

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

6th CALL FOR APPLICATIONS

Progress in prevention, diagnosis, and therapy has led to a significant increase in survival rates and quality of life of cancer patients. 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 this program to set nationwide standards for clinical cancer care and for strengthening translational cancer research.

The Deutsche Krebshilfe issued 5 calls for applications since 2006. Currently, a total of 13 centers are being funded within the program. We are now inviting for a 6th round of applications. In this sixth phase, up to 6 centers can be supported, each with 750,000 Euros per year over a period of four years.

Like in the previous calls the financial support shall primarily be used for the strengthening of the cancer center infrastructure as well as its regional network, 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: **October 05, 2015.**

Subsequent full application deadline: **December 01, 2015.**

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Introduction

The Oncology Centers of Excellence funded by the Deutsche Krebshilfe (DKH) are an essential part of the 'Three-Tier-Model' (3-Stufen-Modell) fixed in the National Cancer Plan which comprises the following structures of cancer care:

- Organ Cancer Centers
- Oncology Centers
- Comprehensive Cancer Centers (Oncology Centers of Excellence)

In the context of the National Cancer Certification Program ('Nationales Zertifizierungsprogramm Krebs') the DKH and the Deutsche Krebsgesellschaft (DKG) have worked out criteria for the certification of the above-mentioned centers in order to ensure multidisciplinary and state-of-the-art cancer care for each patient – independent of the type of cancer center and regional conditions.

Therefore it is strongly recommended, that all centers applying for funding as an Oncology Center of Excellence already fulfill the criteria requested within the National Cancer Certification Program:

(<http://www.krebsgesellschaft.de/deutsche-krebsgesellschaft-wtrl/deutsche-krebsgesellschaft/zertifizierung/erhebungsboegen/onkologische-zentren.html>).

Please note, that from the 7th call, the certification as an Oncology Center will be an obligatory requirement for centers which want to apply for funding within the Deutsche Krebshilfe program.

It is one central goal of the Deutsche Krebshilfe, that the Oncology Centers of Excellence work out exemplary pilot projects, promote innovative developments and set new standards. The results from these activities should then be made available to all oncological health care providers so that all cancer patients can benefit. One very important instrument to achieve this aim is the network of the Oncology Centers of Excellence funded by the Deutsche Krebshilfe (Comprehensive Cancer Center Network/CCC Network).

Therefore, it is a categorical requirement that the funded centers actively participate in the CCC Network.

Criteria for Funding

The Three Important Areas for 'Oncology Centers of Excellence':

- **Translational Research/Clinical Trials**
- **Outreach/Regional Cancer Care Network**
- **Multidisciplinary Care**

Each of these areas is **equally important** and has been broken down into the specific criteria for funding. Their detailed description can be found below. Each application will be carefully evaluated on the basis of these criteria.

The following criterion belongs to each of these areas:

- A. Leadership Structure** is a fundamental criterion. The cancer center director should be a highly qualified scientist with administrative experience. He/She must have their own budget and be supported by an executive committee and scientific advisory board. Sustainable support from the hospital/faculty is essential.

Translational Research/Clinical Trials

B. Research Projects/Translational Cancer Research

Internationally competitive research programs, most importantly in the area of translational cancer research ('bench to bedside'). This must include important solid tumors. The number and quality of ongoing peer-reviewed research projects is important. Active participation in local, national or international collaborative research consortia is expected.

C. Clinical Trials Activity

Obligatory development and realization of innovative clinical trials, including investigator initiated trials. The trials must include a reasonable portfolio of the most important cancer entities. The fraction of patients in trials must approach 90% for pediatric neoplasms, 50% for hematolymphoid and 10% for solid tumors.

D. Clinical Trials Office/Early Clinical Trials Unit

Availability of a specialized clinical trials office for oncology with a central coordination. The office must be involved in the design and management of the clinical trials. Existence of a central early clinical trials unit where all Phase-I/II-cancer trials are performed.

E. Outcomes Research/Epidemiology

Programs in outcomes research, including tumor epidemiology, and the identification of cancer risks and predictive factors.

