

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

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### 8<sup>th</sup> CALL FOR APPLICATIONS

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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 has issued 7 calls for applications since 2006. We are now inviting for a 8<sup>th</sup> round of applications. On the basis of the Deutsche Krebshilfe's decision to support up to a total of 15 'Comprehensive Cancer Centers' (CCCs)/CCC Consortia at one time, a maximum of 9 CCCs or CCC Consortia can be funded within this 8<sup>th</sup> call.

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: **September 26, 2019.**

Subsequent full application deadline: **December 02, 2019.**

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## Introduction

In the National Cancer Plan (Nationaler Krebsplan, NKP), a center (dealing with diagnostics, treatment and aftercare) 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).

Within this National Cancer Plan a 'Three-Tier-Model' (3-Stufen-Modell) of cancer centers is fixed and 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 Deutsche Krebshilfe and the Deutsche Krebsgesellschaft 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.

**Starting with the 7<sup>th</sup> Call, the certification as an Oncology Center within the National Cancer Certification Program became an obligatory requirement for centers applying for funding as an Oncology Center of Excellence by the Deutsche Krebshilfe.**

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

In addition to multidisciplinary state-of-the-art clinical care, a CCC must demonstrate a reasonable depth and breadth of activities in basic laboratory, clinical as well as in prevention, cancer control and population-based research. Substantial transdisciplinary research bridging these scientific areas must be present. A CCC is expected to be a major source of significant advancements in investigating the nature of cancer and in the development of more effective approaches to prevention, diagnosis and therapy. Particularly, translational research covering the entire continuum from 'bench to bedside' is a crucial feature of a CCC. It should be committed to contribute significantly to the development of shared resources which support research. A CCC should be collaborating and coordinating their research efforts with other CCCs and disseminate their research findings for the benefit of the oncological community. One very important instrument to achieve these goals is the Comprehensive Cancer Center Network (CCC Network).

**Therefore, it is a categorical requirement that the funded centers actively participate in the CCC Network and its work groups.**

## **Criteria for Funding**

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

- Translational Oncology/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. Please note: since many of the aspects of multidisciplinary care formerly requested within the Deutsche Krebshilfe funding program are already covered by the certification requirements for Oncology Centers, we focus here on aspects which are most important for Oncology Centers of Excellence.

#### **A. Leadership and Organizational Structure**

The cancer center director should be a highly qualified scientist with administrative experience and outstanding leadership and management skills. The director should serve the center on a full-time or a significant part-time basis. He/She must have his/her own budget and be supported by an executive committee and external advisory board. Sustainable support from the hospital/faculty is essential.

#### **B. Research Activity/Translational Oncology**

Internationally competitive and innovative 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. Research Infrastructure**

Structures which promote interdisciplinary as well as translational research. Core facilities/technology platforms and shared resources available to the center must be presented. A comprehensive and centralized tumor and biobank with defined quality and documentation standards is expected.

#### **D. Clinical Trials Activity**

Obligatory development and realization of innovative cancer 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.

#### **E. Clinical Trials Infrastructure**

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.

**F. Outcomes Research/Epidemiology**

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

**G. Regional Network/Outreach Activities**

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.

**H. Community Outreach and Education**

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

**I. Multidisciplinary Care/Core Activities in One Building**

Obligatory existence of structures for multidisciplinary clinical oncology that encompass all tumor entities. This must include integrated clinical care that reflects the current state of evidence-based oncology by a team of physicians of different disciplines as well as non-physician health care professionals. Concentration of the core activities of the center in one building is an important feature. A central entry portal must be an integral part of these core activities.

**J. Tumor Boards**

Interdisciplinary tumor boards for all organ sites and tumor entities must be in place. Every patient should have the opportunity to be discussed in a tumor board.

**K. Information Technology**

Multidisciplinary care and research must be supported by an up-to-date and adequate information technology.

**L. Documentation/Clinical Cancer Registry**

All diagnostic and therapeutic procedures as well as follow-up data must be documented and available for research activities, e.g. translational and outcomes research.

**M. Palliative Care**

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

**N. Psychosocial Care/Self-Help Groups**

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

**O. Training Programs**

Multidisciplinary training programs for physicians, nurses and related professions. Of particular interest are programs for physician scientists and biomedical researchers, especially in translational research.

## **General Information**

### **Eligibility Requirements**

Public or private cancer centers in Germany that have already met or almost met these criteria. Applications for funding can be submitted from individual CCC sites as well as jointly from several CCC sites (CCC Consortia). If you are planning to apply for funding for a CCC Consortium, please contact the Board of Directors ('Vorstand') of the Deutsche Krebshilfe first.

### **CCC Consortia**

An Interdisciplinary Oncology Center of Excellence funded by the German Cancer Aid can consist of more than one site (Comprehensive Cancer Center Consortium). A Comprehensive Cancer Center (CCC) Consortium is a consolidation of at least two university cancer centers, each of which has already implemented Comprehensive Cancer Center structures and who as equal partners with a common, binding governance structure, aim to collectively share the tasks and objectives of an Oncological Center of Excellence according to the criteria of the German Cancer Aid.

The formation of CCC Consortia should not be an end in itself, but must lead to a recognizable added value. The areas of competence or the different strengths of the CCCs of a consortium must ideally complement each other, so that overall positive synergistic effects are achieved. The added value of a larger catchment area associated with the establishment of a CCC Consortium is alone not sufficient to justify funding of a CCC Consortium as an Interdisciplinary Oncology Center of Excellence.

All participating consortium partners must provide structures for comprehensive interdisciplinary oncological patient care (to be documented by the certification of the individual partner centers as Oncology Center/s by the German Cancer Society/OnkoZert). They must also present a broad portfolio of basic, pre-clinical and clinical cancer research to be able to cover the entire continuum of translational oncological research from basic research to clinical trials (phase I - III).

As part of the application process, **each consortium partner must provide detailed and convincing information for each funding criterion (A-O). The (potential) added value of each individual partner site in the consortium has to be convincingly described for the applicable funding criteria and briefly addressed in the summary (Section 4).**

### **Funding**

Individual CCC sites receive € 750,000 per year for 4 years. Consortia made up of two CCC sites also generally receive € 750,000 per year for 4 years. For consortia with more than two CCC sites, a higher financial support for the 4-year funding is possible. 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. In addition, the comments and recommendations of the reviewers from the last evaluation must be addressed (for more information, see Section 5.).

