

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

11th 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 has issued 10 calls for applications since 2006. We are now inviting for a 11th 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 8 CCCs or CCC Consortia can be funded within this 11th 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: **November 23, 2025.**

Subsequent full application deadline: **January 30, 2026.**

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Preface

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/designation 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 prerequisites.

The certification as an Oncology Center within the National Cancer Certification Program is an obligatory requirement for centers applying for funding as an Oncology Center of Excellence by the Deutsche Krebshilfe. An Oncology Center of Excellence/Comprehensive Cancer Center (CCC) must ensure, that patients with specific tumor entities, not covered by the certifications 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.

A CCC 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' as well as reverse translation are crucial features 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.

General Information

Eligibility Requirements

Public or private cancer centers in Germany that have already met or almost met the criteria for funding (see page 8 ff.).

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 as a CCC Consortium, please contact the Board of Directors ('Vorstand') of the Deutsche Krebshilfe first.

CCC Consortia

An Oncology Center of Excellence (Comprehensive Cancer Center) funded by the Deutsche Krebshilfe can consist of more than one site (Comprehensive Cancer Center Consortium). A CCC Consortium is a consolidation of two or more 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 Deutsche Krebshilfe.

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 in the National Cancer Certification Program). They must also have 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.

In applications of CCC Consortia which incorporate new partner sites that have not yet been funded within this program, each site must provide detailed and convincing information for each funding criterion. Regarding the size/extent of the documents to be submitted, please contact the offices of the Deutsche Krebshilfe in advance. For renewal applications of already funded CCC Consortia and for applications of CCC Consortia which integrate already funded CCC sites, aggregated data/information on the entire consortium is sufficient unless it is explicitly requested.

Funding

The financial support must 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/Renewal Application

Centers which applied in the past and did not receive funding as well as centers which have already been funded can reapply. The comments and recommendations of the reviewers from the last evaluation must be addressed.

Review Process

The review process will proceed in two stages:

1. Evaluation of grant applications by an international panel of experts.
2. Further evaluation will be achieved through hearings, which may be complemented by on-site visits. The hearings are expected to take place **May 04-08, 2026**.

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.

Preparation/Submission of the Letter of Intent and the Application

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 **November 23, 2025**. The Deutsche Krebshilfe office confirms receipt of your Letter of Intent by email.

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) contain a statement to establish or to further develop the 'Interdisciplinary Oncology Center of Excellence',
- (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

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 written **English** and prepared according to the following instructions. It must be ensured, that the applications consist of the following elements:

- **Cover Letter**
- **Table of Contents** including page numbers
- **Abbreviations**
- **Section I. (Introduction):** max. 5 pages
- **Section II. (Central Slide Set):** max. 30 slides; CCC Consortia: max 40 slides. This section must be structured by using the letters/section numbers from the application guidelines.
- **Section III. (Further Information):** max. 20 pages; CCC Consortia: max. 30 pages. This section must be structured by using the letters/section numbers from the application guidelines.
- **Section IV. (Formal Documents)**

To simplify the review process please address the following points:

- header with the name of the cancer center on each page,
- address in the application all points mentioned in the application guidelines, repeating all section numbers/headlines from the guidelines,
- all pre-defined tables and figures must be numbered as specified in the application guidelines,
- In section I., III. and IV. use 'Arial' 11 pt and 1.25-line spacing. In tables and figures, the font size can be variable.

Feel free to adapt the layout of pre-defined tables/figures/diagrams to your needs. However, it is important that they contain all pre-defined information in the given order.

All documents/sections listed above - except section IV. - will be forwarded to the reviewers. Therefore, please provide your final application as 2 separate files in PDF-Format:

- File A: Cover Letter
Table of Contents
Abbreviations
Section I: Introduction
Section II: Central Slide Set
Section III: Further Information
- File B: Section IV: Formal Documents

Please provide the Summary (see Section I.2) also in WORD-Format.

