

Program for the Development of Interdisciplinary Oncology Centers of Excellence in Germany

4th CALL FOR PROPOSALS

Progress in prevention, diagnosis, and therapy has led to a significant increase in survival rates and quality of life of cancer patients. During the past decade, the overall cancer mortality has started to decline in North America and several European countries, including Germany. It is mandatory to accelerate this favorable trend through a better interaction of basic, translational and clinical research, in conjunction with a higher quality of interdisciplinary cancer patient care.

As the major German cancer charity, Deutsche Krebshilfe aims to support the further development of cancer centers in Germany that have already achieved a high standard of research and clinical care and that are willing to develop and implement innovative concepts. In order to contribute to the development of a limited number of interdisciplinary oncology centers of excellence, we have launched this program to set nationwide standards for clinical cancer care and for strengthening translational cancer research.

Deutsche Krebshilfe issued an initial call for proposals in 2006 followed by a second and a third call in 2007 and 2010, respectively. Currently, a total of 11 centers are funded within the program. We are now inviting for a 4th round of applications. In this fourth phase, up to 7 centers can be supported, each with one million Euros per year over a period of three years.

Like in the previous calls the financial support shall primarily be used for the strengthening of the cancer center infrastructure, and not for specific research projects or clinical care.

Centers that wish to participate in this program are subject to a competitive selection process. In order to secure uniform structures and quality standards, applications submitted by oncology/research centers will be judged according to a number of defined criteria.

The evaluation will be carried out by an international panel of experts. Applications must therefore, be written in English.

Please notify the Deutsche Krebshilfe of your intent to submit an application.

Letter of intent deadline: **April 20, 2012.**

Subsequent full application deadline: **June 12, 2012.**

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GENERAL INFORMATION

Preface

In 2005 the Deutsche Krebshilfe Executive Board (Vorstand der Deutschen Krebshilfe) decided to launch a Program for the Development of Interdisciplinary Oncology Centers of Excellence in Germany. A Task Force consisting of members of the Deutsche Krebshilfe Scientific Review Board (Beirat der Krebshilfe-Organisationen) and external experts was commissioned by the Executive Board to work out the details of the Program. The recommendations made by the Program Task Force - including the criteria for funding - were approved by the Deutsche Krebshilfe Scientific Review Board as well as the Executive Board.

Criteria for Funding

Centers that wish to participate in the program are subject to a competitive selection process. In order to secure uniform structures and quality standards, applications submitted by oncology/research centers must be prepared according to the attached guidelines and will be evaluated on the basis of the following criteria:

- a. Number and quality of ongoing research projects funded by the Deutsche Forschungsgemeinschaft (German Research Council), Deutsche Krebshilfe or other grant organizations with peer review. Development of internationally competitive research programs, particularly in the area of translational cancer research. Participation in local, national or European collaborative research consortia. Program in tumor epidemiology with outcome research and identification of cancer risks and predictive factors.
- b. Obligatory participation in structures of multidisciplinary clinical oncology that encompass all tumor entities, with a central entry port for tumor patients. Integrated clinical care by a team of physicians of different disciplines.
- c. Establishment of interdisciplinary tumor boards for all organ sites and tumor entities.
- d. For each patient, proposals for diagnosis and treatment and their implementation have to be documented.
- e. Development and implementation of standard operating procedures for diagnosis and treatment that reflect the current state of evidence-based oncology.
- f. Introduction of a quality assessment system for diagnostics, oncologic surgery, medical oncology and radiotherapy. Development of a centralized quality-controlled outpatient unit for chemotherapy.
- g. Documentation of diagnostic and therapeutic procedures and follow-up data in a clinical cancer registry that should be embedded in or associated with a population based cancer registry. Establishment of a validated system for data collection.
- h. Organizational structure of the cancer center with sustainable support from the hospital/faculty.
- i. Integrated psychosocial and palliative care. The center must interact with patient advocacy groups.

- j. Availability of a dedicated clinical trial center and participation in innovative clinical studies. The fraction of patients in trials should approach 90% for pediatric neoplasms, 50% for haematolymphoid and 10% for solid tumors.
- k. Tumor- and bio-bank with defined quality and documentation standards.
- l. Concentration of the core activities of the center in one building.
- m. Interaction with extramural physicians and regional hospitals (outreach program).
- n. Multidisciplinary training programs for physicians, physician scientists, nurses and related professions.
- o. Willingness to participate in an auditing process conducted for the Deutsche Krebshilfe by an international panel of experts.
- p. Appointment of a highly qualified scientist with administrative experience as dedicated cancer center director who is supported by an executive committee and scientific advisory board.
- q. Willingness to participate in a national consortium of cancer centers, coordinated by the Deutsche Krebshilfe.

Eligibility Requirements

Public or private cancer centers in Germany that approve the above listed criteria and that have already met or at least broadly met these criteria.

Funding Volume and Funding Period

Up to 7 centers can be supported, each with one million Euros per year over a period of three years, followed by re-evaluation. The financial support shall primarily be used for the strengthening of the cancer center infrastructure, and not for specific research projects or patient care. As an example, funding may be used for the establishment of core facilities (centralized shared resources and services) or for outreach activities.

Renewal Proposals

In the context of this call, Comprehensive Cancer Centers that are already funded by Deutsche Krebshilfe and want to apply for further financial support have to submit detailed progress reports combined with applications for renewal of funding.

Application and Review Process

The application process will proceed in two stages:

1. Evaluation of grant proposals by an international panel of experts (review group). Based on the criteria listed above, 'finalists' are selected.

2. Further evaluation of the finalist centers will presumably be completed by end of the first quarter of 2013 (possible time slots: 5 – 9 November 2012 and 14 – 18 January 2013).

Based on the reviewer's recommendations the Deutsche Krebshilfe Executive Board will come to the final decision.

LETTER OF INTENT TO SUBMIT AN APPLICATION

You are requested to notify the Deutsche Krebshilfe of your intent to submit an application. This notification has to be provided by letter no later than **April 20, 2012, 13.00 h** (Emails and Faxes are NOT accepted).

The Deutsche Krebshilfe office acknowledges receipt of each Letter of Intent by letter within two weeks.

The Letter of Intent is to be sent to:

**Deutsche Krebshilfe e. V.
Abteilung Förderung
Buschstrasse 32
53113 Bonn**

The Letter of Intent must

- (1) include the full name, address, phone, and email contact information of the principal applicant,
- (2) briefly describe (one page maximum) the proposed approach to establish or to further develop the 'Interdisciplinary Oncology Center of Excellence' and
- (3) include a list of all members of the external advisory board of the cancer center (if applicable).

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

PROPOSAL GUIDELINES

Please note that proposals

- must be written in English
- will not be screened for completeness upon receipt
- will NOT be accepted if received by Fax or Email
- must be received by **June 12, 2012, 13.00 h**

The Deutsche Krebshilfe office acknowledges receipt of every proposal by letter within two weeks.