F. Tumor and biobank

Centralized tumor and biobank with quality and documentation standards adhering to European guidelines.

G. Research Training Programs

Multidisciplinary training of physician scientists and biomedical researchers, especially in translational research.

Outreach/Regional Cancer Care Network

H. Regional Network

Contractual interaction with extramural physicians and regional hospitals. The role of the cancer center should be that of a driving force which promotes innovative developments in the regional network.

I. Community Service and Education

Continual interaction with the public by way of community service and education (prevention, etc.).

J. Outreach Training Programs

Appropriate training programs in multidisciplinary care for physicians, nurses and related professions in the regional network.

Multidisciplinary Care

K. Multidisciplinary Structure/Tumor Boards

Obligatory existence of structures for multidisciplinary clinical oncology that encompass all tumor entities. This must include integrated clinical care by a team of physicians of different disciplines and interdisciplinary tumor boards for all organ sites and tumor entities.

L. Standard Operating Procedures

Active usage of efficient standard operating procedures for diagnosis and treatment that reflect the current state of evidence-based oncology. The continuous improvement of existing SOPs and the active development of new SOPs is expected.

M. Quality Assessment System

Active application of a quality assessment system for diagnostics, oncologic surgery, medical oncology and radiotherapy. This must include a centralized quality-controlled outpatient unit for chemotherapy.

N. Cancer Registry

All diagnostic and therapeutic procedures must be documented and transferred to the responsible regional clinical cancer registry.

O. Core Activities in One Building/Central Entry Portal

Concentration of the core activities of the center in one building. A central entry portal must be an integral part of these core activities.

P. Palliative Care

Obligatory existence of a palliative care unit which guarantees high quality patient care. Additionally, an ambulatory palliative service must be in place.

Q. Psychosocial Care/Self-Help Groups

Efficient structures must be in place for integrated psychosocial care. The support by self-help and advocacy groups has to be implemented in patient care.

R. Training Programs in Multidisciplinary Care

Programs for physicians, oncology nurses and related professions for the comprehensive care of cancer patients.

Guidelines for Applicants

Eligibility Requirements

Public or private cancer centers in Germany that have already met or almost met these criteria.

Funding

Overall, a maximum of 12 centers can be funded within this program. In this 6th call, up to 6 centers can be supported, each with 750,000 Euros per year over a period of four years. The financial support must primarily be used for the strengthening of the cancer center infrastructure and/or its regional network, and not for specific research projects or patient care.

Reapplications

Centers which applied in the past and did not receive funding, can reapply. The reapplication must consist of a detailed application with all appendices and address the comments and recommendations of the reviewers from the last evaluation (for more information, see 5, p. 10).

Renewal Application

Centers that are already funded by the Deutsche Krebshilfe and want to apply for further financial support have to submit a detailed application with all appendices. The application must address the comments and recommendations of the reviewers from the last evaluation (for more information, see 5., p. 10).

Application and Review Process

The application process will proceed in two stages:

1. Evaluation of grant applications 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 be achieved through hearings which may be complemented by on-site visits. The hearings and on-site visits are expected to take place 11 April – 15 April 2016 and 17 – 20 May 2016, respectively.

Based on the reviewers' recommendations, the Deutsche Krebshilfe will then come to the final decision.

Note:

Contacting of members of the review board in the context of the evaluation of the application (apart from the hearings and on-site visits) can be interpreted as an attempt to influence their decisions and will lead to termination of the evaluation process.

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 **October 05, 2015, 13.00 h** (Emails and Faxes will not be 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.
Bereich Förderung
Buschstrasse 32
53113 Bonn

The Letter of Intent must

- (1) include the full name, address, phone, and email contact information of the corresponding 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 have submitted a Letter of Intent.