In addition to the electronic files please provide:

- one complete unbound application package with original signatures (including Section IV) plus
- 3 bound copies of the grant application WITHOUT Section IV.

The application must be received by **January 30, 2026**. Please provide the electronic version per download-link and send the hard copy of the application to:

Stiftung Deutsche Krebshilfe
Bereich Förderung
Buschstrasse 32
53113 Bonn

Please note that the application will not be screened for completeness upon receipt and that the hard copy application must match the application you submit electronically word-for-word.

The offices of the Deutsche Krebshilfe will confirm receipt of the proposal by email.

Criteria for Funding

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

- Translational Oncology/Access to Innovation/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.

A. Basic Information/Size of the Center

A CCC must have a critical size regarding catchment area, patient numbers and infrastructure as well as have a comprehensive portfolio of specific competences going beyond the requirements for an Oncology Center within the 'National Cancer Center Program'.

B. 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.

C. Research Activity/Translational Oncology

It is important for a CCC to be active in all fields of oncological research (basic research, pre-clinical and clinical translation, late clinical research as well as outcomes research) reaching from prevention/early detection/diagnosis/therapeutic intervention to follow up. The center must have 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 and international collaborative research consortia is expected.

D. Research Infrastructure

Structures which promote interdisciplinary as well as translational research. A CCC must have adequate access to state-of-the-art as well as innovative technology platforms. A comprehensive and centralized tumor and biobank with defined quality and documentation standards is expected.

E. Access to Innovation (Molecular Diagnostics/Precision Medicine/Immunotherapy/Early Clinical Trials)

Access to innovative therapy concepts is a mandatory component of a CCC and is manifested by a broad portfolio of programs in molecular diagnostics, precision medicine, immunotherapy, and early clinical ('first-in-man') trials.

F. 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.

G. 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, I/II cancer trials are performed.

H. 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.

I. Community Outreach

Continual interaction with the public by way of community service and education.

J. Multidisciplinary Care

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. 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. 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.

K. Tumor Documentation/Clinical Cancer Registry and Information Technology

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. Therefore, multidisciplinary care and research must be supported by an up-to-date and adequate information technology. IT interoperability and sharing of data with national initiatives / data networks (e.g., nNGM, DKTK, DNPM, MII etc.) is crucial.

L. 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.

M. Psychosocial Care/Self-Help Groups

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

N. Patient Engagement/Involvement

Involvement of patient representatives in patient-related aspects of clinical care and in boards/committees of the cancer center, responsible for the conceptual design and assessment of 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.

Application Guidelines

General Remarks:

It is most important that the value added through the structure of the Comprehensive Cancer Center over individual activities/efforts existing at your center is clearly visible. In addition, the presented information must be based on your current situation and should be distinguishable from future plans. 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. The strengths/specific expertise(s) of each individual partner site and how they complement each other, and the resulting (potential) value added to the consortium should be convincingly shown.

Regarding the requested data/tables: if there are specific characteristics/features at your center that cannot be presented adequately by the requested data/tables, please feel free to provide additional data. However, the maximum number of slides/pages must not be exceeded.

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 acknowledged.

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.

Table of Contents (with page numbers).

Abbreviations

Section I.: Introduction

1. Name and full work address of the Corresponding Applicant

- The Cancer Center Director is regarded as the corresponding applicant and should provide full name, work address, telephone number and email address.
- For CCC Consortia with a more complex leadership structure, a Cancer Center Director who will be acting as the corresponding applicant, must be named.

2. 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? Please give a short overview how your center has addressed the reviewers' comments from the last evaluation. What is the future vision of your center, and which are the most important goals for the next funding period? What impact would funding by the Deutsche Krebshilfe have for the cancer center? For CCC Consortia, please make clear:

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

3. Requested Funding

Provide an itemized budget/cost proposal in tabular form containing the following information:

Principal cost categories '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 specify 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.