### **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 comments and recommendations of the reviewers from the last evaluation must be also addressed (for more information, see Section 5.).

### **Application and Review Process**

The application process will proceed in two stages:

1. Evaluation of grant applications by an international panel of experts (review board). Based on the scoring of the criteria listed above, 'finalists' are selected. Criticism/comments from the written reviews will be forwarded to the finalists before the hearings.
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 **May 11-15, 2020.**

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

#### **Note:**

Contacting 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

You are requested to notify the Deutsche Krebshilfe of your intent to submit an application. This notification has to be provided by a letter in pdf format no later than **September 26, 2019**. The Deutsche Krebshilfe office acknowledges receipt of each Letter of Intent by email within two weeks.

The Letter of Intent should be sent by email to:

**foerderung@krebshilfe.de**

**Subject: 'Spitzenzentren - LOI'**

The Letter of Intent must

- (1) include the full name, address, phone, and email contact information of the corresponding applicant for the CCC or the CCC Consortium,
- (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.

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 02, 2019, 13.00 h**.

The offices of the Deutsche Krebshilfe will acknowledge receipt of every proposal by email 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, for CCC consortia up to a maximum of 60 pages (excluding appendices),
- use 'Arial' 11 pt and 1.25-line spacing,
- use the forms available from Deutsche Krebshilfe's website for appendices 1, 4, 8, 9, 10, 12, 13, 14, 16, 17 (the forms can be downloaded from our website [www.krebshilfe.de/forschen/foerderung/ausschreibungen/](http://www.krebshilfe.de/forschen/foerderung/ausschreibungen/) ; 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, cover letter) 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 - 19).

**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 the appendices are also required **in PDF format**. Please supply separate PDF files for the application and appendices (**one pdf file containing all appendices**), respectively. Additionally, please provide a separate pdf containing the **center fact sheet (app. 1)** only. Also supply the **Summary** (see Section 4. p. 10) **in Word format**. Send the electronic version on CD-ROM together with the hard copy application to:

**Stiftung 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.**

**In case of a CCC Consortium, it must be made clear which joint structures and activities are already implemented and which are still in the planning state.**

**For all publications: Only published or accepted manuscripts pertaining to oncology 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

In the cover letter, briefly introduce the application, and state the willingness to accept the terms of evaluation and funding. The Chief Physician of the Hospital, the Dean of the Medical Faculty and the fiscally responsible Administrative Director have to declare their commitment for the long-term future of the cancer center. In this letter of support, the importance of oncology for the university hospital and the medical faculty has to be convincingly demonstrated. Point out the crucial measures that have been taken to support this commitment.

The letter has to be signed by the Cancer Center Director and Deputy Director(s), the Chief Physician of the Hospital, the Dean of the Medical Faculty, and the fiscally responsible Administrative Director. For CCC Consortia the letter has to be signed by the respective persons of all individual partner centers.

### 2. Table of Contents (with page numbers).

### 3. Name and full work address of the Corresponding Applicant (in English and in German)

- The Cancer Center Director is regarded as the corresponding applicant.
- For CCC Consortia with a more complex leadership structure, a Cancer Center Director who will be acting as the corresponding applicant, must be named.

### 4. Summary (Mission, Achievements, Vision)

Please describe the center's mission and achievements. Which are the most important achievements/practice-changing innovations? What is the center's contribution to the advancement of oncology? What are the most important goals for this funding period? What impact would funding by the Deutsche Krebshilfe have for the cancer center (max. 3 pages)?

Additionally for CCC Consortia:

- What does each partner site contribute to the added value of the consortium as a whole?
- Existing and/or planned joint projects.

Add the fact sheet (Appendix 1) containing the most important information of your cancer center. This will be used by the reviewer panel to gain a quick and concise overview.

**Appendix 1:** Center Fact Sheet.

### 5. Essentials from the reviewers critical comments/recommendations and summary of the respective actions/response of the cancer center

List the essentials from the reviewers' critical comments/recommendations from the last evaluation by the Deutsche Krebshilfe review board and give a short summary of how you

have addressed each of them. Please 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 D (paragraph D1, D2, page 24-25) ...*

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

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

*Actions/Response: ... Criterion I (paragraph I2, page 35) ...*

**Appendix 2:** Original Comments of the reviewer panel from the last Letter of Approval or Rejection and (when applicable) from the last interim report.

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

## 6. Basic information/Basic numbers

**6.1.** Describe the catchment area of the cancer center. The catchment area must be defined and justified based on the geographic area your center serves and should be population-based.

**Appendix 3:** Catchment area (map, number of inhabitants).

**6.2.** Give details on the entire institution (university hospital).

Please show the following data for 2018 (for CCC Consortia show data for each partner site):

Table 1:

Details on the (University) Hospital	2018		
	CCC Site 1*	CCC Site 2*	CCC Site X*
Number of Departments/ Institutes			
Employees			
Hospital Beds			
Inpatients <sup>1</sup>			
Outpatients <sup>2</sup>			
Patients receiving surgical interventions <sup>3</sup>			
Cancer Inpatients <sup>4</sup>			
Cancer Outpatients <sup>5</sup>			

\*In case of a CCC Consortium only

<sup>1</sup>Numbers of all inpatients (stationary patients only =‘vollstationär’) in the entire hospital in 2018

<sup>2</sup>Numbers of all outpatients in the entire hospital in 2018

<sup>3</sup>Number of all patients receiving surgical interventions in the entire hospital in 2018

<sup>4</sup>Numbers of cancer inpatients (stationary patients only =‘vollstationär’) in the entire hospital in 2018

<sup>5</sup>Numbers of cancer outpatients in the entire hospital in 2018

Describe the organization of oncology at your (university) hospital and show the numbers of cancer patients treated in the following fields/departments in 2018 (for CCC Consortia show the data for each partner site):

Table 2:

Field of Oncology	Number of Patients in 2018*		
	CCC Site 1**	CCC Site 2**	CCC Site X**
Surgical Oncology***			
Radio-Oncology			
Hemato-Oncology			
Solid Tumor Medical Oncology			
Pediatric Oncology			

\* Patients (in-and outpatients) can be counted in more than one field if they received the respective treatments (e. g. a patient who underwent neoadjuvant systemic treatment, tumor surgery and radio-therapy can be counted in the field of Surgical Oncology, Radio-Oncology and in Solid Tumor Medical Oncology). However, a patient can only be counted once in each field, unless he/she has been treated for more than one malignancy in 2018.

