DEUTSCHE KREBSHILFE

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

– SECOND 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, the 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 a new program to set nationwide standards for clinical cancer care and for strengthening translational cancer research.

Deutsche Krebshilfe issued an initial call for proposals in April 2006 which resulted in the funding of 4 centers. We are now inviting for a second round of applications. In this second phase, up to 6 centers will be supported, each with one million Euros per year over a period of three years, followed by a re-evaluation. 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. On the basis of applications received, site visits will be carried out in a limited number of centers.

Please notify the Deutsche Krebshilfe of your intent to submit an application.
Letter of intent deadline: December 14, 2007.
Subsequent full application deadline: May 2, 2008.

There will be an information meeting for all those interested in applying for funding. The meeting will be held in Bonn on Thursday, November 8, 2007, 10.30 to 14.00 h.

GENERAL INFORMATION

Preface

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. Appointment of a highly qualified scientist with administrative experience as cancer center director supported by an executive committee and scientific advisory board.
i. Integrated psychosocial and palliative care. The center should 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 dedicated cancer center director.
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 6 centers will 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.

Deutsche Krebshilfe has decided to continuously fund up to ten centers over the next years with regular re-evaluation and calls for new proposals.

Application and Review Process

The application process will proceed in two stages:

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

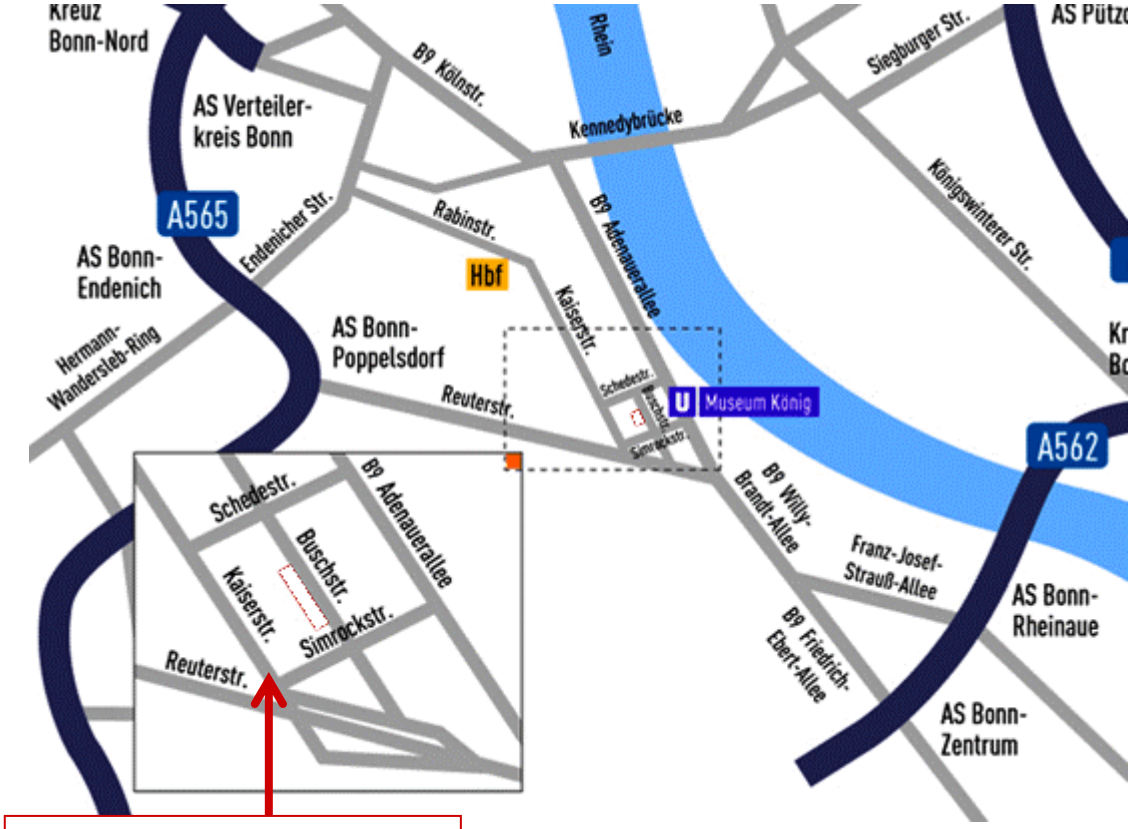
2. Each finalist oncology center will be further evaluated by the review group during a site visit in October/November 2008 and/or January/February 2009.

Based on the applications and the results of the on-site evaluations, the review group will make recommendations to the Deutsche Krebshilfe Executive Board, which will take the final decision.

INFORMATION MEETING

There will be an information meeting for all those interested in applying for funding. The meeting will take place on Thursday, **November 8, 2007, 10.30 to 14.00 h**, at the Deutsche Sparkassenakademie Auditorium, Kaiserstraße 221, 53113 Bonn. The location is close to 'Museum Koenig' Underground station.

The maximum number of participants per cancer center is restricted to 3 representatives. To register, please send an email to spitzenzentren@krebshilfe.de no later than Tuesday, October 30, 2007, with name, title, institution, address, phone number, and e-mail address of all participants; Subject: 'Information Meeting Oncology Centers'.