To simplify the review process it is requested that you

- start the proposal with a table of contents including page numbers,
- insert a header with the name of the cancer center on each page,
- address in the proposal all points mentioned in the guidelines, repeating all section numbers from the guidelines as well as the complete section titles,
- restrict your proposal to a maximum of 30 pages (except appendices), in case of a renewal proposal the progress report should not exceed 30 pages (except appendices), and the corresponding grant application itself should be restricted to 10 pages,
- use 'Arial' 11 pt and 1.25-line spacing,
- use the forms available from Deutsche Krebshilfe's website for appendices 4, 5, 6, 7, 10, 11A, 11B, 13, 15, 16 (the forms can be downloaded from our website www.krebshilfe.de; to fill in these forms, please use 'Arial Narrow' 9 or 10 pt),
- start the appendices with a table of contents
- provide one complete unbound original application package (grant application, appendices and progress report if applicable) with original signatures plus 8 bound copies of the grant application (including copies of the cover letter) and 8 bound copies of the appendix (each appendix copy consisting of appendices 1 - 18) as well as 8 bound copies of the progress report (if applicable).

If applicable, usage of charts, figures etc. is encouraged.

In addition to the paper copy, the **final versions** of the proposal and appendices as well as the progress report are also required **in PDF format**. Please supply separate PDF files for proposal, appendices (one file containing all appendices) and progress report (if applicable), respectively. In addition, please supply paragraph 10 (Summary) also in word format. Please send the electronic version on CD-ROM together with the hard copy application to:

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

Please note that the hard copy application must match the application you submit electronically word-for-word.

General Remarks:

It is most important that you clearly work out the value added through the structure of the Comprehensive Cancer Center over individual activities/efforts existing at your place. In addition, you must precisely differentiate between the cancer center's current situation and future goals/prospects.

A) Proposals of Centers which are not funded yet

Cover Letter

Briefly introduces the application, states the willingness to accept the terms of evaluation and funding. The letter has to be signed by the Cancer Center Director and Deputy Director, the Chief Physician of the Hospital, the Dean of the Medical Faculty, and the fiscally responsible Administrative Director.

Face Page with Full Name of the Cancer Center

1. Table of Contents (with page numbers)

2. Institutional Commitment to the Cancer Center

Discuss the institutional commitment to the cancer center, including its recognition and status as a formal organizational component, the provision of space, positions and discretionary resources. The Chief Physician of the Hospital, the Dean of the Medical Faculty (if applicable) and the fiscally responsible Administrative Director have to declare their commitment for the long term future of the cancer center.

3. Cancer Center Director and Deputy Director

For your information: The cancer center director should be a highly qualified oncologist with a strong scientific background as well as outstanding leadership and management skills. The director should serve the center on a full-time or a significant part-time basis and should have the following authorities:

- *A senior position (at least equivalent to a department chair), with appointments to decision making committees relevant to the cancer center and formally codified authorities.*
 - *Control of faculty appointments to the cancer center, and of their periodic review for continued membership (i.e. ultimate authority for determining which individuals will be productive, contributing members of the cancer center).*
 - *At a minimum, joint control (for example, with a department chairman) of recruitments of individuals who are to be members of the cancer center.*
 - *Full or shared control of specific research and resource space and equipment dedicated to the cancer center; this control provides the independent flexibility to enhance and develop the research capability and resource needs of the center.*
 - *Concerning clinical research, the center director or designee must have sufficient authority over both inpatient and outpatient facilities to achieve center clinical research objectives, and over the appointment and performance of individuals critical to linking oncology care to clinical research.*
 - *Control of philanthropic funds donated to the cancer center.*
-

3.1 Name and Full Work Address of the Cancer Center Director and Deputy Director (in English and in German)

Appendix 1: Biographical sketch, portrait photo, research focus, and the ten most important publications of the Cancer Center Director and the Deputy Director.

Note: The Cancer Center Director is regarded as corresponding author.

3.2 Position / Responsibilities / Authorities of the Cancer Center Director

Describe the qualifications of the Center Director in relation to scientific background and leadership experience and his/her time commitment to the center. Describe the status of the cancer center director within the institution; any appointments to decision-making committees relevant to the cancer center; authorities in relation to integration of research across departments, appointment and review of program members, recruitments and faculty positions, research and resource space and equipment dedicated to the center, revenue streams, and inpatient and outpatient facilities.

4. Overview of the Current and Future Administrative and Organizational Structure of the Cancer Center

For your information: The organization of the center and the evaluation and planning of center activities should promote joint initiatives, collaborations and interactions. The organizational arrangements should take maximum advantage of the parent institution's capabilities in research and patient care; this is a particular challenge in a large and diverse university or when multiple institutions are included.

A center should have:

- an administrative organization with clear lines of authority which is managed efficiently and cost effectively.*
 - the use of an external advisory body (appropriately balanced for laboratory, clinical, cancer control/population science, and administrative experts) which provides objective evaluation and advice in a report to the center director.*
 - internal advisory, decision-making, and priority setting processes for conduct of center activities.*
-

4.1 Overview of the Current Administrative and Organizational Structure of the Cancer Center

Name and describe the current key structural elements/units of the cancer center, their functional duties/responsibilities, levels of authority, and interfaces/relationships. Describe the reporting and advisory structures/pathways as well as the decision making

processes at the center. Please list the members of the center's external advisory board (if applicable).

Appendix 2: Organization chart (current situation).

4.2 Overview of the Future Administrative and Organizational Structure of the Cancer Center

Name and describe the future key structural elements/units of the cancer center, their functional duties/responsibilities, levels of authority, and interfaces/relationships. Please describe the reporting and advisory structures/pathways as well as the decision making processes at the center. In addition, please provide an organization chart.

Appendix 3: Organization chart (future situation).

5. Laboratory and Clinical Research

For your information:

The reviewers will ask the following questions:

- *What is the overall quality of the science going on in the center and its programs?*
 - *What impact has the center **itself** (or is it likely to have) on the quality of the science, the productivity of the scientists, and the interdisciplinary activities of the institution relating to cancer?*
 - *What has the center contributed to the development of more effective prevention, diagnosis and treatment for cancer?*
 - *Does the cancer center **add value** over and above the separately funded research efforts themselves? Have thoughtful, coherent scientific programs been assembled and program members selected to maximize the cancer-related interactive science?*
 - *How do the different cancer-related scientific themes of the parent institution fit together and complement each other in the center?*
 - *Have the choices for center membership made by its leaders resulted in a group of excellent cancer-focused scientists who are also committed to productive interactions with one another?*
 - *Which research programs do exist/have been developed that include both clinicians and basic scientists?*
 - *What measures have been taken to integrate (translational) research into the different multidisciplinary groups responsible for health care?*
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5.1 Research Infrastructure / Research Programs

Please describe what kind of programmatic structures have been developed/implemented to promote interdisciplinary research and translational research, giving special consideration to the questions outlined above. In particular, clearly point out how the structure of the cancer center supports laboratory and translational research (what is the value added by the cancer center regarding the local research efforts). Please identify

the (infrastructural) measures of the cancer center to facilitate such collaborative undertakings (e. g. common programs, teleconferencing, internal grant programs etc).

Give a detailed description of the cancer center's tumor- and bio-bank(s) with special consideration to the center's policies for the operation of the tissue bank and for the use of tumor tissues (comprehensive clinical documentation, standard operating procedures, and quality control). Who is responsible for the operation of the tissue bank?

5.2 Shared Resources / Core Facilities

For your information: Shared Resources provide access to technologies, services, and scientific consultation that enhance scientific interaction and productivity. The support of shared services for an entire center provides stability, reliability, cost-effectiveness, access to specialized technology and methodology, and quality control.

5.2.1 Shared Resources/Core Facilities Operated by the Cancer Center

Appendix 4: Shared Resources/Core Facilities operated by the Cancer Center.
Developmental cores should be clearly identified as such if included.