\*\* In case of a CCC Consortium only.

\*\*\* Number of all cancer patients at your (university) hospital who underwent one or more surgical procedures in 2018 according to **Enclosure 1** (excerpt of the German version of the International Classification of Procedures in Medicine - OPS).

### 6.3. Anatomic cancer sites being treated at the center:

**Appendix 4:** Number of all cancer patients and newly diagnosed cancer patients treated in the cancer center in 2018. In case of a CCC Consortium, show the data for each CCC site as well as the total sum for all sites.

Please describe and comment on the development of the patient numbers from 2016 - 2018. The use of charts/figures etc. is encouraged.

### 6.4 When did your last certification/re-audit as an Oncology Center (OC) take place? Please list the entities covered by the OC certification/corresponding organ cancer center certifications (for CCC Consortia, please specify the certifications at each respective partner site)

Entities, covered by the OC-certification/corresponding organ center certification	
1	
2	
...	

**Appendix 5:** Copy of your current Oncology Center certificate.

### 6.5. Using the following table, list the further certifications/designations of the center which are relevant for oncological clinical care and/or cancer research (e.g. Oncology Center of Excellence, DKTK member, OEI accreditation/designation etc.). For CCC Consortia, please specify the respective partner site.

Current clinic certifications/designations in Oncology	Continuously certified/designated since

**6.6.** Identify fields of specific competence of the cancer center (e.g. rare tumor entities, specific diagnostic or therapeutic options). For CCC Consortia please specify the fields of specific-competence at each partner site.

**7. CCC Network (for renewal applications only)**

The most important goal of the CCC Network is to promote innovative developments, 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**

Describe the specific plans for the next funding period to reach the center's goals, which are summarized under section 4.

**9. Local Funding**

This section should list the financial support by the hospital/medical center, medical faculty etc. 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. In case of a CCC Consortium, please specify for each partner site.

**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 these cost categories 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

**Note:** For a CCC Consortium, each consortium partner must provide detailed and convincing information for each funding criterion even if not explicitly requested in each section. The strengths/specific expertise(s) of each individual partner site and how they complement each other in the consortium should be convincingly described. The consequential resulting (potential) value added to the consortium must be explained.

### A. Leadership and Organizational Structure

#### A 1. Cancer Center Director and Deputy Director(s): Position/Responsibilities/Authorities

Describe the qualifications of the center director and the deputy director(s) in relation to scientific background and leadership experience and his/her time commitment to the center (full or part-time basis). Describe the status of the cancer center director and his deputy within the institution: any appointments to decision-making committees relevant to the cancer center, the authority 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 and the director's authority regarding the allocation of CCC funds.

**Appendix 6:** CV with photo, research focus, and the ten most important publications of the Cancer Center Director and the Deputy Director(s).

#### A 2. Overview of the Organizational Structure of the Cancer Center

Please address the following points (for a CCC Consortium, specify for each partner site):

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



- How does the organization of the center promote joint initiatives, collaborations and interactions within the multiple institutions?
- Describe the reporting and advisory structures/pathways as well as the decision making procedures at the center. How is the director involved in these processes? Please list the members of the center's external advisory board.
- In case of a CCC Consortium please additionally describe the governance and organizational structures of the consortium as a whole.

**Appendix 7:** Organization chart (current situation).

## **B. Research Activity/Translational Oncology**

### **B 1.1. Research Programs**

To describe the overall quality of science at the center please address the following questions:

- What are the most important research programs/main focuses at your center? Describe these programs giving special attention to translational research aspects as well as the integration of both clinicians and basic scientists.
- How do these programs complement each other to reach the scientific goals/visions of your center?
- How do the different cancer-related scientific themes of the parent institution fit together with those of the center? How do they complement each other?
- How does the center contribute to practice changing developments which lead to more effective prevention, diagnosis and treatment of cancer?

In case of a CCC Consortium, please specify the above points for each partner site. Also list the measures to establish joint research programs and strategies.

List up to 25 (for CCC Consortia max. 50) of your most relevant **oncology-related** publications. The publications should be clearly assignable to the above mentioned research programs.

**Appendix 8:** List of the most relevant peer-reviewed oncology-related publications (max. 25, for CCC Consortia max. 50) 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) as well as the current impact factors. In case of a CCC Consortium, please highlight joint publications of consortium partners.

**Appendix 9:** Summary – in 2018 active funded peer-reviewed oncology-related research projects and newly granted funds.  
In case of a CCC Consortium: Please specify for each individual consortium partner.



Additionally, please comment on the development of research funds granted from 2016 to 2018. The use of charts and/or figures is encouraged. It is important, that the reviewers can easily detect trends and developments regarding the publication output and third-party funding.

### **B 1.2. Examples of Translational Research Projects**

Describe up to 3 (for CCC Consortia up to 2 per partner site) current exemplary translational research projects (covering the entire translational continuum from 'bench to bedside') from your main research programs. In this context, it is important to demonstrate the center's power of bringing compounds/therapies, which were pre-clinically developed in its own laboratories, to 'first-in-man' trials.

### **B 2. Innovative Diagnostics and Therapies/Implementation of New Concepts**

Describe your current portfolio of innovative diagnostic and clinical therapy programs, including immunotherapy as well as your strategy to implement new innovative concepts in diagnostics and therapy.

## **C. Research Infrastructure**

### **C 1. Programmatic structures**

Please describe what kind of programmatic structures/mechanisms have been implemented to promote interdisciplinary and translational research. Concentrate on the value added by the cancer center:

- What measures have been taken to support development of scientific excellence and to integrate (translational) research into the different multidisciplinary groups responsible for health care? In particular, clearly point out how the structure of the cancer center supports translational and laboratory research.
- How does the center promote collaborative intramural as well as extramural research programs? Identify the (infrastructural) measures of the cancer center to facilitate such collaborative undertakings (e.g. common programs, teleconferencing, intramural grant programs etc.).