Auditorium
Deutsche Sparkassenakademie
Kaiserstr. 221, 53113 Bonn

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 **December 14, 2007, 13.00 h** (Emails and Faxes are NOT accepted).

The Deutsche Krebshilfe office acknowledges receipt of every 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 and

(2) briefly describe (one page maximum) the proposed approach to establish an 'Interdisciplinary Oncology Center of Excellence'.

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 **May 2, 2008, 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),
- 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, 11, 14, 15, 17, 18, 19 (the forms can be downloaded from our website www.krebshilfe.de; to fill in these forms, please use 'Arial Narrow' 9 or 10 pt),
- provide one complete unbound original application package (proposal itself and appendix) with original signatures plus 15 bound copies of the proposal itself (including copies of the cover letter) and 15 bound copies of the appendix (each appendix copy consisting of appendices 1 - 21).

In addition to the paper copy, the proposal and appendix are also required in electronic format. Please send the electronic version with the hard copy application in PDF format on CD-ROM 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.

Important Note:

As the cancer centers in Germany are in a developing state, it is important that you clearly differentiate between the cancer center's <u>current</u> situation and <u>future</u> goals/prospects.

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, Including Appendices

(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

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

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.

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?*

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.

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 2002 – 2007 and list the relevant publications.

Appendix 6: List all in 2007 active funded, cancer-relevant projects competitively awarded by external sources. Provide a separate form for each principal investigator.

Appendix 7: Summary – in 2007 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.

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 or affiliated institutions and whether the center is placing these patients onto therapeutic protocols:

Appendix 10: Number of all cancer patients treated in the cancer center in 2007.
Provide the number of all cancer patients (inpatients, outpatients, total) treated in the cancer center in 2007. 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 2007. 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.

Appendix 11: (A) Number of cancer patients newly diagnosed in 2007.
Provide the number of patients newly diagnosed in the cancer center or elsewhere in 2007 and whose treatment started in the cancer center in 2007 (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 2007. Do not include patients with recurrent disease.

(B) Number of (A)-patients enrolled in clinical trials in 2007.
Provide the number of (A)-patients by anatomic site that were newly enrolled in therapeutic trials in 2007 (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 6.11 to determine whether a study is an investigator initiated trial or an industry initiated trial.

(C) Number of newly diagnosed cancer patients treated in 2007 in affiliated institutions within the catchment area and who have been reported to the registry of the cancer center.
Provide the number of cancer patients newly diagnosed in the cancer center or elsewhere in 2007 and whose treatment started in 2007 in affiliated institutions within the catchment area and who have been reported to the registry of the cancer center. Reflect the number of patients, not the number of visits in the affiliated institutions. Do not include any patient more than once unless they had two malignancies diagnosed in 2007. Do not include patients with recurrent disease.

(D) Number of (C)-Patients enrolled in clinical trials in 2007.
Provide the number of (C)-patients by anatomic site that were newly enrolled in therapeutic trials in 2007 (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 6.11 to determine whether a study is an investigator initiated trial or an industry initiated trial.

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 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) Standard operating procedures for diagnosis and treatment that reflect the current state of evidence-based oncology. (Are there guidelines/SOPs for the patient care pathways? How are these guidelines/SOPs developed? How are they implemented?)

(3) A centralized quality-controlled outpatient unit for chemotherapy.

6.4 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 (central entry point for all cancer patients), until he/she leaves the center or treatment is completed.

6.4.1 Patient Pathways - General Overview

Describe the general pathways for cancer patients (overview), including responsibilities, key decision-making points (at what points decisions are made).

Appendix 12: Flowchart giving an overview of the general patient pathways.

6.4.2 Patient Pathways - Disease-specific Patient Pathways (examples)

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

Appendix 13: 6 flowcharts showing the patient pathways (a) to (f).

6.5 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.*

6.5.1 Multidisciplinary Tumor Boards - Current Situation

Appendix 14: 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).

6.5.2 Multidisciplinary Tumor Boards - Future Situation

Appendix 15: Multidisciplinary Tumor Boards - Future Situation.

6.6 Psychosocial and Palliative Care

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

6.7 Guidelines / Standard Operating Procedures (SOPs)

Describe how guidelines/standard operating procedures covering all aspects of cancer patient care (e. g. clinical pathways, diagnostics, and treatment) and the underlying organizational activities (e. g. tumor board frequency and attendance requirements) are developed and implemented. Who is responsible for the development and implementation of the guidelines/SOPs?

Appendix 16: Implemented/active guidelines/SOPs.

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

6.8.1 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.

6.8.2 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.

6.9 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?

6.10 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.

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

Appendix 17: Table of ongoing Investigator Initiated Trials in 2007.

Appendix 18: Participation in clinical trials in 2007.

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.

6.12 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 pursing 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). 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. Self-assessment

Appendix 19: Self-assessment of fulfillment of the criteria for funding.

9. 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.

10. Requested Funding

Provide an itemized budget/cost proposal 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 (BAT, 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).

11. Summary

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

12. Bylaws

Appendix 20: Bylaws, e. g. specifying responsibilities/authorities of the Cancer Center Director, clarifying reporting structures, etc.

13. Statements of Support

Appendix 21: Statements of support by institute and department directors participating in the Cancer Center, with name, function, address, date and signature.

14. 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'.