Describe the center's policies about operation and use of each of the shared resources/core facilities, e.g., access, priorities, limitations and charge back systems.

5.2.2 Shared Resources/Core Facilities not Operated by the Cancer Center

Appendix 5: Shared Resources/Core Facilities not operated by the Cancer Center.
Developmental cores should be clearly identified as such if included.

Describe the policies about operation and use of each of the shared resources/core facilities, e.g., access, priorities, limitations and charge back systems.

5.3 Summary of Current Laboratory and Clinical Research Activities

Describe the current laboratory and clinical research activities/programs. Give details on the top-five research projects/milestones 2007 – 2011 and list the relevant publications. The publications should be allocated to these top-five research projects. For the evaluation it is essential, that you work out what is the contribution of the cancer center to the work of the individual research groups and vice versa.

Appendix 6: List all in 2010 and 2011 active funded, cancer-relevant projects competitively awarded by external sources. Provide a separate form for each principal investigator.

Appendix 7: Summary – in 2010 and 2011 active funded research projects.

5.4 Summary of Future Laboratory and Clinical Research Topics / Research Programs

Describe the planned developments concerning laboratory and clinical research activities/programs. In particular, please point out new plans regarding the impact of the cancer center on laboratory and translational cancer research.

6. Clinical Care

6.1 Clinical Care - Basic Information

Give details on the size of the hospital (total number of beds and patients/year).

Appendix 8: Plan of the hospital / university campus indicating the building in which core activities of the cancer center are conducted.

Appendix 9: Catchment area (map, number of inhabitants).

Tabulations documenting which anatomic cancer sites are being treated at the cancer center and whether the center is placing these patients onto therapeutic protocols:

Appendix 10: Number of all cancer patients treated in the cancer center in 2009, 2010 and 2011, respectively.

Provide the number of all cancer patients (inpatients, outpatients, total) treated in the cancer center in 2009, 2010 and 2011, respectively. Reflect the number of patients coming to the cancer center, not the number of visits. Do not include any patient more than once unless they have been treated for two malignancies in one year. All patients should be counted regardless of whether they have a newly diagnosed cancer or have recurrent disease and were referred to the cancer center for further evaluation and primary or secondary treatment. This category excludes consults (e.g., for service or second opinions), diagnoses at autopsy, and former patients admitted for rehabilitation purposes or treatment of some other conditions. It also excludes patient follow up activities after treatment is completed. Please provide separate forms for each year.

Appendix 11: (A) Number of cancer patients newly diagnosed in 2009, 2010 and 2011, respectively.

Provide the number of patients newly diagnosed in the cancer center or elsewhere in 2009, 2010 and 2011 and whose treatment started in the cancer center in the respective year (inpatients, outpatients, total). Reflect the number of patients coming to the cancer center, not the number of visits. Do not include any patient

more than once unless they had two malignancies diagnosed in one year. Do not include patients with recurrent disease. Please provide separate forms for each year.

- (B) Number of (A)-patients enrolled in clinical trials in 2009, 2010 and 2011, respectively.

Provide the number of (A)-patients by anatomic site that were newly enrolled in therapeutic trials in 2009, 2010 and 2011, respectively (Phase I-trials and Phase II- and III-trials with therapeutic intent using drugs, radiation, surgery, other biological agents, or behavioral or other interventions). A patient may appear more than once if he/she was on more than one therapeutic protocol. See explanations in 6.12 to determine whether a study is an investigator initiated trial or an industry initiated trial. Please provide separate forms for each year.

6.2 Fields of Specific Competence

Identify fields of specific competence of the cancer center (e.g. rare tumor entities, specific diagnostic or therapeutic options).

6.3 Certifications

List all certifications of the center which are relevant for clinical care and / or cancer research.

6.4 Multidisciplinary Care

For your information:

Multidisciplinary care for all cancer patients from diagnosis through to palliative care is one of the key principles of a comprehensive cancer center. The aim is to ensure a multidisciplinary team approach to prospective treatment and care planning that is aligned with best-practice and evidenced-based care.

*Comment of a reviewer who was involved in the evaluation of the proposals of the 1st call:
"... A key aspect of a comprehensive cancer center is the expectation that the vertical 'silos' (for example, Departments) that characterize the current university and hospital enterprises in Germany need to be horizontally linked in a manner that supports interdisciplinary integration, albeit to a varying degree in varying situations. ...*

... The continued development of a centralized facility in which all chemotherapy is given is very important for cancer patients and for the further development of an integrated Cancer Center. ...

... The continued evolution and expansion of care guidelines and structures to enhance and support optimal care for cancer patients must be a fundamental element of comprehensive cancer centers."

Please describe the current status of multidisciplinary care at the cancer center, giving special consideration to the status of implementation of:

- (1) Structures of multidisciplinary clinical oncology that encompass all tumor entities, with a central entry port for tumor patients. Integrated clinical care by a team of physicians of different disciplines.
- (2) A centralized quality-controlled outpatient unit for chemotherapy.

6.5 Patient Pathways

For your information: The "patient pathway" is the route that a patient will take from his/her first contact with the cancer center (self-, physician-/hospital-referral), entry into the cancer center, until he/she leaves the center or treatment is completed.

Describe the specific pathways for patients suffering from:

- (a) Breast Cancer
- (b) Prostate Cancer
- (c) Colorectal Cancer
- (d) Lung Cancer
- (e) Melanoma
- (f) Other tumor(s) for which the cancer center has specific competence

At which entry point(s) do the patients enter the cancer center? Please supply the proportions of patients entering via a central entry point, via particular departments, etc. How many of them are discussed in tumor boards? Please describe the routes and possible 'sub' routes and comment on the patient numbers and percentages entering the specific routes.

Appendix 12: 6 flowcharts showing the patient pathways (a) to (f).

6.6 Multidisciplinary Tumor Boards

For your information:

Tumor boards are integral to improve the care of cancer patients by contributing to the patient management process and outcomes, as well as by providing education to physicians and other staff attendance.

Multidisciplinary Cancer Conference (MCC) Objectives:

- *MCC Primary function:*
 - *Ensure that all appropriate diagnostic tests, all suitable treatment options, and the most appropriate treatment recommendations are generated for each cancer patient discussed prospectively in a multidisciplinary forum.*

 - *MCC Secondary functions:*
 - *Provide a forum for the continuing education of medical staff and health professionals.*
 - *Contribute to patient care quality improvement activities and practice audit.*
 - *Contribute to the development of standardized patient management protocols.*
 - *Contribute to innovation, research, and participation in clinical trials.*
 - *Contribute to linkages among regions to ensure appropriate referrals and timely consultation and to optimize patient care.*
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6.6.1 Multidisciplinary Tumor Boards - Current Situation

Appendix 13: Multidisciplinary Tumor Boards - Current Situation.

Please address the following questions:

- (1) Who decides which patients are seen in tumor boards? Who is responsible for identifying patients for discussion in tumor boards?
- (2) Are patients prioritized for tumor board meetings (such that certain cases definitely get discussed)?
- (3) How is the required patient information made available to the members of the tumor board?
- (4) How are decisions made by the tumor board documented?
- (5) How is compliance to tumor board decisions monitored (what are the results)?
- (6) Are tumor board meetings open for local/regional oncologists?