### **C 2. Shared Resources/Core Facilities/Technical Platforms**

Please describe the CCC-internal, as well as the extramural (university, non-university institutes) resources, to which CCC-investigators have access to technologies (e.g. omics platforms), services (bioinformatics) and scientific consultation. Describe the center's policies about operation and use of the shared resources, e.g. access, priorities, limitations and charge back systems (in a CCC Consortium also consortium-wide).

**Appendix 10:** Access to Shared Resources/Core Facilities/Technology Platforms. In case of a CCC Consortium, please indicate the CCC site, where the resource is available.

### C 3. Tumor-/biobank(s)

Give a summary of the cancer center's tumor-/biobank(s) with special consideration to the center's policies for the operation of the biobank(s) and for the use of tumor tissues (project management, standard operating procedures, quality control, connection to clinical documentation system). Is the complete clinical data of each patient accessible? Describe the development of the biobank during the last years with specific reference to the biobank-IT/laboratory information management system (LIMS) and quality management. Include as well a description of your activities in the field of liquid biobanking. Please comment on the size of the tumor-/biobank (current number of patients whose fresh frozen tissue specimens, formalin-fixed paraffin-embedded (FFPE) specimens, liquid and living (organoid) samples are stored in the biobank). Describe whether and how the paraffin blocks archive of the Pathology Institute is accessible for projects of the biobank. Describe the degree of centralization/harmonization of the tumor-/biobank(s). Describe your concept of performance measurement of the biobank.

In case of a CCC Consortium, please describe the interconnection of the biobanks between the individual CCC partner sites, particularly by means of IT technology. Also, describe how accessibility of samples between the partner sites is guaranteed.

Please show the following numbers:

Table 1:

CCC Site**	Total number of all cancer patients* whose specimens are stored in the biobank			
	Fresh Frozen Tissue	FFPE Specimens	Liquid Samples	Living (Organoid) Samples
CCC Site 1				
CCC Site 2				
...				
Total Consortium				

\*Only patients who were treated for a principal diagnosis of cancer can be counted. Do not include any patient more than once, unless he/she has been treated for more than one malignancy.

\*\*In case of a CCC Consortium, indicate the numbers for the individual partner sites and for the entire consortium.

Table 2:

	Oncology-related requests to the biobank											
	Number of requests <sup>1</sup>				Number of approvals				Number of successfully completed requests <sup>2</sup>			
	Site 1*	Site 2*	...*	TC*	Site 1*	Site 2*	...*	TC*	Site 1*	Site 2*	...*	TC*
2016												
2017												
2018												

<sup>1</sup>Irrespective of the kind of biomaterial

<sup>2</sup>Include here only requests which were approved and which led to a supply of biomaterial.

\*In case of a CCC Consortium: please indicate the numbers for the individual CCC sites as well as for the entire Consortium (Site 1 – X: individual CCC partner site; TC: Total Consortium)

If available, provide any other documentation of performance (e.g. researchers' satisfaction numbers, documented publications referring to biobank material, oncology related consor-tional research projects relying on access to the biobank).

Note: 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 body/bodies (e.g. Medical Director of the Hospital, the Dean of the Medical Fac-ulty, fiscally responsible Administrative Director) referring to the above mentioned points (the statement can be included in Appendix 11, see below).

A more detailed description of the cancer center's tumor and biobank should be attached as Appendix 11 (maximum 5 pages; for a CCC Consortium, maximum 8 pages). Here, all presen-tations exceeding the above described summary can be included. In this appendix please address the criteria defined in our attached list of requirements for CCC biobanks (**Enclosure 2**).

**Appendix 11:** Description of the tumor-/biobank(s).

## **D. Clinical Trials Activity**

Please describe and comment on the cancer trials activity of your center with special focus on translational research. How do the clinical trials mirror the research goals of the center? What mechanisms exist to enhance accrual rate in clinical trials?

What measures has the center taken to recruit sufficient numbers of patients for precision medicine trials with rare tumor sub-types?

Relevant information and numbers not requested within the appendices can appear in the text.

### **D 1. Number/Percentage of Patients Enrolled in Clinical Trials**

Please list the percentage of pediatric patients, patients with hematolymphoid and patients with solid tumors enrolled in prospective clinical cancer trials:

*Table 1:*

	<b>Percentage of cancer patients newly enrolled in prospective clinical cancer trials in 2018 in relation to the number of newly diagnosed patients</b>					
	<b>Pediatric Tumors (&lt; 18 y)</b>		<b>Hematolymphoid Tumors (adults only)</b>		<b>Solid Tumors (adults only)</b>	
	<b>T<sub>1</sub>**</b>	<b>T+S***</b>	<b>T<sub>1</sub>**</b>	<b>T+S***</b>	<b>T<sub>1</sub>**</b>	<b>T+S***</b>
CCC Site 1*						
CCC Site 2*						
.....						
Total Con-sortium*						

\* In case of a CCC Consortium, indicate for the individual partner sites as well as for the total consor-tium.

**\*\*T1:** Therapeutic Trials (Phase I-III). Calculate the percentage in Appendix 12 using the first sub-column of column 3a, highlighted in light grey and the number of newly diagnosed patients in column 2, highlighted in green, respectively.

**\*\*\*T + S:** All Therapeutic Trials listed in App. 12 (Phase I-III; Phase IV; trials with medical devices) plus Supportive Care Trials. Use the percentages from Appendix 12 (% Columns Total 3a/2 as highlighted in dark grey)

A detailed presentation of patient accrual is to be given in Appendix 12:

**Appendix 12:** Number of cancer patients newly enrolled in clinical trials in 2018. In case of a CCC Consortium show the data for each CCC site as well as for the total consortium.

Comment on how successful your center is in recruiting patients in the different tumor entities. Also, comment on the development of patient accrual from 2016-2018. Support your statements with charts, figures etc.