For further information, please contact
Dr. Bernhard Sperker (0228/729 90 227)
Dr. Franz Kohlhuber (0228/729 90 222)
Ruth Heinemann (0228/729 90 225)
send email requests to 'spitzenzentren@krebshilfe.de'

'For Further Reading' …
http://cancercenters.cancer.gov/downloads.html
http://www.cancercare.on.ca/index_1744.htm
http://www.health.vic.gov.au/cancer/
http://www.facs.org/cancer/coc/programstandards.html
http://www.simoneconsulting.com/PDF/UCC.pdf

Appendix No. 4 / Shared Resources - Core Facilities Operated by the Cancer Center

Resource(s)	Shared Resource	Develop-mental	Resource Director(s)
1. Laboratory Science			
1.01 Biochemical Analysis			
1.02 General Animal Facility			
1.03 Transgenic Facility			
1.04 Special Breeding			
1.05 Animal Health (Pathology/Histology)			
1.06 Animal Health (QC)			
1.08 Specific Pathogen Free (Barrier Animal Facility)			
1.09 Nude Mouse			
1.10 Specialized Animal Svcs (Irradiation)			
1.11 Biohazard Control			
1.12 Organic & Synthetic Chemistry			
1.13 Chromatography			
1.14 Cytology-Analytic & Immunologic			
1.15 Cytogenetics			
1.16 Genetics			
1.17 Electron Microscopy			
1.18 Flow Cytometry			
1.19 Cyclotron or Radiolabeling			
1.20 Molecular Biology			
1.21 Nucleotide Sequencing			
1.22 Protein & Peptide Sequencing			
1.23 Monoclonal Antibodies			
1.24 NMR			
1.26 MRI			
1.27 Spectrometry, Other (Specify)			
1.28 Radiobiology			
1.29 Oligonucleotide Synthesis			
1.30 Protein/Peptide Synthesis			
1.31 Toxicology/Mutagenesis Testing			
1.33 Confocal Microscopy			
1.34 Xray Diffraction			
1.35 DNA Array			
1.36 Proteomics			
1.37 Other (Define)			
2. Laboratory Support			
2.01 General or Equipment Repair			
2.02 Machine Shop			
2.03 Glassware Washing			
2.04 Illustration/Photography/Typeset			
2.07 Tissue Culture			
2.08 Media Preparation			
2.10 Other (Define)			
3. Epidemiology, Cancer Control			
3.01 Cancer Control			
3.03 Epidemiology			
3.04 Survey			
3.05 Nutrition			
3.06 Other (Define)			

Shared Resource: Please tick if appropriate
Developmental: Please tick if appropriate
Resource Director(s): Provide Name, academic status, institution

4. Clinical Research			
4.01 Clinical Trials Protocol & Data Management			
4.02 Clinical – Other			
4.03 Pharmacology (Animal)			
4.04 Pharmacology (Lab Tests)			
4.05 Human Tissue Acquisition & Pathology/Histology			
4.06 Gene Therapy/Vector			
4.07 Other (Define)			
5. Administrative			
5.01 Secretarial/Word Processing			
5.02 Other (Define)			
6. Biostatistics			
6.01 Biostatistics			
6.02 Other (Define)			
7. Informatics			
7.01 Clinical Research Informatics			
7.02 Bioinformatics			
7.03 Public Health/Epidemiology Informatics			
7.04 Other (Define)			
8. Miscellaneous			
8.01 (Define)			
8.02 (Define)			

Shared Resource: Please tick if appropriate
Developmental: Please tick if appropriate
Resource Director(s): Provide Name, academic status, institution

Appendix No. 5 / Shared Resources - Core Facilities NOT Operated by the Cancer Center

Resource(s)	Shared Resource	Develop-mental	Resource Director(s)
1. Laboratory Science			
1.01 Biochemical Analysis			
1.02 General Animal Facility			
1.03 Transgenic Facility			
1.04 Special Breeding			
1.05 Animal Health (Pathology/Histology)			
1.06 Animal Health (QC)			
1.08 Specific Pathogen Free (Barrier Animal Facility)			
1.09 Nude Mouse			
1.10 Specialized Animal Svcs (Irradiation)			
1.11 Biohazard Control			
1.12 Organic & Synthetic Chemistry			
1.13 Chromatography			
1.14 Cytology-Analytic & Immunologic			
1.15 Cytogenetics			
1.16 Genetics			
1.17 Electron Microscopy			
1.18 Flow Cytometry			
1.19 Cyclotron or Radiolabeling			
1.20 Molecular Biology			
1.21 Nucleotide Sequencing			
1.22 Protein & Peptide Sequencing			
1.23 Monoclonal Antibodies			
1.24 NMR			
1.26 MRI			
1.27 Spectrometry, Other (Specify)			
1.28 Radiobiology			
1.29 Oligonucleotide Synthesis			
1.30 Protein/Peptide Synthesis			
1.31 Toxicology/Mutagenesis Testing			
1.33 Confocal Microscopy			
1.34 Xray Diffraction			
1.35 DNA Array			
1.36 Proteomics			
1.37 Other (Define)			
2. Laboratory Support			
2.01 General or Equipment Repair			
2.02 Machine Shop			
2.03 Glassware Washing			
2.04 Illustration/Photography/Typeset			
2.07 Tissue Culture			
2.08 Media Preparation			
2.10 Other (Define)			
3. Epidemiology, Cancer Control			
3.01 Cancer Control			
3.03 Epidemiology			
3.04 Survey			
3.05 Nutrition			
3.06 Other (Define)			