Please describe the role of the tumor boards in facilitating research (case finding and facilitation of recruitment are areas in which Cancer Center researchers might be catalytic in enhancing efforts going forward).

6.6.2 Multidisciplinary Tumor Boards - Future Situation

Please describe the future perspectives referring to the points in 6.6.1.

6.7 Psychosocial and Palliative Care

Describe how psychosocial and palliative care is integrated in the multidisciplinary-based treatment of cancer patients. How does the cancer center interact with patient advocacy groups?

Note: Wherever available, the support of patients by self-help groups has to be implemented in professional care. Immediately after diagnosis each patient should be informed about possible support by members of self-help groups. Additionally, representatives of self-help groups have to be involved in the boards/committees responsible for conceptual design and assessment of patient care. The criteria of certification for organ-specific cancer centers and oncology centers published by Deutsche Krebsgesellschaft regarding supportive care, particularly the collaboration with cancer self-help groups, have to be considered.

6.8 Standard Operating Procedures (SOPs)

Describe the existing standard operating procedures that reflect the current state of evidence-based oncology (e. g. diagnostics, treatment). How far are they based on current guidelines (e. g. 'S3-Leitlinien')? How are these SOPs developed and implemented? If there are no (current) guidelines existing, how are SOPs developed and implemented? Who is responsible for the development and implementation of SOPs?

Appendix 14: Implemented/active SOPs.

6.9 Information Technology at the Cancer Center – Current Situation / Future Plans

6.9.1 Information Technology at the Cancer Center – Current Situation

Describe the current Information Technology structure and systems operated at the cancer center. Please give special consideration to the following points/issues:

- clinical information system
- electronic medical record for each patient
- documentation of tumor board decisions
- electronic clinical pathways / care plans
- access to information about clinical trials
- clinical cancer registry
- user access (Who has access?)
- responsibilities / support from IT-Department.

6.9.2 Information Technology at the Cancer Center – Future Plans

Describe the Information Technology structure and systems that are planned to be operated at the cancer center. Please give special consideration to the following points/issues:

- clinical information system
- electronic medical record for each patient
- documentation of tumor board decisions
- electronic clinical pathways / care plans
- access to information about clinical trials
- clinical cancer registry
- user access (Who has access?)
- responsibilities / support from IT-Department.

6.10 Documentation, Clinical Cancer Registry, Long Term Follow-up

Describe the current state of documentation of diagnostic and therapeutic procedures and follow-up data in a clinical cancer registry. What data is collected in the clinical cancer registry? How is accurate and timely collection of cancer patient data ensured? Who is responsible for the successful operation of the clinical cancer registry? Is the clinical cancer registry embedded in or associated with a population based cancer registry?

Long-term follow-up is essential to evaluate outcomes of cancer care. How is follow-up information obtained? What is the mean follow-up rate?

6.11 Clinical Performance Monitoring / Quality Management and Assessment

Describe the current state of 'Clinical performance monitoring / Quality management and assessment' giving special consideration to the following issues:

- measuring adherence to guidelines and standard operating procedures,
- monitoring quality of care and patient outcomes (what methods are used to measure patient outcomes?),
- ensuring continuous improvement in the safety and quality of care.

Exemplify your statements by describing the quality assessment systems for diagnostics, oncologic surgery, medical oncology and radiotherapy.

6.12 Cancer Trials Activity

Is there a clinical trial office that is integral part of the comprehensive cancer center that offers assistance in planning, initiating, and conducting clinical trials, or is there a clinical trial office that serves all disciplines among which cancer is one?

What services does the (cancer) clinical trial office offer (e. g. protocol development support, centralized collection and dissemination of protocols to cancer center investigators, registration of patients onto approved protocols, monitoring of patient eligibility, data monitoring during protocol treatment, assistance in data analysis, and adverse event reporting)?

Is there a mechanism in place to close poorly accruing trials?

Is there a central Phase-I-Unit where all Phase-I-cancer trials are performed? How many beds does the Phase-I-Unit have?

Appendix 15: Table of accrual in Investigator Initiated Trials (IITs) in 2010 and 2011.

Appendix 16: Table of accrual in clinical trials (without IITs) in 2010 and 2011.

The following explanations help to determine whether a study is an investigator initiated trial or an industry initiated trial:

An investigator initiated trial is a clinical trial that has the following characteristics:

- A pharmaceutical company is not acting as the sponsor (Pharmaceutical Act, 'Arzneimittelgesetz/AMG').
- The sponsor has exclusive ownership of all data.
- The principal investigator or a Hospital/Institution is the primary author and custodian of the clinical trial protocol.
- The design, conduct, recording and reporting of the clinical trial is under the control of the sponsor.
- The clinical trial addresses relevant clinical questions and not industry needs.
- A pharmaceutical company is not directly funding the conduct of the study, that is, making payment to the relevant hospital/institution or investigator. Supplying an investigational medicinal product free or at reduced cost and/or providing support in a limited way does not disqualify the clinical trial from being regarded as an Investigator Initiated Trial.

An industry initiated trial is a clinical trial that has the following characteristics:

- It is initiated by a pharmaceutical company or other commercial entity and not by an investigator at the cancer center.
- The trial is conducted to investigate a drug/device for commercial exploitation by its manufacturer.

- The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.

6.13 Documentation of Attempts to Establish a Stable Interaction with Local Oncologists and Hospitals / Community Outreach

For your information: Comments of one of the reviewers involved in the evaluation of the proposals of the 1st call: "The establishment of regional networks needs to be better understood in the context of both the overall mission of a comprehensive cancer center and its specific goals. Among these goals should be efforts to provide patients with the opportunity to participate in clinical trials; opportunities to receive state-of-the-art, evidence-based therapy; and opportunities to be informed regarding the manner in which lifestyle changes might affect their cancer risk. Obviously these diverse goals require diverse strategies, and pursuing a comprehensive view of regional involvement should be a priority of German Comprehensive Cancer Centers in the future. The appointment of an Associate Director for Regional Activities/Affairs may facilitate efforts of a comprehensive cancer center in this regard."

"Comprehensive Cancer Centers should act as a powerful driving force for developing regional cancer networks. Cooperation with local and regional oncologists and hospitals is important for accrual of patients for clinical trials and research projects."

(1) Interaction with local oncologists and hospitals

Give a detailed overview of existing cooperations/collaborations/partnerships of the cancer center with local and regional hospitals, office-based oncologists, general practitioners etc. Describe the mode(s) of cooperation(s). Are there cooperation contracts existing? Please comment on the numbers of patients treated in affiliated institutions who have been reported to the registry of the cancer center. Discuss the numbers of such patients enrolled in clinical trials where the principal investigator is member of the cancer center/not member of the cancer center and the proportion of industry initiated trials. Do you have a structured system for consultations and second opinions? Give details on planned measures to improve and/or expand cooperations. In case there is a situation of competition for patients with another hospital/other hospitals, give some details on how this affects the cancer center. What measures are planned to foster cooperation rather than competition and conflict?

(2) Community Service and Outreach / Education of the public

A comprehensive cancer center must define the community or region that it serves, and maintain productive outreach efforts to address issues related to cancer. Which outreach programs are offered by the cancer center (e.g. promoting cancer prevention and early detection; preventing cancer through community education; encouraging behaviors that foster healthier lifestyles)? Discuss how the Center evaluates the impact of its outreach activities.