APPLICATION GUIDELINES

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 must be prepared according to the following guidelines:

The application and all appendices

- 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 **December 01, 2015, 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 application with a table of contents including page numbers,
- insert a header with the name of the cancer center on each page,
- address in the application all points mentioned in the guidelines, repeating all section numbers/letters from the guidelines as well as the complete section titles,
- restrict your application to a maximum of 40 pages (excluding appendices),
- use 'Arial' 11 pt and 1.25-line spacing,
- use the forms available from Deutsche Krebshilfe's website for appendices 3, 6, 7, 8, 9, 10, 11, 13, 14 (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) with original signatures plus 5 bound copies of the grant application (including copies of the cover letter) and 5 bound copies of the appendix volume (each appendix volume consisting of appendices 1 - 18).

If applicable, usage of charts, figures etc. is encouraged. **Even if defined numbers, dates or figures are not requested in the context of specific funding criteria, it is recommended to support your statements/descriptions with quantitative data/figures whenever possible.**

In addition to the paper copy, the **final versions** of the application and appendices are also required **in PDF format**. Please supply separate PDF files for the application and appendices (one file containing all appendices), respectively. In addition, please supply the Summary (see 4. p. 10) also in Word format. Please send the electronic version on CD-ROM together with the hard copy application to:

**Deutsche Krebshilfe
Bereich 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 describe the value added through the structure of the Comprehensive Cancer Center over individual activities/efforts existing at your center. In addition, all descriptions, explanations, facts, graphs and charts must be based on your current situation, and not what is planned for the future. Future plans and visions can be addressed in a specific chapter.

For all publications: Only published or accepted manuscripts may be cited within the proposal; manuscripts at any other stage (e. g. planned, submitted, under revision, conditionally accepted, forthcoming, etc.) will not be accepted.

Application

1. Cover Letter/Institutional Commitment to the Cancer Center

Briefly introduce the application, and state the willingness to accept the terms of evaluation and funding. 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. 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.

2. Table of Contents (with page numbers).

3. Name and full work address of the Cancer Center Director (in English and in German)

Note: The Cancer Center Director is regarded as the corresponding applicant.

4. 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 (max. 2 pages).

5. Essentials from the reviewers critical comments/recommendations and summary of the respective actions/response of the cancer center (for reapplications and renewals only)

List the essentials from the reviewers' critical comments/recommendations resulting from the last evaluation by the Deutsche Krebshilfe review panel and give a short summary of how you have addressed each of them. Please then specify under which funding criteria (refer to the respective page numbers) in the application a detailed description of your actions/response to the above mentioned criticism is to be found.

(Examples:

Reviewer comments 1: ... number of patients enrolled in clinical trials ...

Summary: ... We have started a process ...

Actions/Response: ... Criterion C (paragraph C1, C2, page 24-25) ...

Reviewer comments 2: ... a central entry portal ...

Summary: ... Currently, the new building ...

Actions/Response: ... Criterion O (paragraph O1, page 35) ...)

Appendix 1: Original Comments of the reviewer panel from the last Letter of Approval and (when applicable) from the last interim report.

In case your center applies for the first time, please state: 'Not Applicable' (N/A).

6. Basic information/Basic numbers

- 6.1. Identify fields of specific competence of the cancer center (e.g. rare tumor entities, specific diagnostic or therapeutic options).
- 6.2. List all certifications of the center which are relevant for clinical care and/or cancer research.
- 6.3. Give details on the size of the hospital (total number of beds and patients/year) and its catchment area.

Appendix 2: Catchment area (map, number of inhabitants).

Tabulations documenting which anatomic cancer sites are being treated at the cancer center:

Appendix 3: Number of all cancer patients and newly diagnosed cancer patients treated in the cancer center.

Please describe and comment on the development of the patient numbers from 2012 - 2014. The use of charts / figures etc. is encouraged.

7. CCC Network (for renewal applications only)

The most important goal of the CCC Network is to promote innovative developments and to set new standards so that all cancer care providers as well as patients can benefit from new diagnostic and therapeutic advancements. Therefore, the Deutsche Krebshilfe attaches importance to an active participation in its CCC Network. Please describe here the contribution of your center to the CCC Network.

In case your center applies for the first time, please state: 'Not Applicable' (N/A).