Section II.: Central Slide Set

The 'Central Slide Set' should give a concise and compact overview over the most crucial aspects of a CCC. It must be structured along the funding criteria of the Deutsche Krebshilfe and is restricted to 30 slides (for CCC Consortia: max. 40 slides). For many items, pre-defined templates/tables (see below) should be used. For items without provided templates, please use bullet points, tables or graphical presentations.

Most importantly, the structure and performance of a center should be understandable on the basis of the slide set without having to read any further information. The reviewer committee will primarily be assessing the performance of your center through the slide set. Nevertheless, you have the opportunity to present additional information in Section III ('Further Information') if you feel this is necessary or it is asked for in the application guidelines. **In the individual slides please refer to the respective chapter/page numbers in Section III, if there is additional information given.** However, be aware that the slide set is the most important part of the application for the reviewer committee. Therefore, it is essential that the slides are concise and the presented information is immediately understandable.

A. Basic Information/Size of the Center

A.1 Catchment Area

Please provide information on your catchment area by using the following maps:

- Figure II.A.1.1
Population density in Germany:
Map of Germany showing the inhabitants per square kilometer (based on postal code areas).

- Figure II.A.1.2
Patient's Place of Residence:
Map of Germany showing the catchment area of the center, colored by the range of numbers of the patients cared for at the center (bases on postal code areas). Each color represents 25 % of the patients.

- Figure II.A.1.3
Proportion of Coverage:
Map of Germany colored by the number of patients cared for at the center in relation to a population of 100,000 inhabitants (based on postal code areas).

Guidelines for the creation of the above-mentioned maps (Figures II.A.1.1-3) are attached as **Enclosure 7**. You have the opportunity to use a software tool which has been developed in the context of the 'ONConnect' joint application of the CCC network. The development of the tool was also supported by members of the Working Group 'Digital Oncology' of the CCC network. Prerequisite is, that you prepare a list of patient numbers per postal code area. Then, data import and processing/calculation is performed locally at your center by using the above-mentioned software tool. If you wish to use the software, please contact the offices of the Deutsche Krebshilfe (contact information: see page 60).

Optional explanations on your catchment area are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

A.2 Size of the Center/Patient Numbers

Table II.A.2.1

Details on the Hospital and the Cancer Center/Number of Patients (2024)				
		CCC Site 1 ¹	CCC Site 2 ¹	CCC Site X ¹
Details on the entire (University) Hospital	Number of beds			
	Total Inpatients ³			
	Total Outpatients ⁴			
Cancer Patients	Total Cancer Patients ⁵			
	Cancer Inpatients ⁶			
	Cancer Outpatients ⁷			
Patients per Therapeutic Modalities ²	Surgical Oncology ⁸			
	Radio-Oncology			
	Nuclear Medicine			
	Hematologic Malignancies			
	Solid Malignancies			
	Precision Medicine ⁹			
	Pediatric Oncology			

¹In case of a CCC Consortium only.

²Patients (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, respectively). However, a patient can only be counted once in each field, unless he/she has been treated for more than one malignancy in 2024.

³Number of all inpatients (stationary patients only = "vollstationär") in the entire hospital in 2024.

⁴Number of all outpatients in the entire hospital in 2024.

⁵Number of all cancer patients in 2024 matching one of the following criteria: reported to the state clinical cancer registry, follow up, second opinion, tumor board, trials participation. Each patient may only be counted once per year. Note: Only patients can be counted, who visited the cancer center in the context of their tumor disease. Cases like the following example cannot be counted: A patient with a history of prostate cancer 10 years ago, who achieved complete remission and has had an unremarkable course since, is being treated in the trauma surgery department of the center due to a fracture but is not receiving any tumor-specific treatment or medication.

⁶Numbers of cancer inpatients (stationary patients only = "vollstationär") in the entire hospital in 2024.

⁷Numbers of cancer outpatients in the entire hospital in 2024.