7. Education and Training

For your information: Education and multidisciplinary training of biomedical researchers and health care professionals must be considered as one of the main missions for a comprehensive cancer center. Training of biomedical researchers should include appropriate programs for training MDs and PhDs in laboratory, clinical and translational research. Of special interest are MD/PhD-programs. Cancer centers should also offer education and training programs for nurses.

Comment of a reviewer involved in the evaluation of the proposals of the 1st call: "The increased professionalization of oncology nurses and support for the expansion of their skill set is an important area in which cancer centers should be active. ... There is a need for specific programs that engage physicians-in-training and oncologists early in their careers to enhance their understanding of the molecular basis of the disease and where possible their understanding of how research is conducted and reported. The research strategies used to meet the needs of cancer patients are diverse, and supporting those efforts is an important activity for Comprehensive Cancer Centers. Also, training opportunities for young physicians to pursue careers that include research will be important in the future. A Comprehensive Cancer Center should seek to train the next generation of cancer investigators, both laboratory-based and clinic-based. ... It is important to organize a structural program for PhD - MD oncology training including attendance to tumor boards, training in basic research."

Describe the current activities/programs offered by the cancer center for multidisciplinary training of physicians, physician scientists, scientists, nurses and related professions. Which career development options are available for researchers and physician scientists? It is important that you focus on the value added by the cancer center; do not elaborate on 'standard' or 'routine' education/training.

8. Local Funding for the Cancer Center

This section should list the local support available for core-structures, research programs, and additional activities of the cancer center. Funds for standard clinical care should not be included.

9. Requested Funding

Provide an itemized budget/cost proposal (in English and in German) as well as a budget narrative which explains the reason for each requested budget item and which provides the basis for its cost. All requested items must be thoroughly justified and clearly related to the goals/objectives of the application.

The principal cost categories are 'Staff/Personnel', 'Equipment/Instrumentation', 'Consumables', and 'Other Expenses'.

For Equipment/Instrumentation, Consumables and Other Expenses please state the requested funds separately for each year in Euros.

For Staff/Personnel do not quote amounts in Euros. Please quote at which wage level (TVöD, TVÄ) he/she will be employed (max. 3 years). The necessary totals will be calculated by the Deutsche Krebshilfe. For each person to be funded by the Deutsche Krebshilfe, please describe their task(s).

10. Summary

Please provide a concise, comprehensive summary describing the current state/activities of the cancer center and what impact funding by Deutsche Krebshilfe would have for the cancer center.

11. Bylaws

Appendix 17: Bylaws, e. g. specifying responsibilities/authorities of the Cancer Center Director, clarifying reporting structures, etc.

12. Statements of Support

Appendix 18: Statements of support by institute and department directors participating in the Cancer Center, with name, function, address, date and signature.

13. Declaration

Please state if you have already submitted the same or a similar request for funding to other institutions, providing an explanation. If this is not the case then the following statement must be made:

'The same or a similar request for funding has not been submitted to any other addressee. If any such proposal should be submitted, the Deutsche Krebshilfe will be informed immediately'.

14. Further Information

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

B) Renewal Proposals

Renewal proposals consist of the following 3 parts which should be supplied as separate bound copies:

- Progress Report
- Grant Application
- Appendices (Progress report as well as grant application refer to the same 'volume' of appendices)

Progress Report

Please notice that this progress report is the critical part of a renewal proposal and therefore must be detailed, sound and comprehensive.

Face Page with Full Name of the Cancer Center

1. **Table of Contents** (with page numbers)

2. **Name and Full Work Address of the Cancer Center Director and Deputy Director**
(in English and in German)

Appendix 1: Biographical sketch, portrait photo, research focus, and the ten most important publications of the Cancer Center Director and the Deputy Director.

Note: The Cancer Center Director is regarded as corresponding author.

3. **Summary of the developments and changes since the last on-site evaluation**

Describe the developments and changes since the last on-site evaluation, laying special emphasis on the reviewer's comments/recommendations resulting from the site visit as well as the comments on the interim reports. Please specify the reviewer's comments/recommendations and comment on each of them (usage of figures, tables, charts etc. is encouraged).

4. **Development and current situation of the Structure of the Cancer Center**

- 4.1 **Administrative and Organizational Structure**

Name and describe the current key structural elements/units of the cancer center, their functional duties/responsibilities, levels of authority, and interfaces/relationships.

Describe the reporting and advisory structures/pathways as well as the decision making processes at the center. Please describe and comment on the development of these structures since the last on-site evaluation. List the members of the center's external advisory board (if available).

Appendix 2: Organization chart (current situation).

4.2 Position / Responsibilities / Authorities of the Cancer Center Director

Describe the developments and changes since the last on-site evaluation regarding the status of the cancer center director within the institution; any appointments to decision-making committees relevant to the cancer center; authorities in relation to integration of research across departments, appointment and review of program members, recruitments and faculty positions, research and resource space and equipment dedicated to the center, revenue streams, and inpatient and outpatient facilities. In case of replacement of the cancer center director, please describe the qualifications of the current cancer center director in relation to scientific background and leadership experience and his/her time commitment to the center.

5. Laboratory and Clinical Research

For your information:

The reviewers will ask the following questions:

- *What is the overall quality of the science going on in the center and its programs?*
 - *What impact has the center **itself** (or is it likely to have) on the quality of the science, the productivity of the scientists, and the interdisciplinary activities of the institution relating to cancer?*
 - *What has the center contributed to the development of more effective prevention, diagnosis and treatment for cancer?*
 - *Does the cancer center **add value** over and above the separately funded research efforts themselves? Have thoughtful, coherent scientific programs been assembled and program members selected to maximize the cancer-related interactive science?*
 - *How do the different cancer-related scientific themes of the parent institution fit together and complement each other in the center?*
 - *Have the choices for center membership made by its leaders resulted in a group of excellent cancer-focused scientists who are also committed to productive interactions with one another?*
 - *Which research programs do exist/have been developed that include both clinicians and basic scientists?*
 - *What measures have been taken to integrate (translational) research into the different multidisciplinary groups responsible for health care?*
-

In the following paragraphs (5.1 – 5.3) please describe and comment on the current status and the development of the research infrastructure/programs since the last on-site evaluation.

5.1 Research Infrastructure / Research Programs

Please describe what kind of programmatic structures have been developed/implemented to promote interdisciplinary research and translational research, giving special consideration to the questions outlined above. In particular, clearly point out how the structure of the cancer center supports laboratory and translational research (what is the value added by the cancer center regarding the local research efforts). Please identify the (infrastructural) measures of the cancer center to facilitate such collaborative undertakings (e. g. common programs, teleconferencing, internal grant programs etc).

Give a detailed description of the cancer center's tumor- and bio-bank(s) with special consideration to the center's policies for the operation of the tissue bank and for the use of tumor tissues (comprehensive clinical documentation, standard operating procedures, and quality control). Who is responsible for the operation of the tissue bank?

5.2 Shared Resources / Core Facilities

For your information: Shared Resources provide access to technologies, services, and scientific consultation that enhance scientific interaction and productivity. The support of shared services for an entire center provides stability, reliability, cost-effectiveness, access to specialized technology and methodology, and quality control.

5.2.1 Shared Resources/Core Facilities Operated by the Cancer Center

Appendix 4: Shared Resources/Core Facilities operated by the Cancer Center.
Developmental cores should be clearly identified as such if included.