8. Future Plans and Visions

Describe the future plans for your center. What are the center's short-term, middle-term and long-term goals? Please lay special emphasis on the 3 important areas of 'Oncology Centers of Excellence' (Translational Research/Clinical Trials, Outreach/Regional Cancer Care Network, Multidisciplinary Care). In which direction is your center heading? What is/are the vision/s for your center?

9. Local Funding

This section should list the local support available for core-structures, research programs, and additional activities of the cancer center. Also summarize the financial support for multidisciplinary structures and quality assessment provided by the public health system. Funds for standard clinical care should not be included.

10. Use of previous Deutsche Krebshilfe Funds (for renewals only)

List the measures (staff/personnel, equipment, others) for which the funds from the Deutsche Krebshilfe (Program: 'Oncology Centers of Excellence') have been used so far and explain their impact 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 were used to support the activities in the areas of translational research, outreach and multidisciplinary care in your center. How do you monitor the efficiency of your budget decisions?

11. 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. All requested items must be thoroughly justified and clearly related to the goals/objectives of the program.

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 please quote at which wage level (TVöD, TVÄ) the personnel will be employed (max. 4 years) and calculate the costs. For each person to be funded by the Deutsche Krebshilfe, please describe their task(s).

The Deutsche Krebshilfe reserves the right to exclude certain items which do not adhere to the goals and objectives of this funding program.

Information referring to the respective Criteria for Funding

A. Leadership Structure

A 1. Cancer Center Director and Deputy Director(s)

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.*
 - *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.*
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Appendix 4: Biographical sketch, portrait photo, research focus, and the ten most important publications of the Cancer Center Director and the Deputy Director(s).

A 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. Describe the financial budget of the Cancer center Director.

A 3. Overview of the 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 and 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.*
-

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 5: Organization chart (current situation).

Translational Research/Clinical Trials

B. Research Projects/Translational Cancer 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?*
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 - *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?*
-

B 1.1. Research Programs

Give details on the most important research programs / main focuses in research (examples: tumor microenvironment; metastasis; therapy resistance; immunotherapy; targeted radiotherapy), especially in terms of the above mentioned questions. List up to 25 relevant publications. The publications should be allocated to these research programs.

Appendix 6: List of the most relevant peer-reviewed publications (max. 25) from the last 5 years resulting from the most important research programs. Please provide a full list of authors (no 'et al.'), full title and full citation and date in chronological order (recent first).

Appendix 7: Summary – in 2014 active funded peer-reviewed oncology-related research projects and newly granted funds.

Additionally, please comment on the development of research funds granted from 2012 to 2014 (please indicate 'Sum II' from appendix 7 for each of these years). The use of charts and/or figures is encouraged. It is important, that the reviewers easily can detect trends and developments regarding the publication output and third-party funding.

B 1.2. Translational Research Projects

Describe 2 -3 current translational research projects ('bench to bedside') at your center. In this context, it is important to demonstrate the center's power of bringing compounds/therapies, which were pre-clinically developed in own laboratories, to 'first-in-man' trials.

B 2. Research Infrastructure

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 (see B. 'For your information'). In particular, clearly point out how the structure of the cancer center supports translational and laboratory research. Identify the (infrastructural) measures of the cancer center to facilitate such collaborative undertakings (e. g. common programs, teleconferencing, internal grant programs etc).

B 3. Core Facilities / Shared Resources

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.

Please describe the CCC-internal, as well as the extramural resources (university, non-university institutes), to which CCC-investigators have access. Describe the center's policies about operation and use of the shared resources/core facilities, e.g., access, priorities, limitations and charge back systems.

Appendix 8: Access to Core Facilities/Shared Resources.

B 4. Implementation of Precision Medicine / Innovative Molecular Diagnostics and Therapy Programs

How does your center implement new concepts of precision medicine? Describe the portfolio of innovative molecular diagnostic and clinical therapy programs.

C. Clinical Trials Activity

Please describe and comment on the clinical trials activity of your center. Relevant information and numbers not requested within the appendices can appear in the text.