Comment on patient accrual in early clinical trials and use the following table to describe the numbers for early clinical trials as compared to other types of trials:

Table 2:

	2018											
	Number of Trials				Number of patients enrolled <sup>1</sup>				Percentage of patients enrolled <sup>2</sup>			
	Site 1*	Site 2*	...	Total Consortium*	Site 1*	Site 2*	...	Total Consortium.*	Site 1*	Site 2*	...	Total Consortium.*
<b>Early Clinical Trials (Phase I, I/II, II)</b>												
<b>Therapeutic + Supportive Care Trials</b>												
<b>Other Prospective Trials</b>												

<sup>1</sup>Numbers of patients newly enrolled in 2018 (numbers of patients enrolled in early clinical trials can be extracted from appendix 13 and 14; numbers for therapeutic and supportive care as well as other prospective trials can be extracted from appendix 12 (highlighted in yellow): Total 3a, and Total 4, respectively).

<sup>2</sup>Percentage of newly enrolled cancer patients in relation to the number of newly diagnosed patients (percentages of patients enrolled in therapeutic and supportive care as well as other trials can be extracted from appendix 12 (highlighted in yellow): Total 3a/2, and Total4/2, respectively).

\*In case of a CCC Consortium: indicate the numbers/percentages for the individual partner sites as well as for the total consortium.

## **D 2. Specific Clinical Trials**

Please discuss your center's role in initiating clinical trials (PI at your center) and describe your measures to foster investigator initiated trial activities.

**Appendix 13:** Specific Clinical Trials - Investigator-Initiated Trials (IITs only). In case of a CCC Consortium, please provide the appendix for each of the individual partner sites.

**Appendix 14:** Specific Clinical Trials - without Investigator-Initiated Trials. In case of a CCC Consortium, please provide the appendix for each of the individual partner sites.

**Note:**

Appendices 12-14 must only contain patients who are actively participating in the study.

See **Enclosure 3** for determining the difference between investigator-initiated and industry initiated trials.

## **E. Clinical Trials Infrastructure**

### **E 1. Clinical Trials Office**

Is there a clinical trials 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 trials office that serves all disciplines among which cancer is one?

What services does the (cancer) clinical trials 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], 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.

In case of a CCC Consortium, please describe how the clinical trials infrastructures of the individual consortium partners are linked and how information about open trials is made available to each partner site.

### **E 2. Early Clinical Trials Unit**

Describe your early clinical trials unit (ECTU): location, structure, number of beds, number of employees. If an ECTU does not (yet) exist at your site, please describe where and how the early clinical trials are performed at your center.

How many trials were performed and how many patients (in total) were treated in the ECTU in 2018? Highlight (in yellow) the respective trials in the **appendices 13 and 14**. Comment on these numbers and the degree of centralization of early clinical trials at your center.

## **F. Outcomes Research/Epidemiology**

- F 1.** Please describe your program(s) in the field of outcomes research/epidemiology and your active projects since 2015 (e.g. benchmarking, identification of cancer risks, predictive factors, cancer screening programs etc.). Clinical trials in the area of outcomes research/epidemiology can be specified in the **appendices 13 and 14**. List the 5 (for a CCC Consortium max. 10) most relevant peer-reviewed publications (with a major focus on cancer only) since 2015 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. In case of a CCC Consortium, please specify for each partner site and highlight joint publications of consortium partners.

## **G. Regional Network/Outreach Activities**

### **G 1. 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. Describe the interactions of your center with other members of the 3-tier-system (local oncology centers, organ cancer centers). Also describe how your center promotes innovative developments in the regional network.

### **G 2. Documentation of Stable Interactions 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 form(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? What is the percentage of cases from cooperation partners which are discussed in tumor boards? How is the integration of physicians from cooperation partners in the tumor boards organized? Are there data privacy issues which prevent participation of external physicians in joint tumor board sessions?

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 in place to foster cooperation rather than competition and conflict?

### **G 3. Regional Network for Cancer Trials**

Describe your regional network for cancer trials (e.g. participating hospitals/oncologists, trial recruitment policy within the regional network, agreements regarding joint trials, trials register, services provided by the CCC: GCP training, flying study nurses etc.).

Analyze the impact of your outreach activities to the accrual in clinical trials. If possible, please provide numbers of patients from regional network partners enrolled in clinical studies of the CCC (particularly interesting for IITs initiated by the CCC) and discuss patient flows concerning clinical trials in the regional network.

In case of a CCC Consortium, please describe, whether and how the regional trials networks of the individual CCC sites are interconnected and coordinated.

### **H. Community Service and Education**

**H 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).

### **I. Multidisciplinary Care/Core Activities in One Building**

#### **I 1. Multidisciplinary Care**

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 as elaborated in the national (S3) guidelines and their corresponding local standard operating procedures. For entities where no (S3) guidelines exist, implementation of appropriate standard operating procedures is expected.

Give a short summary of the current status of multidisciplinary clinical care at your cancer center. Use a flowchart to show the multidisciplinary structures and the general cancer patient pathway through your center.



Due to the obligatory certification as an Oncology Center, many of the aspects of multidisciplinary care formerly requested within the Deutsche Krebshilfe funding program are already covered by the certification requirements for Oncology Centers. Therefore, please focus here on issues of multidisciplinary care going beyond the requirements of this certification.

How do you ensure that patients with specific tumor entities, not covered by the certifications at your center (in the context of the National Cancer Certification Program), have access to best-practice and evidence-based care and are being adequately discussed in tumor boards? Please list the respective tumor entities.

How many personal patient managers/patient navigators ('Lotsen') do you have to support your cancer patients during diagnostics, treatment and after-care? Describe their duties and responsibilities. To what extent are they exclusively dedicated to personal patient guidance? On the average, how many patients per patient manager are attended per year?

## **I 2. Central Building**

Describe how you concentrate the core activities in your center. 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 15:** Plan of the hospital/university campus indicating the building in which core activities of the cancer center are conducted.

## **J. Tumor Boards**

### **J 1. Tumor Boards**

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') must be fulfilled.

Regarding the tumor board structures, describe the measures your center has undertaken to go above and beyond the requirements of the certification as an Oncology Center? For example, do you have tumor boards for rare entities and how often do they meet? Do you have a molecular tumor board? Describe its structure and function.

How is compliance to tumor board recommendations monitored? What are the results? What are the consequences of low compliance?