⁸Number of all cancer patients at your (university) hospital who underwent one or more surgical procedures in 2024 according to **Enclosure 1** (excerpt of the German version of the International Classification of Procedures in Medicine – OPS).

⁹Aggregated numbers from 'MTB discussions' and 'Number of patients discussed in an MTB/lung tumor board at the CCC in the context of the National Network Genomic Medicine Lung Cancer' from Table II.E.1.1. (page 20, lines 6 and 11)

Table II.A.2.2

Number of Cancer Patients per selected anatomic tumor sites in 2024		
	Newly diagnosed ¹	Newly diagnosed + patients with recurrence and metastasis ²
<i>A. Tumor Entities covered by a certification within the 'National Cancer Certification Program'³</i>		
Colorectal		
Pancreas		
Hematological systemic disease		
Breast		
Gynecological tumors		
Skin (invasive malignant melanoma)		
Prostate		
Head/Neck tumors		
Neuro-oncological tumors		
Lung		
Pediatric Tumors (Patients < 18 y.)		
Others ⁴		
thereof Entity X ⁵ (optional)		
TOTAL (A)		
<i>B. Tumor Entities not covered by a certification within the 'National Cancer Certification Program'⁶</i>		
Others		
thereof Entity Y (optional)		
TOTAL (A+B)		

¹Newly diagnosed: Patients with initial diagnosis treated at the center. Please list here the 'Primary Cases' according to the definition as in the 'National Cancer Certification Program'.

²Newly diagnosed + patients with recurrence and metastasis. Please list here the 'Centre Cases' according to the definition as in the 'National Cancer Certification Program' (primary cases + patients with (locoregional) recurrence + patients with secondary distant metastasis). In contrast to the National Cancer Certification Program, 'Centre Cases' can also be listed for Hematological systemic disease.

³Encompasses the following entities, that may be certifiable within the 'National Cancer Certification Program' independent of whether a center is certified for all of these possible entities.

⁴Please show here the aggregated patient numbers of all other entities certifiable within the 'National Cancer Certification Program' but not listed above.

⁵Here, you have the possibility to present (a) tumor entity(ies) for which your cancer center has specific competence but which is not listed above.

⁶Tumor Entities not covered by a certification within the 'National Cancer Certification Program': Please show here (rare) tumor entities for which your cancer center has specific competence which are not certifiable within the 'National Cancer Certification Program'.

In Section III.A.2 a more detailed listing of patient numbers per anatomic cancer sites is requested. Please refer in the slide(s) to this Section (incl. page number).

Optional explanations are also possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

A.3 Fields of Specific Competence in Oncology

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

Table II. A.3

Fields of Specific Competence in Oncology (max. 5; for consortia max. 10*)

*In case of a CCC Consortium, please specify at which CCC site the specific competence is available.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

A.4 Participation in National and CCC Network-wide Initiatives

Table II.A.4

Participation in National and CCC-Network wide Initiatives/Programs	
Initiative (e.g.)	Role within the Initiative (e.g. Lead, participation in Task Force XY etc.)
nNGM (national Network Genomic Medicine Lung Cancer)	
DNPM (German Network for Personalized Medicine)	
NCT (National Center for Tumor Diseases)	
DKTK (German Cancer Consortium)	
MII (Medical Informatics Initiatives)	
...	

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

A.5 Local Funding of the CCC

Please list information on the financial support by the hospital/medical center, medical faculty, federal state, public health system etc. available for core-structures, research programs or additional activities of the cancer center. Funds for standard clinical care should not be included.