C 1. Number/Percentage of Patients Enrolled in Clinical Trials

Appendix 9: Number of cancer patients newly enrolled in clinical trials. Please provide separate forms for the years 2012, 2013 and 2014, respectively.

In addition to appendix 9, please describe and comment on the development of patient accrual in clinical trials from 2012 - 2014. The use of charts, figures etc. is encouraged.

C 2. Specific Clinical Trials

Appendix 10: Specific Clinical Trials - Investigator Initiated Trials (IITs only)

Appendix 11: Specific Clinical Trials - without Investigator Initiated Trials

Note:

Appendices 9-11 must only contain patients who are actively participating in the study.

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 commercial entity is not acting as the sponsor (Pharmaceutical Act, 'Arzneimittelgesetz/AMG'; Medical Devices Act, 'Medizinproduktegesetz/MPG').
- The principal investigator 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 principal investigator.
- The clinical trial addresses relevant clinical questions and not industry needs.

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

- A commercial entity is acting as the sponsor (Pharmaceutical Act, 'Arzneimittelgesetz/AMG'; Medical Devices Act, 'Medizinproduktegesetz/MPG').
- 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.

D. Clinical Trials Office /Early Clinical Trials Unit

D 1. Clinical Trials Office

Is there a clinical trial office which is an integral part of the Comprehensive Cancer Center and offers assistance in planning, initiating, and conducting of 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 [biometrics/statistics], and adverse event reporting)?

Who decides which clinical trials will be conducted at the cancer center? Is there a central supervision for patient accrual in the clinical trials? Describe the mechanism to close poorly recruiting trials.

D 2. Early Clinical Trials Unit

Please describe your facility for early clinical trials and address the following questions:

- (1) Is there a central Early Clinical Trials Unit (ECTU) where all Phase-I/II-cancer trials are performed?
- (2) How many beds does the Phase-I/II-Unit have?
- (3) Does it have its own personnel?
- (4) Describe and comment on the numbers of patients being treated in the ECTU.

E. Outcomes Research/Epidemiology

E 1. Please describe your program(s) in the field of outcomes research/epidemiology and your active projects since 2012 (e.g. benchmarking, identification of cancer risks, predictive factors, cancer screening programs etc.). Trials in the area of outcomes research / epidemiology can be specified in the **appendices 10 and 11**. List the 5 most relevant peer-reviewed publications since 2012 resulting from the center's outcomes research / epidemiology projects (please provide a full list of authors - no 'et al.', full title and full citation and date in chronological order -recent first).

F. Tumor and biobank

F 1. 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). Describe your concept of performance measurement of the biobank. Comment on available sample numbers and sample quality as well as participation of the biobank in research projects of the cancer center and describe the development of the numbers during the last years. Describe the degree of centralization / harmonization of the tumor- / biobank. Is the complete clinical data of each patient accessible? Who is responsible for the operation of the tissue bank? Describe the biobank's sustainability

concept and the composition of its financial budget. Please note that the financing of the biobank should not only be dependent on third-party funding or fee-for-service. Rather, a sustainable basic funding should be ensured by the responsible body operating the biobank. Please add a statement of support by the representatives of the responsible bodie(s) (e.g. Medical Director of the Hospital, the Dean of the Medical Faculty, fiscally responsible Administrative Director) referring to the above mentioned points (the statement can be included in Appendix 18).

G. Research Training Programs

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.

- G 1.** Describe the current activities/programs offered by the cancer center for multidisciplinary training of physicians, physician scientists, scientists, nurses and related professions. Does your center have a MD and/or PhD program? Which career development options are available for researchers and physician scientists? Does your center have appropriate programs for the training of MDs and PhDs in laboratory, clinical and translational research? Support your descriptions with quantitative data / figures ('success record' e.g. numbers of registered research students, numbers of successful PD/MD degrees, drop-outs etc.).

It is important that you focus on the value added by the cancer center; do not elaborate on 'standard' or 'routine' education/training.