Shared Resource: Please tick if appropriate
Developmental: Please tick if appropriate
Resource Director(s): Provide Name, academic status, institution

4. Clinical Research			
4.01 Clinical Trials Protocol & Data Management			
4.02 Clinical – Other			
4.03 Pharmacology (Animal)			
4.04 Pharmacology (Lab Tests)			
4.05 Human Tissue Acquisition & Pathology/Histology			
4.06 Gene Therapy/Vector			
4.07 Other (Define)			
5. Administrative			
5.01 Secretarial/Word Processing			
5.02 Other (Define)			
6. Biostatistics			
6.01 Biostatistics			
6.02 Other (Define)			
7. Informatics			
7.01 Clinical Research Informatics			
7.02 Bioinformatics			
7.03 Public Health/Epidemiology Informatics			
7.04 Other (Define)			
8. Miscellaneous			
8.01 (Define)			
8.02 (Define)			

Shared Resource: Please tick if appropriate
Developmental: Please tick if appropriate
Resource Director(s): Provide Name, academic status, institution

Appendix No. 6 - Active Funded Research Projects - Principal Investigator: ______________________________

(Name, academic status, institution)

No	Project Title	Start Date	End Date	Grant Amount	Grant Giver	peer-reviewed	Internal Collaborators	External Collaborators	Publications
		xx.xx.xxxx	xx.xx.xxxx						
			Total Amount						

Title: Provide a concise title for this project

Start Date: Provide the date that this project started (date-format: dd.mm.yyyy)

End Date: Provide the date this project is expected to be finished. (date-format: dd.mm.yyyy)

Grant Amount: Provide the total amount of the awarded grant in Euro / €

Grant Giver: Provide the name of the grant giver

Peer-Reviewed: Indicate whether the grant application has been peer-reviewed (Yes/no)?

Internal Collaborators (Collaborations with cancer center members): Provide Name, academic status, function

External Collaborators (Collaborations outside the cancer center): Provide Name, academic status, affiliation

Publications: List all peer-reviewed publications resulting from the project (List publications in chronological order (oldest first). Include full list of authors (no "et al."), full title, and full citation and date. Manuscripts accepted but not yet published can be included as "In Press" after the name of the Journal. Submitted manuscripts may be included, but inclusion of “planned” or “in preparation” manuscripts is discouraged.

Appendix No. 7 – Summary – In 2007 Active Funded Research Projects

No	Principal Investigator	Total Amount in Euro
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
	Total Amount of All Active Funded Research Projects	

Principal Investigator (PI): Provide Name, academic status, institution

Total Amount: Provide the total amount of active funded grants in Euro / €

Appendix No. 10 - Number of all cancer patients treated in the cancer center in 2007

Disease Site	Number of all cancer patients treated in the cancer center in 2007				
	1	2	3	4	5
	total number	inpatients	% inpatients	outpatients	% outpatients
Lip, Oral Cavity and Pharynx					
Esophagus					
Stomach					
Small Intestine					
Colon					
Rectum					
Anus					
Liver					
Pancreas					
Other Digestive Organ					
Larynx					
Lung					
Other Respiratory and Intrathoracic Organs					
Bones and Joints					
Soft Tissue					
Melanoma, skin					
Kaposi's sarcoma					
Mycosis Fungoides					
Other Skin					
Breast – Female					
Breast – Male					
Cervix					
Corpus Uteri					
Ovary					
Other Female Genital					
Prostate					
Other Male Genital					
Urinary Bladder					
Kidney					
Other Urinary					
Eye and Orbit					
Brain & Nervous System					
Thyroid					
Other Endocrine System					
Non-Hodgkin's Lymphoma					
Hodgkin's Lymphoma					
Multiple Myeloma					
Lymphoid Leukemia					
Myeloid and Monocytic Leukemia					
Leukemia, other					
Leukemia, not otherwise specified					
Other Hematopoietic					
Unknown Sites					
Ill-Defined Sites					
TOTAL					

Number of all cancer patients treated in the cancer center in 2007: Provide the number of in- and outpatients (column 1); number of inpatients (column 2); percentage inpatients (column 3); number of outpatients (column 4); percentage of outpatients (column 5). 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 2007. 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.

