include, for example, commissions to third parties.

5.6 Summary of requested funding (in English)

Application period: x years

Personnel:

1 Scientific Assistant, TV-L 13, for x years (for Dr. ...)

1 Technician, TV-L 8, for x years (N.N.)

Equipment (non-recurring):

1	Instrument	€	
1	Instrument	€	
		€	TOTAL

Consumables:

- For	p. a.	€	
- For	p. a.	€	
	p. a.	€	TOTAL

Travel expenses:

- For travels to cooperation partners	p. a.	€	
	p. a.	€	TOTAL

Other costs:

- For	p. a.	€	
- For	p. a.	€	
	p. a.	€	TOTAL

5.7 Summary of requested funding (in German)

Beantragte Förderungsdauer: x Jahre

Personalmittel

1 Wiss. Mitarbeiter/in, TV-L 13, für x Jahre (für Dr. ...)
 1 Techn. Assist., TV-L 8, für x Jahre (N.N.)

Investitionsmittel (einmalig)

1	Gerät	€	
1	Gerät	€	
		€	TOTAL

Mittel für Verbrauchsmaterialien

- Für	p. a.	€	
- Für	p. a.	€	
	p. a.	€	TOTAL

Reisemittel

- Für Reisen zu Kooperationspartnern	p. a.	€	
	p. a.	€	TOTAL

Mittel für Sonstiges

- Für	p. a.	€	
- Für	p. a.	€	
	p. a.	€	TOTAL

6. Prerequisites for carrying out the project

6.1 Your team

Please indicate name, academic degree and professional position of all participants (scientists, assistants, employees) who may work on the planned project. Please give a short and well-defined description of the duties of each project participant.

6.2 Cooperations

Please only name those scientists, physicians or other cooperation partners with whom you have or have agreed on specific collaboration in the project for which funding is requested. Please attach a written statement of intent for each cooperation partner.

6.3 Cooperation with companies

Please state whether you are cooperating with an industrial partner as part of the planned project and, if so, to what extent. Include the confirmation of the industrial partner.

6.4 Equipment available

Please provide information about the scientific instrumentation and equipment on site which is available to you for the project.

6.5 Your institution's contribution to basic equipment

Please indicate the contribution of the participating institutions to the basic equipment (e.g. provision of personnel, of funds for consumables or of equipment for the planned project).

6.6 Your contribution as applicant

Please indicate the contribution of the applicants to the project as percentage of your working hours.

7. Further particulars

7.1 Statement(s) of the ethics committee(s) (if necessary)

A statement on the planned research project from the ethics committee of your institution is necessary, if investigations are to be performed in individual persons (e.g. qualitative interviews, if individual personal data are involved), or if human material (e.g. blood or tissue sample) is used. The statement of the ethics committee must make it clear that there are no reservations about conducting the project applied for funding by German Cancer Aid. Include the statement of the ethics committee as an attachment or, if applicable, write that the ethics committee statement will be submitted subsequently. A favourable statement from the ethics committee must be available not later than the start of funding or payment of the funds.

If several sites are involved in the research project for which funding is requested, corresponding statements from the responsible ethics committees may have to be presented.

7.2 Third party funding

A list of all third party funding which the applicants receive at the time of the application (i.e. **current** third party funding) - containing each project title, the source of funding, the duration, start and end date of funding. Please also list all planned projects for which you have applied for funding, each with the project title and the funding organisation to which you have applied.

7.3 No legal claim to funding

A submission of application to German Cancer Aid does not constitute a legal claim to funding. Furthermore, the applicant has no right to claim the return of the application.

8. Declaration

German Cancer Aid must be informed if you have submitted the application or parts hereof to another funding organisation before.

In all cases, the following declaration must be made:

'A request for funding this or a similar project has not been submitted to any other addressee. The same or a similar request for funding will not be submitted to other institutions during the review process. German Cancer Aid reserves the right to inquire at other funding organisations about the submission of this or a similar application and to request further information hereof.'

9. Signatures

Place, date and signatures of all applicants.

10. Attachments

The following attachments are to be included with the application. Please remember to include the attachments with each copy of the application as well as with the pdf-version.

10.1 Curriculum vitae

Curricula vitae of all applicants, emphasising their scientific careers (table format).

10.2 Current list of publications

Please give a list of all articles published by the applicants within the last five years. Publications which have not yet appeared should be designated as 'in print in..', 'accepted by..' or 'submitted to...'. Manuscripts may be included as an attachment. Please do not include any publications which are still in preparation.

10.3 Approval of the application by the head of the institution

Please attach a signed approval from the director or head of the institution/organisation at which the project in the application is to be performed. This should make it clear that the director or head of the unit has been informed of the application and agrees that the project can be conducted with participation of the applicant. This approval must not be submitted if the director or head of the unit is himself the applicant. If the project is to be performed at several institutions/organisations, equivalent approvals may have to be submitted by the heads of all units involved.

10.4 Statement(s) of the ethics committee(s) (if necessary)

These can be submitted later, see chapter 7.1.

10.5 Further attachments

E.g. reprints and manuscripts

11. Obligations

We wish to point out that the acceptance of funding obligates the recipients to comply with the rules of good scientific practice. The rules of good scientific practice are described in detail in the German Research Foundation's Guidelines for the Use of Funding (DFG forms 2.01 or 2.02, www.dfg.de/formulare).

In the event of scientific misbehaviour, sanctions may be taken. In particular, scientific misbehaviour is present when false information is supplied in a scientific context, either deliberately or as the result of gross negligence, the intellectual property of others is violated or their research work is impaired. The circumstances of the individual case are decisive.