Outreach/Regional Cancer Care Network

H. Regional Network

For your information: In the National Cancer Plan (Nationaler Krebsplan, NKP), a center is defined as a network made up of qualified and jointly certified multi- and interdisciplinary, cross-sectoral, and where applicable, cross-regional sites (Hospitals, contractual medical services, rehabilitation facilities), which provide the complete possible care for cancer patients. (NKP, Handlungsfeld 2, Ziel 5).

A Comprehensive Cancer Center (CCC) or Oncology Center of Excellence is therefore to be understood as part of a regional care network and should act as a driving force which promotes innovative developments in the regional network.

Cooperation with local and regional oncologists and hospitals is important for accrual of patients for clinical trials and research projects.

H1. Contribution to the Regional Cancer Care Network

Please comment on the role and the contribution of your cancer center to regional cancer care and quality assurance. Also describe how your center promotes innovative developments in the regional network.

H2. Documentation of Stable Interactions with Local Oncologists and Hospitals/Community Outreach

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? What kind of agreements are included within these contracts?

Describe your cooperations regarding tumor boards (for example: are tumor boards open for external oncologists/physicians, do physicians from the cancer center join external tumor boards, do you use video conferences or other IT solutions?). How often do joint tumor board sessions take place? How many cases from cooperation partners are discussed? Are there data privacy issues which prevent participation of external physicians in joint tumor board sessions?

Discuss the numbers of patients from collaborating partners enrolled in the clinical trials of your cancer center.

Explain the structure of your 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. What measures are planned to foster cooperation rather than competition and conflict?

I. Community Service and Education

- I 1.** 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. In case of a renewal or reapplication, please describe additionally how the external presentation and the perception of the Comprehensive Cancer Center have changed since the last evaluation of the cancer center by the Deutsche Krebshilfe review committee.

Support your descriptions with quantitative data / figures (e.g. regarding the question how well the programs are received by the public; numbers of participants etc.).

J. Outreach Training Programs

- J 1.** Describe the current activities/programs offered by the cancer center for multidisciplinary training of physicians, nurses and related professions in the regional network. Please focus on the value added by the cancer center. Comment on the effects of the teaching efforts on the cooperation within the network.

Support your descriptions with quantitative data / figures (e.g. numbers and of participants, outcome of potential ratings of the teaching efforts by the participants).

Multidisciplinary Care

K. Multidisciplinary Structure/Tumor Boards

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.

- K 1.** Give an overview of the current status of multidisciplinary clinical care at the cancer center.

Appendix 12: Flowchart showing a general patient pathway from your cancer center.

K 2. 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 Tumor Board Objectives:

- *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.*
- *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.*

Documentation of the proposals for diagnosis, treatment and their implementation must be ensured.

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 (so 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 recommendations made by the tumor board documented?
- (5) How is compliance to tumor board recommendations monitored? What are the results?

Please describe the role of the tumor boards in facilitating research/clinical trials.

Appendix 13: Numbers and Percentages of Cancer Patients discussed in Tumor Boards.

Appendix 14: Multidisciplinary Tumor Boards - Current Situation.

(Also add your weekly schedule of tumor board sessions.)

Note:

The requirements for tumor boards as expressed within the 'National Cancer Certification Program' ('Erhebungsbogen für Onkologische Spitzenzentren und Onkologische Zentren' and 'Definition der Schwerpunkte Onkologischer Zentren') - particularly with regard to the time of discussion in the tumor board - must be fulfilled.

L. Standard Operating Procedures (SOPs)

L 1. Describe the existing standard operating procedures that reflect the current state of evidence-based oncology (e. g. diagnostics, treatment). Please address the following questions:

- (1) Are they based on current guidelines (e. g. 'S3-Leitlinien' etc.)?
- (2) How are these SOPs developed and implemented?
- (3) If there are no (current) guidelines existing, how are SOPs developed and implemented?
- (4) Who is responsible for the development and implementation of SOPs?
- (5) Describe the quality control-mechanisms. How is the adherence to SOPs monitored? Are there data available about adherence to SOPs?
- (6) Who has access to the SOPs?