Describe the center's policies about operation and use of each of the shared resources/core facilities, e.g., access, priorities, limitations and charge back systems.

5.2.2 Shared Resources/Core Facilities not Operated by the Cancer Center

Appendix 5: Shared Resources/Core Facilities not operated by the Cancer Center.
Developmental cores should be clearly identified as such if included.

Describe the policies about operation and use of each of the shared resources/core facilities, e.g., access, priorities, limitations and charge back systems.

5.3 Summary of Laboratory and Clinical Research Activities

Describe the laboratory and clinical research activities/programs. Give details on the top-five research projects/milestones 2007 – 2011 and list the relevant publications. The publications should be allocated to these top-five research projects. For the evaluation it

is essential, that you work out what is the contribution of the cancer center to the work of the individual research groups and vice versa.

Appendix 6: List all in 2010 and 2011 active funded, cancer-relevant projects competitively awarded by external sources. Provide a separate form for each principal investigator.

Appendix 7: Summary – in 2010 and 2011 active funded research projects.

Please comment on the development of research funds (cancer relevant projects competitively awarded by external sources) since the last on-site evaluation.

6. Clinical Care

In the following paragraphs (6.1- 6.13) please describe and comment on the current status and the development of oncology care since the last on-site evaluation (usage of charts, figures etc. is encouraged).

6.1 Clinical Care - Basic Information

Give details on the size of the hospital (total number of beds and patients/year).

Appendix 8: Plan of the hospital / university campus indicating the building in which core activities of the cancer center are conducted.

Appendix 9: Catchment area (map, number of inhabitants).

Tabulations documenting which anatomic cancer sites are being treated at the cancer center and whether the center is placing these patients onto therapeutic protocols:

Appendix 10: Number of all cancer patients treated in the cancer center in 2009, 2010 and 2011, respectively.

Provide the number of all cancer patients (inpatients, outpatients, total) treated in the cancer center in 2009, 2010 and 2011, respectively. Reflect the number of patients coming to the cancer center, not the number of visits. Do not include any patient more than once unless they have been treated for two malignancies in one year. All patients should be counted regardless of whether they have a newly diagnosed cancer or have recurrent disease and were referred to the cancer center for further evaluation and primary or secondary treatment. This category excludes consults (e.g., for service or second opinions), diagnoses at autopsy, and former patients admitted for rehabilitation purposes or treatment of some other conditions. It also excludes patient follow up activities after treatment is completed. Please provide separate forms for each year.

- Appendix 11:
- (A) Number of cancer patients newly diagnosed in 2009, 2010 and 2011, respectively.
Provide the number of patients newly diagnosed in the cancer center or elsewhere in 2009, 2010 and 2011 and whose treatment started in the cancer center in the respective year (inpatients, outpatients, total). Reflect the number of patients coming to the cancer center, not the number of visits. Do not include any patient more than once unless they had two malignancies diagnosed in one year. Do not include patients with recurrent disease. Please provide separate forms for each year.
- (B) Number of (A)-patients enrolled in clinical trials in 2009, 2010 and 2011, respectively.
Provide the number of (A)-patients by anatomic site that were newly enrolled in therapeutic trials in 2009, 2010 and 2011, respectively (Phase I-trials and Phase II- and III-trials with therapeutic intent using drugs, radiation, surgery, other biological agents, or behavioral or other interventions). A patient may appear more than once if he/she was on more than one therapeutic protocol. See explanations in 6.12 to determine whether a study is an investigator initiated trial or an industry initiated trial. Please provide separate forms for each year.

6.2 Fields of Specific Competence

Identify fields of specific competence of the cancer center (e.g. rare tumor entities, specific diagnostic or therapeutic options).

6.3 Certifications

List all certifications of the center which are relevant for clinical care and / or cancer research.

6.4 Multidisciplinary Care

For your information:

Multidisciplinary care for all cancer patients from diagnosis through to palliative care is one of the key principles of a comprehensive cancer center. The aim is to ensure a multidisciplinary team approach to prospective treatment and care planning that is aligned with best-practice and evidenced-based care.

*Comment of a reviewer who was involved in the evaluation of the proposals of the 1st call:
"... A key aspect of a comprehensive cancer center is the expectation that the vertical 'silos' (for example, Departments) that characterize the current university and hospital enterprises in Germany need to be horizontally linked in a manner that supports interdisciplinary integration, albeit to a varying degree in varying situations. ...*

... The continued development of a centralized facility in which all chemotherapy is given is very important for cancer patients and for the further development of an integrated Cancer Center. ...

... The continued evolution and expansion of care guidelines and structures to enhance and support optimal care for cancer patients must be a fundamental element of comprehensive cancer centers."

Please describe the development and current status of multidisciplinary care at the cancer center, giving special consideration to the status of implementation of:

- (1) Structures of multidisciplinary clinical oncology that encompass all tumor entities, with a central entry port for tumor patients. Integrated clinical care by a team of physicians of different disciplines.
- (2) A centralized quality-controlled outpatient unit for chemotherapy.

6.5 Patient Pathways

For your information: The "patient pathway" is the route that a patient will take from his/her first contact with the cancer center (self-, physician-/hospital-referral), entry into the cancer center, until he/she leaves the center or treatment is completed.

Describe the specific pathways for patients suffering from:

- (a) Breast Cancer
- (b) Prostate Cancer
- (c) Colorectal Cancer
- (d) Lung Cancer
- (e) Melanoma
- (f) Other tumor(s) for which the cancer center has specific competence

At which entry point(s) do the patients enter the cancer center? Please supply the proportions of patients entering via a central entry point, via particular departments, etc. How many of them are discussed in tumor boards? Please describe the routes and possible 'sub' routes and comment on the patient numbers and percentages entering the specific routes. Were there changes since the last on-site evaluation?

Appendix 12: 6 flowcharts showing the patient pathways (a) to (f).

6.6 Multidisciplinary Tumor Boards – Developments and Current Situation

For your information:

Tumor boards are integral to improve the care of cancer patients by contributing to the patient management process and outcomes, as well as by providing education to physicians and other staff attendance.

Multidisciplinary Cancer Conference (MCC) Objectives:

- *MCC Primary function:*
 - *Ensure that all appropriate diagnostic tests, all suitable treatment options, and the most appropriate treatment recommendations are generated for each cancer patient discussed prospectively in a multidisciplinary forum.*

 - *MCC Secondary functions:*
 - *Provide a forum for the continuing education of medical staff and health professionals.*
 - *Contribute to patient care quality improvement activities and practice audit.*
 - *Contribute to the development of standardized patient management protocols.*
 - *Contribute to innovation, research, and participation in clinical trials.*
 - *Contribute to linkages among regions to ensure appropriate referrals and timely consultation and to optimize patient care.*
-

Appendix 13: Multidisciplinary Tumor Boards - Current Situation.

Please address the following questions:

- (1) Who decides which patients are seen in tumor boards? Who is responsible for identifying patients for discussion in tumor boards?
- (2) Are patients prioritized for tumor board meetings (such that certain cases definitely get discussed)?
- (3) How is the required patient information made available to the members of the tumor board?
- (4) How are decisions made by the tumor board documented?
- (5) How is compliance to tumor board decisions monitored (what are the results)?
- (6) Are tumor board meetings open for local/regional oncologists?