Table II.A.5

Local Funding of the CCC		
	Financial Support in 2024 (€)	
	CCC Site 1*	CCC Site X*
Hospital/medical center/medical faculty, federal state etc.		
Public Health System (e.g. 'Zentrumszuschlag')		
TOTAL		

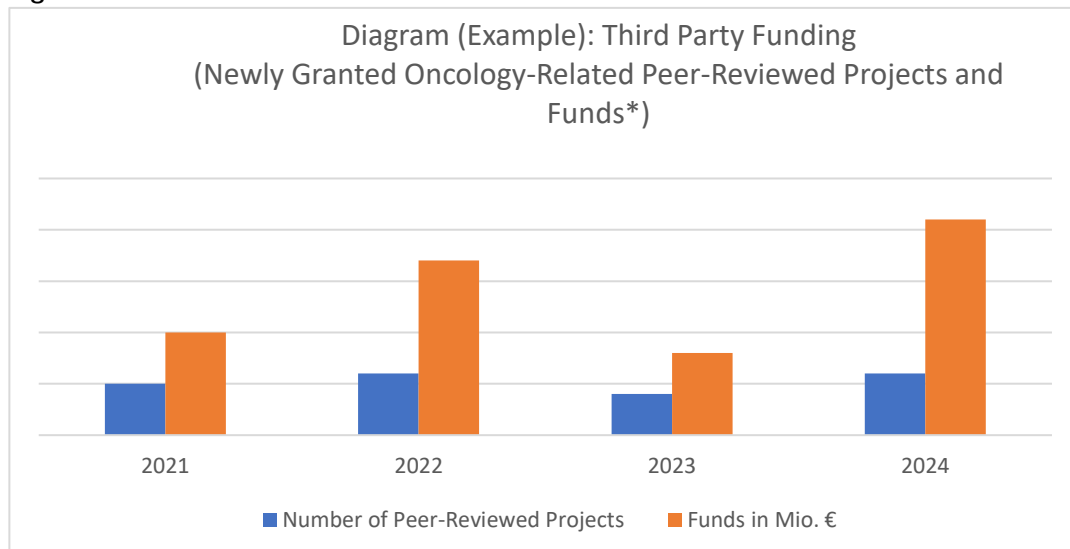
*In case of a CCC Consortium only

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

A.6 Third-Party Funding

Please present the development of the third-party funding of your CCC in the years 2021-2024 (number of newly granted projects and newly granted funds in Mio. € in the respective year) by using the following diagram:

Figure II.A.6



*Provide the total amount of funds in Euro (€) newly granted in the respective year (date of approval letter). In case of multicenter projects, please provide the amount of funds given to your center only. In case of Coordinated Programs (e.g. Collaborative Research Centers - 'Sonderforschungsbereiche') etc. which are not oncology-related as a whole, only sub-projects with a clear focus in oncology are relevant.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

B. Leadership and Organizational Structure

B.1 Cancer Center Director and Deputy Director(s):

Table II.B.1

Cancer Center Director and Deputy Director(s)		
CCC Director	Function (scientific and/or clinical appointment)	Fulltime or part time, % of working time designated to CCC
CCC Deputy Director(s)	Function (scientific or clinical appointment)	% of working time designated to CCC

In Section III.B.1 CV(s) of the Cancer Center Director and the Deputy Director(s) are requested. Please refer in the slide to this Section (incl. page number). Optional explanations are also possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

B.2 Overview of the Organizational Structure of the Cancer Center

Please provide a comprehensive organization chart of your center specifying the key structural elements/units of the cancer center, their functional duties/responsibilities, levels of authority, and interfaces/relationships including patient representatives and nurses as well as the center's external advisory board. In case of a CCC consortium, please specify also the governance and organizational structures of the consortium as a whole.

In Section III.B.2 additional information on the organizational structure of the cancer center is requested. Please refer in the slide to this Section (incl. page number). Optional explanations are also possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

C. Research Activity/Translational Oncology

A crucial aspect of this chapter is to demonstrate the ability of the center to contribute to practice changing developments which lead to more effective prevention, diagnosis, and treatment of cancer. It is important for a CCC to be active in all fields of oncological research (basic research, pre-clinical and clinical translation, late clinical research as well as outcomes research) reaching from prevention/early detection/diagnosis/therapeutic intervention to follow up.