Appendix 11 A - Number of cancer patients newly diagnosed in 2007

Disease Site	Number of cancer patients newly diagnosed in 2007				
	1	2	3	4	5
	total number	inpatients	% inpatients	outpatients	% outpatients
Lip, Oral Cavity and Pharynx					
Esophagus					
Stomach					
Small Intestine					
Colon					
Rectum					
Anus					
Liver					
Pancreas					
Other Digestive Organ					
Larynx					
Lung					
Other Respiratory and Intrathoracic Organs					
Bones and Joints					
Soft Tissue					
Melanoma, skin					
Kaposi's sarcoma					
Mycosis Fungoides					
Other Skin					
Breast – Female					
Breast – Male					
Cervix					
Corpus Uteri					
Ovary					
Other Female Genital					
Prostate					
Other Male Genital					
Urinary Bladder					
Kidney					
Other Urinary					
Eye and Orbit					
Brain & Nervous System					
Thyroid					
Other Endocrine System					
Non-Hodgkin's Lymphoma					
Hodgkin's Lymphoma					
Multiple Myeloma					
Lymphoid Leukemia					
Myeloid and Monocytic Leukemia					
Leukemia, other					
Leukemia, not otherwise specified					
Other Hematopoietic					
Unknown Sites					
Ill-Defined Sites					
TOTAL					

Number of patients newly diagnosed in the cancer center or elsewhere in 2007 and whose treatment started in the cancer center in 2007: Provide the number of in- and outpatients (column 1); number of inpatients (column 2); percentage inpatients (column 3); number of outpatients (column 4); percentage of outpatients (column 5). 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 2007. Do not include patients with recurrent disease.

Appendix 11 B - Number of (A)-patients enrolled in clinical trials in 2007

Disease Site	Number of (A)-patients enrolled in clinical trials in 2007						
	1	2	3	4	5	6	7
	total number	IIT: PI in cancer center	% columns 2/1	IIT: PI elsewhere	% columns 4/1	Industry Initiated Trials	% columns 6/1
Lip, Oral Cavity and Pharynx							
Esophagus							
Stomach							
Small Intestine							
Colon							
Rectum							
Anus							
Liver							
Pancreas							
Other Digestive Organ							
Larynx							
Lung							
Other Respiratory and Intrathoracic Organs							
Bones and Joints							
Soft Tissue							
Melanoma, skin							
Kaposi's sarcoma							
Mycosis Fungoides							
Other Skin							
Breast – Female							
Breast – Male							
Cervix							
Corpus Uteri							
Ovary							
Other Female Genital							
Prostate							
Other Male Genital							
Urinary Bladder							
Kidney							
Other Urinary							
Eye and Orbit							
Brain & Nervous System							
Thyroid							
Other Endocrine System							
Non-Hodgkin's Lymphoma							
Hodgkin's Lymphoma							
Multiple Myeloma							
Lymphoid Leukemia							
Myeloid and Monocytic Leukemia							
Leukemia, other							
Leukemia, not otherwise specified							
Other Hematopoietic							
Unknown Sites							
Ill-Defined Sites							
TOTAL							

Number of (A)-patients' that were newly enrolled in therapeutic trials in 2007: Provide the number of (A)-patients (in- and outpatients; column 1); number of patients enrolled in investigator initiated trials (IIT), where the Principal Investigator (PI) is member of the cancer center (column 2); Percentage of patients/column 2 to total number of patients/column 1 (column 3); number of patients enrolled in investigator initiated trials, where the PI is not member of the cancer center (column 4); Percentage of patients/column 4 to total number of patients/column 1 (column 5); number of patients enrolled in clinical trials initiated by the industry (column 6); Percentage of patients/column 6 to total number of patients/column 1 (column 7). A patient may appear more than once if he/she was on more than one therapeutic protocol.

Appendix 11 C - Number of newly diagnosed cancer patients treated in 2007 in affiliated institutions within the catchment area and who have been reported to the registry of the cancer center

Disease Site	Total number
Lip, Oral Cavity and Pharynx	
Esophagus	
Stomach	
Small Intestine	
Colon	
Rectum	
Anus	
Liver	
Pancreas	
Other Digestive Organ	
Larynx	
Lung	
Other Respiratory and Intrathoracic Organs	
Bones and Joints	
Soft Tissue	
Melanoma, skin	
Kaposi's sarcoma	
Mycosis Fungoides	
Other Skin	
Breast – Female	
Breast – Male	
Cervix	
Corpus Uteri	
Ovary	
Other Female Genital	
Prostate	
Other Male Genital	
Urinary Bladder	
Kidney	
Other Urinary	
Eye and Orbit	
Brain & Nervous System	
Thyroid	
Other Endocrine System	
Non-Hodgkin's Lymphoma	
Hodgkin's Lymphoma	
Multiple Myeloma	
Lymphoid Leukemia	
Myeloid and Monocytic Leukemia	
Leukemia, other	
Leukemia, not otherwise specified	
Other Hematopoietic	
Unknown Sites	
Ill-Defined Sites	
TOTAL	

Number of newly diagnosed cancer patients treated in 2007 in affiliated institutions within the catchment area and who have been reported to the registry of the cancer center: Provide the number of cancer patients newly diagnosed in the cancer center or elsewhere in 2007 and whose treatment started in 2007 in affiliated institutions within the catchment area and who have been reported to the registry of the cancer center. Reflect the number of patients, not the number of visits in the affiliated institutions. Do not include any patient more than once unless they had two malignancies diagnosed in 2007. Do not include patients with recurrent disease.