Please describe the role of the tumor boards in facilitating research (case finding and facilitation of recruitment are areas in which Cancer Center researchers might be catalytic in enhancing efforts going forward).

6.7 Psychosocial and Palliative Care

Describe how psychosocial and palliative care is integrated in the multidisciplinary-based treatment of cancer patients. How does the cancer center interact with patient advocacy groups?

6.8 Standard Operating Procedures (SOPs)

Describe the existing standard operating procedures that reflect the current state of evidence-based oncology (e. g. diagnostics, treatment). How far are they based on current guidelines (e. g. 'S3-Leitlinien')? How are these SOPs developed and implemented? If there are no (current) guidelines existing, how are SOPs developed and implemented? Who is responsible for the development and implementation of SOPs?

Appendix 14: Implemented/active SOPs.

6.9 Information Technology at the Cancer Center

Describe the current Information Technology structure and systems operated at the cancer center. Please give special consideration to the following points/issues:

- clinical information system
- electronic medical record for each patient
- documentation of tumor board decisions
- electronic clinical pathways / care plans
- access to information about clinical trials
- clinical cancer registry
- user access (Who has access?)
- responsibilities / support from IT-Department.

6.10 Documentation, Clinical Cancer Registry, Long Term Follow-up

Describe the current state of documentation of diagnostic and therapeutic procedures and follow-up data in a clinical cancer registry. What data is collected in the clinical cancer registry? How is accurate and timely collection of cancer patient data ensured? Who is responsible for the successful operation of the clinical cancer registry? Is the clinical cancer registry embedded in or associated with a population based cancer registry?

Long-term follow-up is essential to evaluate outcomes of cancer care. How is follow-up information obtained? What is the mean follow-up rate?

6.11 Clinical Performance Monitoring / Quality Management and Assessment

Describe the current state of 'Clinical performance monitoring / Quality management and assessment' giving special consideration to the following issues:

- measuring adherence to guidelines and standard operating procedures,
- monitoring quality of care and patient outcomes (what methods are used to measure patient outcomes?),
- ensuring continuous improvement in the safety and quality of care.

Exemplify your statements by describing the quality assessment systems for diagnostics, oncologic surgery, medical oncology and radiotherapy.

6.12 Cancer Trials Activity

Is there a clinical trial office that is integral part of the comprehensive cancer center that offers assistance in planning, initiating, and conducting clinical trials, or is there a clinical trial office that serves all disciplines among which cancer is one?

What services does the (cancer) clinical trial office offer (e. g. protocol development support, centralized collection and dissemination of protocols to cancer center investigators, registration of patients onto approved protocols, monitoring of patient eligibility, data monitoring during protocol treatment, assistance in data analysis, and adverse event reporting)?

Is there a mechanism in place to close poorly accruing trails?

Is there a central Phase-I-Unit where all Phase-I-cancer trials are performed? How many beds does the Phase-I-Unit have?

Appendix 15: Table of accrual in Investigator Initiated Trials (IITs) in 2010 and 2011.

Appendix 16: Table of accrual in clinical trials (without IITs) in 2010 and 2011.

The following explanations help to determine whether a study is an investigator initiated trial or an industry initiated trial:

An investigator initiated trial is a clinical trial that has the following characteristics:

- A pharmaceutical company is not acting as the sponsor (Pharmaceutical Act, 'Arzneimittelgesetz/AMG').
- The sponsor has exclusive ownership of all data.
- The principal investigator or a Hospital/Institution is the primary author and custodian of the clinical trial protocol.

- The design, conduct, recording and reporting of the clinical trial is under the control of the sponsor.
- The clinical trial addresses relevant clinical questions and not industry needs.
- A pharmaceutical company is not directly funding the conduct of the study, that is, making payment to the relevant hospital/institution or investigator. Supplying an investigational medicinal product free or at reduced cost and/or providing support in a limited way does not disqualify the clinical trial from being regarded as an Investigator Initiated Trial.

An industry initiated trial is a clinical trial that has the following characteristics:

- It is initiated by a pharmaceutical company or other commercial entity and not by an investigator at the cancer center.
- The trial is conducted to investigate a drug/device for commercial exploitation by its manufacturer.
- The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.

6.13 Documentation of Attempts to Establish a Stable Interaction with Local Oncologists and Hospitals / Community Outreach

For your information: Comments of one of the reviewers involved in the evaluation of the proposals of the 1st call: "The establishment of regional networks needs to be better understood in the context of both the overall mission of a comprehensive cancer center and its specific goals. Among these goals should be efforts to provide patients with the opportunity to participate in clinical trials; opportunities to receive state-of-the-art, evidence-based therapy; and opportunities to be informed regarding the manner in which lifestyle changes might affect their cancer risk. Obviously these diverse goals require diverse strategies, and pursuing a comprehensive view of regional involvement should be a priority of German Comprehensive Cancer Centers in the future. The appointment of an Associate Director for Regional Activities/Affairs may facilitate efforts of a comprehensive cancer center in this regard."

"Comprehensive Cancer Centers should act as a powerful driving force for developing regional cancer networks. Cooperation with local and regional oncologists and hospitals is important for accrual of patients for clinical trials and research projects."

(1) Interaction with local oncologists and hospitals

Give a detailed overview of existing cooperations/collaborations/partnerships of the cancer center with local and regional hospitals, office-based oncologists, general practitioners etc. Describe the mode(s) of cooperation(s). Are there cooperation contracts existing? Please comment on the numbers of patients treated in affiliated

institutions who have been reported to the registry of the cancer center. Discuss the numbers of such patients enrolled in clinical trials where the principal investigator is member of the cancer center/not member of the cancer center and the proportion of industry initiated trials. Do you have a structured system for consultations and second opinions? In case there is a situation of competition for patients with another hospital/other hospitals, give some details on how this affects the cancer center.

(2) Community Service and Outreach / Education of the public

A comprehensive cancer center must define the community or region that it serves, and maintain productive outreach efforts to address issues related to cancer. Which outreach programs are offered by the cancer center (e.g. promoting cancer prevention and early detection; preventing cancer through community education; encouraging behaviors that foster healthier lifestyles)? Discuss how the Center evaluates the impact of its outreach activities. Figure out how the external presentation and the perception of the comprehensive cancer center have changed since the last on-site evaluation.

7. Education and Training

For your information: Education and multidisciplinary training of biomedical researchers and health care professionals must be considered as one of the main missions for a comprehensive cancer center. Training of biomedical researchers should include appropriate programs for training MDs and PhDs in laboratory, clinical and translational research. Of special interest are MD/PhD-programs. Cancer centers should also offer education and training programs for nurses.

Comment of a reviewer involved in the evaluation of the proposals of the 1st call: "The increased professionalization of oncology nurses and support for the expansion of their skill set is an important area in which cancer centers should be active. ... There is a need for specific programs that engage physicians-in-training and oncologists early in their careers to enhance their understanding of the molecular basis of the disease and where possible their understanding of how research is conducted and reported. The research strategies used to meet the needs of cancer patients are diverse, and supporting those efforts is an important activity for Comprehensive Cancer Centers. Also, training opportunities for young physicians to pursue careers that include research will be important in the future. A Comprehensive Cancer Center should seek to train the next generation of cancer investigators, both laboratory-based and clinic-based. ... It is important to organize a structural program for PhD - MD oncology training including attendance to tumor boards, training in basic research."