Please list the most important research programs/main focuses at your center:

Table II.C

Top Cancer Research Programs/Main Research Focuses

Show concise information on a selection of the most relevant projects and corresponding publications and assign them to the above presented research programs. Please focus on projects which demonstrate the capability of bringing compounds/therapies, which were pre-clinically developed at your center/university to 'first-in-man' trials.

For the respective programs as well as for the individual presented projects/publications, please indicate to which field/category of oncological research they belong to (see page 17; e.g. basic research, clinical translation, outcomes research, prevention, early detection, therapeutic intervention ...).

Also provide information on how your center contributes to international collaborative research consortia.

Please note: projects focusing on prevention, early detection, survivorship and outcomes research are of importance and should therefore be presented.

In Section III.C, a list of the most relevant publications from the last 5 years (Table III.C) is requested. Please refer in the slide to this Section (incl. page number). Optional explanations are also possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

D. Research Infrastructure

D.1 Structures promoting interdisciplinary/translational research activities

Please provide information on the structures/mechanisms that have been implemented to promote interdisciplinary and translational research activities (e.g. interdisciplinary task forces, common programs, intramural grant programs etc.). Concentrate on the value added by the cancer center. In case of a CCC consortium, please indicate the measures to establish joint research programs and strategies.

Please also provide information on cooperations with extramural research institutions (e.g. Max Planck Institutes, Helmholtz Institutes) as well as possible cooperations with innovative technology partners beyond pharma industry if applicable.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

D.2 Innovative Technology Platforms

Graphical/tabular information on innovative technology platforms and services your CCC has access to (e.g. omics platforms, bioinformatics, AI).

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

D.3 Tumor-/biobank(s)

Note: The 'Requirements for a CCC Biobank' as listed in **Enclosure 2** must be fulfilled. 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 Faculty, fiscally responsible Administrative Director) referring to the above mentioned points (the statement can be included in Section IV.).

Please provide the following data:

Figure II.D.3.1

Total number of all cancer patients* whose specimens are stored in the Biobank in 2024**

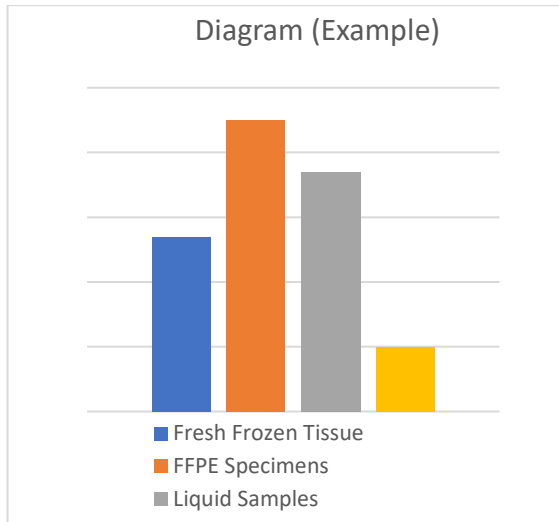
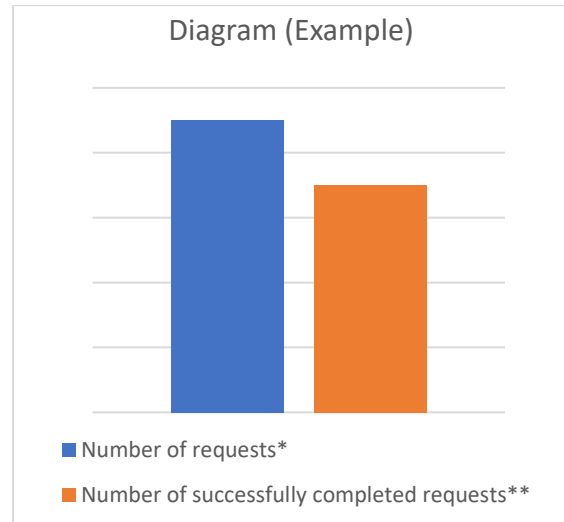


Figure II.D.3.2

Oncology-related requests to the biobank in 2024



*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.