Appendix 11 D - Number of (C)-Patients enrolled in clinical trials in 2007

Disease Site	Number of (C)-Patients enrolled in clinical trials in 2007						
	1	2	3	4	5	6	7
	total number	IIT: PI in cancer center	% columns 2/1	IIT: PI elsewhere	% columns 4/1	Industry Initiated Trials	% columns 6/1
Lip, Oral Cavity and Pharynx							
Esophagus							
Stomach							
Small Intestine							
Colon							
Rectum							
Anus							
Liver							
Pancreas							
Other Digestive Organ							
Larynx							
Lung							
Other Respiratory and Intrathoracic Organs							
Bones and Joints							
Soft Tissue							
Melanoma, skin							
Kaposi's sarcoma							
Mycosis Fungoides							
Other Skin							
Breast – Female							
Breast – Male							
Cervix							
Corpus Uteri							
Ovary							
Other Female Genital							
Prostate							
Other Male Genital							
Urinary Bladder							
Kidney							
Other Urinary							
Eye and Orbit							
Brain & Nervous System							
Thyroid							
Other Endocrine System							
Non-Hodgkin's Lymphoma							
Hodgkin's Lymphoma							
Multiple Myeloma							
Lymphoid Leukemia							
Myeloid and Monocytic Leukemia							
Leukemia, other							
Leukemia, not otherwise specified							
Other Hematopoietic							
Unknown Sites							
Ill-Defined Sites							
TOTAL							

Number of (C)'-patients' that were newly enrolled in therapeutic trials in 2007: Provide the number of (C)-patients (column 1); number of patients enrolled in investigator initiated trials (IIT), where the Principal Investigator (PI) is member of the cancer center (column 2); Percentage of patients/column 2 to total number of patients/column 1 (column 3); number of patients enrolled in investigator initiated trials, where the PI is not member of the cancer center (column 4); Percentage of patients/column 4 to total number of patients/column 1 (column 5); number of patients enrolled in clinical trials initiated by the industry (column 6); Percentage of patients/column 6 to total number of patients/column 1 (column 7). A patient may appear more than once if he/she was on more than one therapeutic protocol.

Appendix No. 14 - Multidisciplinary Tumor Boards – Current Situation

1	2	3	4	5	6	7	8	9	10	11	12
Tumor Board	**Frequency**	**Time**	**Duration**	**Location**	**Disciplines**	**Established**	**ICD-Number(s)**	**Average**	**Cases discussed**	**%**	**Number of Cases**

Attention: Do not include any patient more than once unless they have two malignancies diagnosed in 2007.

1. **Tumor Board:** provide the name of the Board
2. **Frequency:** Indicate how often the board meets (e.g. weekly, monthly, every other day, every second week, each Monday)
3. **Time:** Indicate weekday and hour (e.g. Monday, 14.00 h)
4. **Duration:** Indicate the duration of the board meetings (e.g. 1 hour, 30 minutes)
5. **Location:** Indicate where the board meetings take place (e.g. Surgical conference room, varying locations)
6. **Disciplines**: indicate the participating disciplines of the tumor board meetings
7. **Established**: Indicate the date when the board has been established
8. **ICD**: Indicate the ICD numbers of the anatomic cancer site(s) on which the board is focused
9. **Average**: Indicate the average number of cases discussed in a board meeting
10. **Cases discussed:** How many cases were discussed in the year 2007?
11. **%:** Provide percentage 'cases discussed' / 'Number of Cases' (Column 10 / 12)
12. **Number of Cases**: Indicate the total number of cases with the ICD- Numbers (according to column 8) diagnosed in 2007

Appendix No. 15 - Multidisciplinary Tumor Boards – Future Situation

1	2	3	4	5	6	7	8	9	10	11	12
Tumor Board	**Frequency**	**Time**	**Duration**	**Location**	**Disciplines**	**Established**	**ICD-Number(s)**	**Average**	**Cases discussed**	**%**	**Number of Cases**

Attention: Do not include any patient more than once unless they have two malignancies diagnosed in 2007.

1. **Tumor Board:** provide the name of the Board
2. **Frequency:** Indicate how often the board meets (e.g. weekly, monthly, every other day, every second week, each Monday)
3. **Time:** Indicate weekday and hour (e.g. Monday, 14.00 h)
4. **Duration:** Indicate the duration of the board meetings (e.g. 1 hour, 30 minutes)
5. **Location:** Indicate where the board meetings take place (e.g. Surgical conference room, varying locations)
6. **Disciplines**: indicate the participating disciplines of the tumor board meetings
7. **Established**: Indicate the date when the board has been established
8. **ICD**: Indicate the ICD numbers of the anatomic cancer site(s) on which the board is focused
9. **Average**: Indicate the average number of cases discussed in a board meeting
10. **Cases discussed:** How many cases were discussed in the year 2007?
11. **%:** Provide percentage 'cases discussed' / 'Number of Cases' (Column 10 / 12)
12. **Number of Cases**: Indicate the total number of cases with the ICD- Numbers (according to column 8) diagnosed in 2007

Appendix No. 17 - Clinical Research Studies – Initiated by an investigator of the applying institution (Investigator initiated trials – IITs - only) -

No	PI	Title	Site	Type	Phase	Accrual Start	Accrual End	Targeted Accrual	Accrual in 2007	Sponsor AMG	Financial Sponsor	peer-reviewed
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												

PI: provide the last name and first initial of the Principal Investigator
Title: Provide a concise title for this trial/study
Site: Identify the anatomic cancer site(s) on which the trial or study is focused. If a trial or other clinical study is applicable to a number of potential anatomic sites, enter the term "multiple" in this column.
Type: identify the type of trial or clinical research study, as follows:

- **Therapeutic (The) Trial:** Clinical trials with therapeutic intent using drugs, radiation, surgery, other biological agents, or behavioral or other interventions.
- **Prevention (Pre) Trial:** Clinical trials for the modulation of cancer risk and inhibition of cancer progression using chemoprevention drugs, nutritional, dietary, behavioral, or other interventions.
- **Supportive Care (Sup) Trial:** Clinical trials intended to improve the comfort and quality of life for the patient using drugs, nutritional, dietary, behavioral or other interventions.
- **Screening (Scr), Early Detection (Det), or Diagnostic (Dia) Trials:** Clinical trials directly testing the efficacy of devices, techniques, procedures; or tests for earlier or more accurate detection or diagnosis of disease.
- **Epidemiologic (Epi), Observational (Obs), or Outcome (Out) Trials:** Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.

Phase: For clinical trials, provide the study phase. Acceptable phases are pilot, feasibility, I, II, III, IV, or combinations such as I/II. For other studies, indicate "N/A."
Accrual Start: Provide the date that this protocol or study was opened to accrual (dd.mm.yyyy)
Accrual End: Provide the date that the accrual for this protocol or study is expected to be closed (dd.mm.yyyy)
Targeted Accrual: total number of patients or participants needed for the entire study as stated in the trial protocol (no target range).
Multi-Centered: Indicate whether the trial/study is conducted at more than one medical center or clinic
Sponsor - AMG: In accordance to AMG (Pharmaceutical Act) indicate the sponsor of this trial. Otherwise indicate "N/A."
Financial Sponsor: Indicate who financially supports this trial/study by a grant
Peer-Reviewed: If the trial is supported by a grant: indicate whether the grant application has been peer-reviewed (Yes/No), otherwise, indicate "N/A"

Appendix No. 18 - Participation in Clinical Trials

No	Title	Site	Type	Phase	Accrual Start	Accrual End	Targeted Accrual	Accrual in 2007	Sponsor AMG	Financial Sponsor	peer-reviewed
1.											
2.											
3.											
4.											
5.											
6.											
7.											
8.											
9.											
10.											

Title: Provide a concise title for this trial/study

Site: Identify the anatomic cancer site(s) on which the trial or study is focused. If a trial or other clinical study is applicable to a number of potential anatomic sites, enter the term “multiple” in this column.

Type: identify the type of trial or clinical research study, as follows:

- **Therapeutic (The) Trial:** Clinical trials with therapeutic intent using drugs, radiation, surgery, other biological agents, or behavioral or other interventions.
- **Prevention (Pre) Trial:** Clinical trials for the modulation of cancer risk and inhibition of cancer progression using chemoprevention drugs, nutritional, dietary, behavioral, or other interventions.
- **Supportive Care (Sup) Trial:** Clinical trials intended to improve the comfort and quality of life for the patient using drugs, nutritional, dietary, behavioral or other interventions.
- **Screening (Scr), Early Detection (Det), or Diagnostic (Dia) Trials:** Clinical trials directly testing the efficacy of devices, techniques, procedures; or tests for earlier or more accurate detection or diagnosis of disease.
- **Epidemiologic (Epi), Observational (Obs), or Outcome (Out) Trials:** Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.

Phase: For clinical trials, provide the study phase. Acceptable phases are pilot, feasibility, I, II, III, IV, or combinations such as I/II. For other studies, indicate “N/A.”

Accrual Start: Provide the date that this protocol or study was opened to accrual (dd.mm.yyyy)

Accrual End: Provide the date that the accrual for this protocol or study is expected to be closed (dd.mm.yyyy)

Targeted Accrual: total number of patients or participants needed for the entire study as stated in the trial protocol (no target range).

Accrual in 2007: number of patients enrolled in 2007 in the applying center only

Sponsor - AMG: In accordance to AMG (Pharmaceutical Act) indicate the sponsor of this trial. Otherwise indicate “N/A.”

Financial Sponsor: Indicate who financially supports this trial/study by a grant

Peer-Reviewed: If the trial is supported by a grant: indicate whether the grant application has been peer-reviewed (Yes/No), otherwise, indicate "N/A"

Appendix No. 19 / Self Assessment

Criterion		very good	good	satis-factory	basical	not established
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 from different disciplines.					
C	Establishment of interdisciplinary tumor boards for all organ sites and tumor entities.					
D	For each patient, board recommendations 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. 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. Appointment of a highly qualified scientist with administrative experience as cancer center director supported by an executive committee and scientific advisory board.					
I	'Integrated psychosocial and palliative care. The center should 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 dedicated cancer center director.					
Q	Willingness to participate in a national consortium of cancer centers, coordinated by the Deutsche Krebshilfe.					

Please tick as appropriate

International Classification of Diseases for Oncology
ICD-9-CM Codes and cross references to ICD-O-3 Codes to be used with Summary 3, Patient Information.