Describe the role of your tumor boards in facilitating research/clinical trials. How are tumor board patients chosen for clinical trials?

**Appendix 16:** Numbers and Percentages of Cancer Patients discussed in Tumor Boards. In case of a CCC Consortium, please provide the appendix for each of the individual partner sites as well as for the total consortium.



**Appendix 17:** Multidisciplinary Tumor Boards - Current Situation. In case of a CCC Consortium, please specify for each individual partner site.

## **K. Information Technology**

### **K 1. Adequate 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
- local clinical cancer registry
- documentation of tumor board decisions
- electronic clinical pathways/care plans
- access to information about clinical trials/study management
- biobank IT system
- data warehouse
- user access (Who has access?)
- responsibilities/support from IT-Department

How are these systems interlinked with each other and linked to the hospital information system? To what extent are the cooperating partners within the regional network linked to your IT systems? In case of a CCC Consortium, please describe, how the individual partner sites are interconnected regarding their IT systems.

## **L. Documentation/Clinical Cancer Registry**

**L 1.** What has your center undertaken to go over and above the requirements of the certification as Oncology Center? What documentation structures exist at your center which go beyond the requirements and legal documentation of cancer in Germany? What is the purpose of these documentation structures? How is the research aspect involved? What data is collected in addition to the obligatory basic data set ('ADT/GEKID-Basisdatensatz') and how is it used?

## **M. Palliative Care**

**M 1.** The criteria for palliative care requested within the 'National Cancer Certification Program' ('Erhebungsbogen für Onkologische Spitzenzentren und Onkologische Zentren') 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') and the 'Best Practice in Palliative Care' as worked out by the German CCC Network (Enclosure 4) is expected. A separate, closed-off palliative care unit at the Comprehensive Cancer Center must be in place.

Please show the following data (in case of a CCC Consortium, provide the information for each individual CCC site):

Palliative Care Structures at the Comprehensive Cancer Center	Yes/No	Number of Beds*	Personnel (physicians, nurses, others)	Number of patients treated in 2018	Number of cancer patients treated in 2018
Palliative Care Unit					
Multiprofessional Palliative Care Service**					
Palliative Outpatient Care Clinic**					

\*Exclusively for patients with a need for palliative care

\*\*As defined in Enclosure 4

Describe when and how palliative care is integrated in the multidisciplinary-based treatment of cancer patients. How do you ensure a specialized palliative home care ('SAPV') for your patients? Is there a professorship/chair for palliative medicine in place? If not, are there plans to establish such a professorship in the near future?

Describe the research activities in the field of palliative care/medicine at your cancer center.

## **N. Psychosocial Care/Self-Help Groups**

**N 1.** The criteria for supportive care requested within the 'National Cancer Certification Program' ('Erhebungsbogen für Onkologische Spitzenzentren und Onkologische Zentren', Chapter 1.4-1.6), must be fulfilled. The implementation of the guideline for psycho-oncology of the German Guideline Program in Oncology ('S3-Leitlinie Psychoonkologische Diagnostik, Beratung und Behandlung von erwachsenen Krebspatienten') is expected.

Describe how psychosocial care is integrated in the multidisciplinary-based treatment of cancer patients. How is a low-threshold psychosocial counseling service ensured? Please support your description with figures/numbers/data. In particular, please provide the following figures in the table below. In case of a CCC Consortium, please provide the numbers for each individual CCC site.

	1 Number of all cancer patients treated in the cancer center; take from App. 4; Total (A+B)	2 Number of cancer patients of the cancer center who had at least one consultation with a psycho-oncologist (minimum 25 min.)
2018		
2017		
2016		

Please show, if available, the number of cancer patients who were screened for psychological distress in 2 representative months in 2018 and describe how the screening is implemented in every day clinical care. If such a systematic screening is not offered, or is in the process of being set up or if screening is not documented, please provide your concept for the implementation of a structured screening and/or its documentation. Please note: In our upcoming calls for applications, corresponding key numbers will be expected.

Please describe your further programs/activities in the area of psycho-social oncology which go beyond the requirements of the 'National Cancer Certification Program' (e.g. survivorship programs, psycho-oncological ambulatory service, training activities concerning communication skills).

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.

## **O. Training Programs**

### **O 1. Multidisciplinary Training**

Describe the current activities/programs offered by the cancer center for multidisciplinary training of physicians, physician scientists, scientists, nurses and related professions. If your center has a MD and/or PhD program please lay special focus on this program. Does the center have intramural funds set aside for the training of MDs, PhDs, young researchers and junior scientists? Which career development options are available for researchers and physician scientists? Are physician scientists released from their clinical duties during his/her research? Does your center have appropriate programs for the training of MDs and PhDs in laboratory, clinical and translational research? Do you have communication training for managing medical staff?

Support your descriptions with quantitative data/figures ('success record' e.g. numbers of registered research students, numbers of successful PD/MD degrees, drop-outs, board numbers of successful participants, certified physicians, oncology nurses).

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

In case of a CCC Consortium, please provide the information for each individual partner site. How are the partner sites interlinked regarding their training structures? Are there programs for employees of an individual site to participate in training programs offered at the other partner site(s)?

## **O 2. Outreach Training Programs**

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).

In case of a CCC Consortium, please provide the information for each individual CCC partner site.

## **Additional Information**

### **Bylaws**

**Appendix 18:** Bylaws, e. g. specifying responsibilities/authorities of the Cancer Center Director, clarifying reporting structures, etc.

### **Statements of Support**

**Appendix 19:** 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.

With the submission of a signed application, the applicants agree that the Deutsche Krebshilfe may obtain access to the audit reports from the certifications of the Oncology Centers as well as the corresponding Organ Centers, Modules, and Foci for the purpose of our own random assessment.