**Reference date: December 31, 2024.

*Irrespective of the kind of biomaterial

**Include here only requests which were approved and which led to a supply of biomaterial.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

E. Access to Innovation (Molecular Diagnostics/Precision Medicine/Immunotherapy/Early Clinical Trials)

E.1 Innovative Diagnostics and Clinical Therapy Programs

Please provide the following information:

- Is there a dedicated precision oncology program at your center? If yes, show a graphical overview including the most important corresponding program-associated research projects (if applicable) and the crucial multidisciplinary structures e.g. Molecular Tumor Boards (MTB). Also present concisely which technologies/technology platforms for molecular diagnostics are used at your center (e.g. panel sequencing, whole exome sequencing etc.). If a dedicated precision oncology program is currently being established, please present the planned concept and the developments so far.

Table II.E.1.1:

Number of Cases/Patients in Precision Medicine in 2024	
	Number of Cases/Patients
Molecular diagnostics cases ¹ :	
Panels < 1 Mbp	
Panels ≥ 1 Mbp	
Whole Exome Sequencing	
Whole Genome Sequencing	
MTB discussions ²	
Thereof MTB discussions of external patients ³	
Thereof number of patients receiving therapeutic MTB recommendations ⁴	
Thereof number of patients treated according to therapeutic MTB recommendations ⁵	
Number of patients discussed in an MTB/lung tumor board at the CCC in the context of the nNGM ('National Network Genomic Medicine Lung Cancer')	

¹All patient-centered diagnostics (aiming at a patient-relevant intervention) conducted at the CCC.

Basic science-only analyses are excluded.

²Number of postdiagnostic patients (all patients discussed in MTB; no standard diagnostics, no nNGM patients as standard of care; do not include any patient more than once unless he/she has been treated for more than one malignancy in 2024).

³Number of postdiagnostic patients not primarily treated at the CCC (only true MTB cases – no standard diagnostics, no nNGM patients as standard of care; do not include any patient more than once unless he/she has been treated for more than one malignancy in 2024).

⁴Recommendations for a molecular therapy based on molecular diagnostics.

⁵Treatment within clinical trials as well as off-label treatment outside of trials.

- Is there a dedicated immunotherapy program at your center? If yes, show a graphical overview including the most important corresponding program-associated research projects (if applicable) and the crucial multidisciplinary structures and technological platforms. If a dedicated immunotherapy program is currently being established, please present the planned concept and the developments so far.

Table II.E.1.2:

Number of Patients in Immunotherapy Programs in 2024	
	Number of Patients
Immunotherapy within clinical trials ¹	
CAR T-cell therapy ²	

¹Number of patients treated with immunotherapeutic approaches in interventional clinical trials phase I-III.

²Number of patients receiving CAR T-cell therapy (in-label, off-label, clinical trials).

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

E.2 Early Clinical Trials

Please provide the following information:

- Summary of your early clinical trials activity ('first-in-man') by using the following table:

Table II.E.2.1:

Early Clinical Trials Activity				
	Number of early clinical trials open for patient enrolment in 2024		Number of patients newly enrolled in 2024*	
	Investigator Initiated	Industry Initiated	Investigator Initiated	Industry Initiated
Phase I, I/II**				
Thereof PI at the Center				

*Number of patients newly enrolled in 2024. A patient is considered to be newly enrolled in 2024, if he/she has signed the informed consent in 2024 and has actively participated in the trial. He/She may appear only once per trial protocol. A patient may appear more than once if he/she was on more than one trial protocol.

For explanations, see footnotes to Table II.F as well as **Enclosure 3.