Appendix 15: List of implemented/active SOPs.

Please provide one example of a significant SOP at your cancer center in English.

M. Quality Assessment System

M 1. 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. This must include a centralized quality-controlled outpatient unit for chemotherapy.

Please make sure that the reviewers can judge from the documents the impact of the quality assessment system on every day's clinical care.

M 2. Information Technology at the Cancer Center

Describe the 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
- biobank IT system
- user access (Who has access?)
- responsibilities / support from IT-Department

N. Cancer Registry

N 1. Describe the current state of documentation of diagnostic and therapeutic procedures and follow-up data in a clinical cancer registry. To which regional cancer registry is the data transferred (add contact data)? How is accurate and timely collection of cancer patient data ensured?

What data is collected in addition to the obligatory basic data set ('ADT/GEKID-Basisdatensatz')?

O. Core Activities in One Building/Central Entry Portal

O 1. Describe, how you achieve to concentrate the core activities. Does a central cancer center building exist? How is it organized? Describe the central entry portal. If there is no central entry portal, describe your plans for it.

Appendix 16: Plan of the hospital/university campus indicating the building in which core activities of the cancer center are conducted.

P. Palliative Care

P 1. Describe when and how palliative care is integrated in the multidisciplinary-based treatment of cancer patients. Are there quantitative data about the numbers of patients treated on a palliative care ward or as out-patients? How is the development of these numbers? Is there a professorship/chair for palliative care in place? If not, are there plans to establish such a professorship?

Are there research activities in the field of palliative care / medicine at your cancer center?

Note:

The criteria for palliative care requested within the 'National Cancer Certification Program' ('Erhebungsbogen für Onkologische Spitzenzentren und Onkologische Zentren', Chapter 9) must be fulfilled. The implementation of the new guideline for palliative medicine of the German Guideline Program in Oncology ('S3-Leitlinie Palliativmedizin für Patienten mit einer nicht heilbaren Krebserkrankung') is expected.

Q. Psychosocial Care/ Self-Help Groups

Q 1. Describe how psychosocial care is integrated in the multidisciplinary-based treatment of cancer patients.

How does the cancer center interact with self-help and patient advocacy groups? Are there cooperation contracts existing? If yes, what kinds of agreements are included within these contracts?

Note:

A low-threshold psychosocial counseling service must be offered and documented with figures/numbers/data. Wherever available, the support by self-help and advocacy groups has to be implemented in patient care. Immediately after diagnosis each patient should be informed about possible support by members of self-help groups (quantitative data, e. g. about numbers of self-help groups and / or numbers of patient contacts should be given whenever available). 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 for supportive care requested within the 'National Cancer Certification Program' ('Erhebungsbogen für Onkologische Spitzenzentren und Onkologische Zentren', Chapter

1.4-1.6), particularly the collaboration with cancer self-help groups, must be fulfilled. The implementation of the new guideline for psycho-oncology of the German Guideline Program in Oncology ('S3-Leitlinie Psychoonkologische Diagnostik, Beratung und Behandlung von erwachsenen Krebspatienten') is expected.

R. Training Programs in Multidisciplinary Care

R 1. Describe the programs for physicians, oncology nurses and related professions which are provided by the cancer center to ensure adequate training in multidisciplinary oncological care. Please focus on the value added by the cancer center.

Support your descriptions with quantitative data / figures (e.g. numbers of successful participants, board certified physicians, oncology nurses etc.).

Additional Information

Bylaws

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

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.

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'.

Further Information

A submission of application to the 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 application guidelines)

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- Appendix 2: Catchment area (map, number of inhabitants)
- Appendix 3*: Number of all cancer patients and newly diagnosed cancer patients treated in the cancer center
- Appendix 4: Biographical sketch of the Cancer Center Director and the Deputy Director(s)
- Appendix 5: Organization chart (current situation)
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- Appendix 7*: Summary – in 2014 active funded peer-reviewed oncology-related research projects and newly granted funds
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**Forms can be downloaded as word files*

CONTACT

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