PRIMARY DISEASE SITE	ICD-9-CM [1]	ICD-O-3 [2]
Lip, Oral Cavity and Pharynx	140.0-140.6, 140.8, 140.9 141.0-141.6, 141.8, 141.9 142.0-142.2, 142.8, 142.9 143.0, 143.1, 143.8, 143.9 144.0, 144.1, 144.8, 144.9 145.0-145.6, 145.8, 145.9 146.0-146.9 147.0-147.3, 147.8, 147.9 148.0-148.3, 148.8, 148.9 149.0, 149.1, 149.8, 149.9	C000-C006, C008-C009, C019-C024, C028-C029, C030-C031, C039-C041, C048-C052, C058-C062, C068-C069, C079-C081, C088-C089, C090-C091, C098-C104, C108-C109, C110-C113, C118-C119, C129-C132, C139-C139, C140, C142, C148
Esophagus	150.0-150.5, 150.8, 150.9	C150-C155, C158-C159
Stomach	151.0-151.6, 151.8, 151.9	C160-C166, C168-C169
Small Intestine	152.0-152.3, 152.8, 152.9	C170-C173, C178-C179
Colon	153.0-153.9	C180, C182-C189, C199
Rectum	154.0, 154.1	C209
Anus	154.2, 154.3, 154.8	C210-C212, C218
Liver	155.0, 155.1	C220
Pancreas	157.0-157.4, 157.8, 157.9	C250-C254, C257-C259
Other Digestive Organ	156.0-156.2 159.0, 159.1, 159.8, 159.9	C221, C239-C241, C248-C249
Larynx	161.0-161.3, 161.8, 161.9	C320-C323, C328-C329
Lung	162.0, 162.2-162.5, 162.8, 162.9	C340-C343, C348-C349
Other Respiratory and Intrathoracic Organs	160.0-160.5, 160.8, 160.9 163.0, 163.1, 163.8, 163.9 164.0-164.3, 164.8, 164.9 165.0, 165.8, 165.9	C300, C301, C310-C313, C318-C319, C339, C379, C380, C381-C383, C384, C388, C390, C398-C399
Bones and Joints	170.0-170.9	C400-C403, C408-C414, C418-C419
Soft Tissue	158.0, 158.8, 158.9 171.0, 171.2-171.9	C470-C476, C478-C479, C480-C482, C488, C490-C496, C498-C499
Melanoma, skin	172.0-172.9	C440-C449
Kaposi's sarcoma	176.0-176.5, 176.8, 176.9	9140
Mycosis Fungoides	202.1	9700
Other Skin	173.0-173.9	8720-8790
Breast - Female	174.0-174.6, 174.8, 174.9	C500-C506, C508-C509
Breast – Male	175.0, 175.9	C500-C506, C508-C509

Cervix Uteri	180.0, 180.1, 180.8, 180.9	C530-C531, C538-C539
Corpus Uteri	182.0, 182.1, 182.8, 179	C519, C540-C543, C548-C549, C559
Ovary	183.0	C569
Other Female Genital	181 183.2-183.5, 183.8, 183.9 184.0-184.4, 184.8, 184.9	C510-C512, C518-C519, C570-C574, C577-C579
Prostate	185	C619
Other Male Genital	186.0, 186.9 187.1-187.9	C600-C602, C608-C609, C620-C621, C629, C630, C631, C632, C637-C639
Bladder	188.0-188.9	C670-C679
Kidney	189.0, 189.1	C649
Other Urinary	189.2-189.4, 189.8, 189.9	C659, C669, C680-C681, C688-C689
Eye and Orbit	190.0-190.9	C690-C691, C692, C693, C694, C695-C698, C699
Brain and Nervous System	191.0-191.9 192.0-192.3, 192.8, 192.9	C700-C701, C709, C710-C714, C715, C716, C717-C719, C720-C725, C728-C729
Thyroid	193	C739
Other Endocrine System	194.0, 194.1, 194.3-194.6, 194.8, 194.9	C740-C741, C749, C750, C751-C752, C753, C754-C755, C758-C759
Non-Hodgkin's Lymphoma	200.0-200.2, 200.8 202.0, 202.8	9590-9591, 9596, 9670-9671, 9673, 9675, 9678-9680, 9684, 9687, 9689-9691, 9695, 9698-9699
Hodgkin's Lymphoma	201.0-201.2, 201.4-201.7, 201.9	9650-9655, 9659, 9661-9665, 9667
Multiple Myeloma	203.0, 203.1	9732-9733
Lymphoid Leukemia	204.0-204.2, 204.8, 204.9	9820, 9823, 9826-9828, 9832-9837
Myeloid and Monocytic Leukemia	205.0-205.3, 205.8, 205.9 206.0-206.2, 206.8, 206.9	9860-9861, 9863, 9866-9867, 9870-9876, and 9891, 9895-9897, 9910, 9920, 9930-9931
Leukemia, other	202.4 207.0-207.2, 207.8	9940, 9945-9946, 9948
Leukemia, not otherwise specified	208.0-208.2, 208.8, 208.9	9800-9801, 9805
Other Hematopoietic	202.3, 202.5, 202.6, 202.9 203.8 238.6, 238.7	9731, 9760-9762, 9740-9741, 9750, 9754-9758, 9950, 9960-9964, 9980, 9982-9987,9989
Unknown Sites	199.0, 199.1	C809
Ill-Defined Sites	195.0-195.5, 195.8	C760-C768

[1] The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) is based on the World Health Organization's Ninth Revision, International Classification of Diseases (ICD-9).

[2] International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3). Used principally in tumor or cancer registries for coding the site (topography) and the histology (morphology) of neoplasms, usually obtained from a pathology report.