## **LIST OF APPENDICES**

(for more details see application guidelines)

Appendix 1\*: Center Fact Sheet

Appendix 2: Original comments of the reviewer panel

Appendix 3: Catchment area (map, number of inhabitants)

Appendix 4\*: Number of all cancer patients and newly diagnosed cancer patients treated in the cancer center

Appendix 5: Copy of your current Oncology Center certificate

Appendix 6: CV of the Cancer Center Director and the Deputy Director(s)

Appendix 7: Organization chart (current situation)

Appendix 8\*: List of the most relevant peer-reviewed publications from the last 5 years

Appendix 9\*: Summary – in 2018 active funded peer-reviewed oncology-related research projects and newly granted funds

Appendix 10\*: Access to Shared Resources/Core Facilities/Technology Platforms

Appendix 11: Description of the tumor-/biobank

Appendix 12\*: Number of cancer patients newly enrolled in clinical trials in 2018

Appendix 13\*: Specific Clinical Trials - Investigator Initiated Trials (IITs only)

Appendix 14\*: Specific Clinical Trials - without Investigator Initiated Trials

Appendix 15: Plan of the hospital/university campus indicating the building in which core activities of the cancer center are conducted

Appendix 16\*: Numbers and Percentages of Cancer Patients discussed in Tumor Boards

Appendix 17\*: Multidisciplinary Tumor Boards - Current Situation

Appendix 18: Bylaws

Appendix 19: Statements of Support

*\*Forms can be downloaded as word files*

## **CONTACT**

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## Enclosure 1

### Counting of Patients in Surgical Oncology on the Basis of OPS Codes (Table 2 under 6.2)

<b>Surgical Therapy</b>	<b>OPS Codes</b>
Neuro-oncological Surgery	5-012.7...5-012.8; 5-014...5-018; 5-035; 5-041
Endocrine Surgery	5-06...5-07
Ophthalmologic resections	5-081; 5-082; 5-085; 5-091; 5-112; 5-135; 5-155; 5-158...5-159; 5-162...5-164; 5-168.1
Head and neck surgery	5-081...5-082; 5-091; 5-181...5-182; 5-203; 5-205; 5-208; 5-212...5-213; 5-221...5-224; 5-242.2; 5-250...5-252; 5-261...5-262; 5-272...5-273; 5-277...5-278; 5-281...5-282; 5-284; 5-292; 5-295...5-296; 5-300...5-303; 5-314; 5-403; 5-770...5-772;
Thoracic surgery	5-320...5-329; 5-342...5-345; 5-347.3; 5-372...5-373
Visceral Surgery	5-422...5-426; 5-433...5-443; 5-451...5-452; 5-454...5-456; 5-470; 5-482; 5-484...5-485; 5-492; 5-501...5-502; 5-504; 5-511.3; 5-515.1...5-515.2; 5-518.3...5-518.5; 5-521; 5-524...5-525; 5-542; 5-543; 5-547; 5-549.2
Urologic surgery	5-552; 5-553...5-554; 5-563; 5-573...5-576; 5-582...5-583; 5-590.5; 5-591.1; 5-601...5-605; 5-612; 5-621...5-622; 5-633; 5-641...5-642
Breast and gynecological surgery	5-651; 5-652; 5-653; 5-661; 5-665; 5-671; 5-672...5-673; 5-681...5-688; 5-692; 5-702; 5-714...5-715; 5-870...5-877
Tumor orthopedics	5-782; 5-829.c; 5-832; 5-852; 5-862...5-865
Dermatological surgery	5-862; 5-864; 5-894; 5-895; 5-915; 5-919
Spleen and bone marrow operations*	5-411; 5-413

Counting is carried out on the basis of patients per calendar year. Patients with at least one of the OPS codes listed above can be counted. Revision operations must not be counted. Only patients may be counted whose surgery was based on an oncological diagnosis. Patients can be counted more than once, if they have been treated for more than one malignancy in 2018. Please use the ICD-10 diagnoses in Appendix 4 as a filter.

\*Patients undergoing these procedures may be counted in a separate category ('Others').

## **Enclosure 2**

### **Requirements for a CCC Biobank**

#### **Introduction**

A biobank, like in any active biomedical research institution, is a mandatory requirement for all CCCs. The biobank should fully support the research needs of the CCC. Whenever possible, an affiliation or collaboration is recommended with the following structures:

- Comprehensive biobank on site
- A comprehensive IT structure on site
- A clinical cancer registry
- Interaction with a Biobank Network (e.g. The German Biobank Alliance (GBA), Biobanking and BioMolecular Resources Research Infrastructure (BBMRI), Biobanking workgroup of the TMF (Technology, Methods, and Infrastructure for Networked Medical Research))

A registration in the National Biobank Registry is obligatory.

Whenever possible and when covered by its regulations, the biobank should be willing to support projects across different sites.

The following requirements have been defined based on the experience with tissue banks. The same high quality standards are intended to prospectively apply for liquid biobanking. A concrete draft of the specific requirements for liquid biobanking will be drawn up at a later date.

#### **Specific Requirements**

The following functions must be defined and properly presented in the CCC Biobank:

- **Structure, Regulations, and Administration:**  
Structure (organigram), responsibilities, agreed upon regulations and decision-making processes must be clear and transparent. The available resources used for the administrative maintenance (personnel, offices) and relevant procedures (documentation of projects, quality management, appraisals, etc.) must be depicted in relation to their functions.
- **Specimen collection and storage techniques:**  
Description of the current conditions and capacity, in particular the following points:
  - How are samples recorded and documented (scanning, databank)?
  - Which storage conditions (-80°C/liquid nitrogen; automation, on-site storage facilities) exist?
  - Is an emergency breakdown plan (alarm system, emergency plans, back-up, etc.) in place?



Proposed future plans: automated sample registration system, protection regulations for the handling of older samples.