Give an overview of the developments since the last on-site evaluation and describe the current activities/programs offered by the cancer center for multidisciplinary training of physicians, physician scientists, scientists, nurses and related professions. Which career development options are available for researchers and physician scientists? It is important that you focus on the value added by the cancer center; do not elaborate on 'standard' or 'routine' education/training.

8. Use of Funds

List the measures (staff/personnel, equipment, others) for which the funds have been used so far and explain their impact on the development on the comprehensive cancer center (it is important to demonstrate the value added by the approved funds). You should clearly work out how the funds are used to support clinical services and research. In addition, it is useful to know what metrics are being used to monitor the effectiveness of budget decisions and ultimately the outcome of these evaluations.

Grant Application

Cover Letter

Briefly introduces the application, states the willingness to accept the terms of evaluation and funding. The letter has to be signed by the Cancer Center Director and Deputy Director, the Chief Physician of the Hospital, the Dean of the Medical Faculty, and the fiscally responsible Administrative Director.

Face Page with Full Name of the Cancer Center

1. Table of Contents (with page numbers)

2. Institutional Commitment to the Cancer Center

Discuss the institutional commitment to the cancer center, including its recognition and status as a formal organizational component, the provision of space, positions and discretionary resources. The Chief Physician of the Hospital, the Dean of the Medical Faculty (if applicable) and the fiscally responsible Administrative Director have to declare their commitment for the long term future of the cancer center.

3. Name and Full Work Address of the Cancer Center Director and Deputy Director
(in English and in German)

Appendix 1: Biographical sketch, portrait photo, research focus, and the ten most important publications of the Cancer Center Director and the Deputy Director.

Note: The Cancer Center Director is regarded as corresponding author.

In the following paragraphs, please describe the future perspectives and planned measures of the Comprehensive Cancer Center

Note: The respective goals for the (near-term) future and their prioritization should be described in a manner that allows the reviewers to understand how these decisions are contributing to the realization of the cancer center's strategic goals.

Please use the respective appendices if applicable.

4. Structure of the Cancer Center

4.1 Overview of the Future Administrative and Organizational Structure

For further information see 4.2, page 11.

4.2 Position / Responsibilities / Authorities of the Cancer Center Director

Please comment on planned changes if applicable.

5. Future Research Infrastructure and Laboratory and Clinical Research Topics / Research Programs

Describe the planned developments concerning laboratory and clinical research activities/programs (as well as infrastructural measures). Please point out new plans regarding the impact of the cancer center on laboratory and translational cancer research.

6. Clinical Care

6.1 Clinical Care - Summary

Please summarize the future perspectives and planned measures regarding clinical care (e. g. increase of patient numbers, building measures; accrual for clinical trials etc).

6.2 Fields of Specific Competence

For further information see 6.2, page 14.

6.3 Certifications

For further information see 6.3, page 14.

6.4 Multidisciplinary Care

For further information see 6.4, page 14/15.

6.5 Patient Pathways

For further information see 6.5, page 15.

6.6 Multidisciplinary Tumor Boards – Future Situation

For further information see 6.6.2, page 16.

6.7 Psychosocial and Palliative Care

Describe how integration of psychosocial and palliative care in the multidisciplinary-based treatment of cancer patients as well as interaction with patient advocacy groups will be further improved.

Note: Wherever available, the support of patients by self-help groups has to be implemented in professional care. Immediately after diagnosis each patient should be informed about possible support by members of self-help groups. Additionally, representatives of self-help groups have to be involved in the boards/committees responsible for conceptual design and assessment of patient care. The criteria of certification for organ-specific cancer centers and oncology centers published by Deutsche Krebsgesellschaft regarding supportive care, particularly the collaboration with cancer self-help groups, have to be considered.

6.8 Standard Operating Procedures (SOPs)

For further information see 6.8, page 17.

6.9 Information Technology at the Cancer Center – Future Plans

For further information see 6.9.2, page 17/18.

6.10 Documentation, Clinical Cancer Registry, Long Term Follow-up

For further information see 6.10, page 18.

6.11 Clinical Performance Monitoring / Quality Management and Assessment

For further information see 6.11, page 18.

6.12 Cancer Trials Activity

For further information see 6.12, page 18-20.

6.13 Establishment of a Stable Interaction with Local Oncologists and Hospitals / Community Outreach

Give details on planned measures to improve and/or expand cooperations. In case there is a situation of competition for patients with another hospital/other hospitals, give some details on planned measures to foster cooperation rather than competition and conflict.

7. Education and Training

Describe the planned measures to further improve the multidisciplinary training activities/programs offered by the cancer center. It is essential that you focus on the value added by the cancer center.

8. Local Funding for the Cancer Center

This section should list the local support available for core-structures, research programs, and additional activities of the cancer center. Funds for standard clinical care should not be included.

9. Requested Funding

Provide an itemized budget/cost proposal (in English and in German) as well as a budget narrative which explains the reason for each requested budget item and which provides the basis for its cost. All requested items must be thoroughly justified and clearly related to the goals/objectives of the application.

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For Equipment/Instrumentation, Consumables and Other Expenses please state the requested funds separately for each year in Euros.

For Staff/Personnel do not quote amounts in Euros. Please quote at which wage level (TVöD, TVÄ) he/she will be employed (max. 3 years). The necessary totals will be calculated by the Deutsche Krebshilfe. For each person to be funded by the Deutsche Krebshilfe, please describe their task(s).

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Please provide a concise, comprehensive summary describing the future perspectives and planned measures of the cancer center and what impact further funding by Deutsche Krebshilfe would have for the cancer center.

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Appendix 17: Bylaws, e. g. specifying responsibilities/authorities of the Cancer Center Director, clarifying reporting structures, etc.

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Appendix 18: Statements of support by institute and department directors participating in the Cancer Center, with name, function, address, date and signature.

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Please state if you have already submitted the same or a similar request for funding to other institutions, providing an explanation. If this is not the case then the following statement must be made:

'The same or a similar request for funding has not been submitted to any other addressee. If any such proposal should be submitted, the Deutsche Krebshilfe will be informed immediately'.

14. Further Information

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

LIST OF APPENDICES

(for more details see proposal guidelines)

Appendix 1: Biographical sketch of the Cancer Center Director and the Deputy Director

Appendix 2: Organization chart (current situation)

Appendix 3: Organization chart (future situation)

Appendix 4*: Shared Resources/Core Facilities operated by the Cancer Center

Appendix 5*: Shared Resources/Core Facilities not operated by the Cancer Center

Appendix 6*: Active funded, cancer-relevant projects (per principal investigator)

Appendix 7*: Active funded, cancer-relevant projects (summary)

Appendix 8: Plan of the hospital / university campus

Appendix 9: Catchment area

Appendix 10*: Number of all cancer patients treated in the cancer center

Appendix 11:

11A*: Number of newly diagnosed cancer patients

11B*: Number of (A)-patients enrolled in clinical trials

Appendix 12: Flowcharts showing patient pathways

Appendix 13*: Multidisciplinary Tumor Boards – Current Situation

Appendix 14: Implemented/active guidelines/SOPs

Appendix 15*: Table of accrual in Investigator Initiated Trials (IITs)

Appendix 16*: Table of accrual in clinical trials (without IITs)

Appendix 17: Bylaws

Appendix 18: Statements of Support

**Forms can be downloaded as word files*

CONTACT

For further information, please contact the offices of Deutsche Krebshilfe:

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