- **Biobank-associated technology platforms:**  
It must be shown how the histological basic technology (tissue sections and staining technology) is guaranteed. Generally, there should be an organizational separation between the biobank and routine pathology. All technologies/platforms, which exceed the standard techniques, should be represented. The information, as to whether these technologies are provided by the biobank or from another institution/department, should be included in the description.
- **Documentation and structured IT-System:**  
The biobank must be linked to or integrated into the relevant clinical IT-System of the CCC. The possibility to adequately link samples and patient data should be existent. A description of the functionality and sustainability of the existing documentation/IT system, which should preferably be an adequate laboratory information management system (LIMS), must be included.
- **ELSI-Concept: (data protection, ethic committee vote, donor information)**
  - Specific regulations for sample use, current donor information, and valid ethic committee recommendations (review procedure, updated?)
  - Current data protection regulations (review procedure; how are these regulations integrated in the overall context of the CCC, the tumor documentation system and the clinical cancer registry? How is genetic data dealt with?)
- **Structural project management: (project management incl. project processing, and tracking)**
  - Mandatory feasibility-check and project consultancy
  - Project decisions
  - Conflict management
  - Documentation
  - Material transfer agreement
  - Documentation of all biobank projects (the biobanks must be able to demonstrate, which research projects they were/are involved in)
- **Structured Quality Management:**
  - Quality assurance measures (SOPs, audits, training, responsibilities, quality assessment measures, etc.) Note: Each individual center can decide whether the Quality Management is responsible for the whole CCC or only for the specific clinic.
  - Concept for project tracing (tracking)
  - External assessments (e.g. DAkkS - Germany's National Accreditation Body,
  - DZGs - German Centers for Health Research, BMBF - The Federal Ministry of Education and Research, joint projects with documentation of results)

- **Sustainability Concept:**  
How is the sustainability of the biobank, in regard to **organization** and **financial affairs**, guaranteed?  
Note that the biobank does not necessarily have to be a part of the CCC. The interaction between the biobank and the CCC **must** however be adequately managed.
- **Communication Concept:**  
Information about the Biobank should be easily accessible for interested researchers. The biobank should be integrated in either the CCC-Homepage or have a separate website, preferably with the possibility of electronically ordering samples.
- **Training Concept:**  
Depiction of the training opportunities available to the employees of the biobank.

#### **Equipment/Resources of a CCC Biobank**

It must be ensured that the following resources, in adequate quality and quantity, are available at all times:

- Budgets for personnel and resources
- Adequate premises and equipment
- Biobank-associated technology and laboratory facilities (extraction technology is optional)
- Administration
- Adequate IT-System (preferably LIMS)

### **Enclosure 3**

**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.

## **Enclosure 4**

<b>Palliative Care Best Practice Recommendations</b>	
<b>Time, when palliative medicine should begin</b>	
1.	All patients must be offered palliative care immediately after receiving a diagnosis of an incurable cancerous disease, regardless of whether a tumor-specific therapy is being performed.
<b>Palliative Care Unit</b>	
2.	A Palliative Care Unit is an essential requirement for a CCC. In order to ensure high quality care for cancer patients, the CCC must avoid providing palliative care only through their network of cooperating acute care hospitals.
3.	A Palliative Care Unit must be an organizational and structurally independent unit.
4.	The minimum size of a Palliative Care Unit is 6 beds.
5.	Experts, specialized in palliative care, should be made available to the patients within the CCC on a 24-hour/7-day a week basis.
<b>Palliative Service</b>	
6.	A multi-professional palliative care consultation team should consist of at least three employees who are accessible in the core working hours and who come from the fields of medicine and nursing and at least one other therapeutic profession (psychology, social work, or pastoral).
7.	It is necessary that a CCC offers a multi-professional palliative care consultation team which provides advice and support for cancer patients and their relatives in other departments.
8.	Information concerning the availability of the palliative care consultation team must be accessible in all departments.
<b>Day Clinic and Palliative Outpatient Care Clinic</b>	
9.	An outpatient clinic with competence in palliative medicine is an important criteria for early information and treatment of cancer patients. A CCC must offer such a structure or the possibility of a specialized interdisciplinary outpatient palliative care consultation by appointment at least two hours twice a week.

10.	Patients must have access to specialized palliative care in the day clinics of all departments where cancer patients are treated.
<b>Regional Network</b>	
11.	Specialized palliative home care ('SAPV') must be provided by the institution itself and/or in cooperation with regional and national providers specializing in palliative home care.
12.	If a cooperation with an external provider exists, a written contract should be part of the agreement.
13.	A cooperation with a hospice must be in place.
14.	Support from qualified hospice volunteers must be made available to CCC patients with an incurable cancer.
<b>Inclusion of specialized palliative care in decision-making processes within a CCC</b>	
15.	Specialized palliative care must be integrated in the steering committees of the CCC to promote potential interdisciplinary cooperation.
16.	All CCC patients with an incurable cancer must be assessed for symptoms as well as psychosocial stress using validated multidimensional assessment tools.
17.	The possibility of inviting palliative care specialists when needed to consultation hours should be communicated to the patients by the attending oncologists.
18.	Information on palliative care must be displayed visibly in waiting areas of outpatient clinics treating cancer patients.
<b>Documentation</b>	
19.	All palliative units of the CCC are to document their records in the national hospice and palliative registry.
20.	Regardless of the stage of the illness, inquiries must be made during the doctor-patient consultation of the existence of a health care proxy and/or an advance directive.
21.	The health care proxy and/or the advance directive must be available - centrally and electronically - for all the different attending professions in the CCC.

<b>Treatment pathways for terminally ill patients</b>	
22.	The CCC must have a quality concept when dealing with terminally ill patients.
23.	A treatment pathway for dealing with dying patients should include elements such as: steps for assessing the terminally ill patient by a multi-professional team, documentation of the decision-making process, and an information sheet on what must be considered after a family member dies.
<b>Research</b>	
24.	To promote interdisciplinary research projects in a CCC, specialized palliative care must be integrated in the research structures of the CCC.
25.	Research achievements of the palliative care department should be regularly evaluated.
<b>Education and Teaching</b>	
26.	Each CCC must have a structural concept for strengthening research and teaching in the area of palliative care. This may include establishing a chair for palliative medicine.
27.	Each CCC must offer an annually evaluated training in palliative care.
28.	All professionals offering general palliative care to patients with an incurable cancer, must be qualified in basic palliative care through an undergraduate or postgraduate training (according to the 40 hours of a basic qualification course in Germany). Training should be updated regularly.
29.	To recognize the need for specialized palliative care, the emergency departments must offer medical and nursing staff qualified (and competent) in basic palliative care acquired through an undergraduate or postgraduate training (according to the 40 hours of a basic qualification course in Germany). Training should be updated regularly.
30.	Emergency personnel should be explicitly invited to in-house training on care and counselling of patients with incurable cancer to sensitize them about decisions concerning palliative and intensive care.