- Development of the numbers of phase I, I/II-trials and of patient enrolment:

Figure II.E.2.2 Development of numbers of phase I, I/II-trials open for patient enrolment in the respective year (2021-2024)

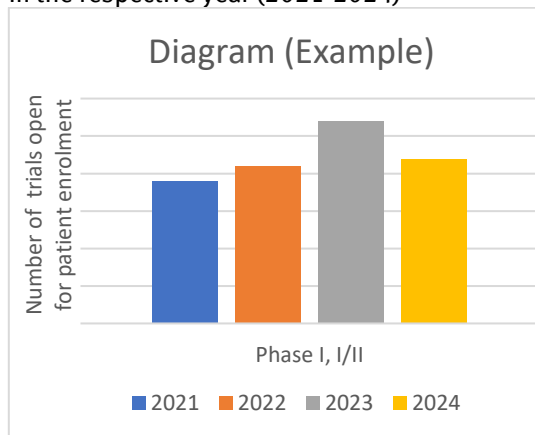
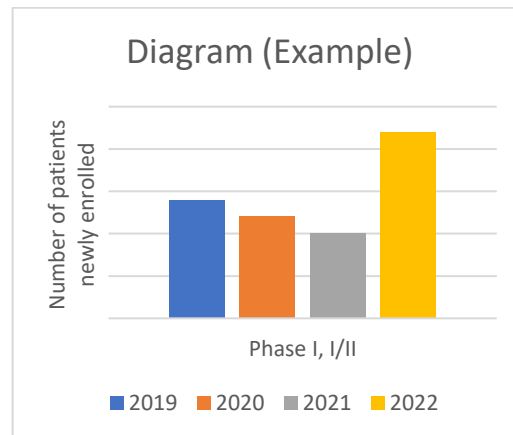


Figure II.E.2.3 Development of patient enrolment in phase I, I/II-trials from 2021-2024



Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

F. Clinical Trials Activity

Please provide information on the number of clinical trials and patient enrolment by using the following table:

Table II.F:

Number of Clinical Trials and Patient Enrolment					
	Number of open cancer trials ¹ in 2024		Number of Patients newly enrolled in cancer trials in 2024 ²		% of cancer patients newly enrolled in 2024 ³
	Investigator Initiated	Industry Initiated	Investigator Initiated	Industry Initiated	
<i>Medicinal Product Trials:</i>					
Phase I, I/II					
Phase II					
Phase III					
Phase IV					
<i>'Non-Medicinal Product Trials':</i>					
Surgery, Radiotherapy, Interventional Radiology, Nuclear Medicine					
Medical Devices					
Biomarker trials with direct therapeutic intention					
Supportive Care					
Screening/Diagnostic/Early Detection/Prevention					
Epidemiologic/Observational/Outcome/Observational Biomarker					

¹In case a trial fits in more than one category, it must only be counted once.

²A patient is considered to be newly enrolled in 2024, if he/she has signed the informed consent in 2024 and has actively participated in the trial. A patient may appear more than once if he/she was on more than one trial protocol. Please note, that numbers shown under 'Non-Medicinal Product Trials' may also include healthy volunteers e.g. in case of prevention or screening trials.

³Percentage of cancer patients newly enrolled in 2024 in relation to the total number of newly diagnosed cancer patients in 2024 (for definition of 'newly diagnosed cancer patients' see footnote to Table II.A.2.2).

Categories of Trials:

Medicinal Products ('AMG'):

- **Phase I, I/II:** Clinical trials on medicinal products for human use according to EU-regulation 536/2014, phase I and I/II. Interventional and minimal-interventional clinical trials can be included.
- **Phase II:** Clinical trials on medicinal products for human use according to EU-regulation 536/2014, phase II (including Phase II/III trials). Interventional and minimal-interventional clinical trials can be included.

- **Phase III:** Clinical trials on medicinal products for human use according to EU-regulation 536/2014, phase III (including Phase III/IV trials). Interventional and minimal-interventional clinical trials can be included.
 - **Phase IV:** Clinical trials according to EU-regulation 536/2014, phase IV (including non-interventional and clinical studies).
- 'Non-Medicinal Product Trials':
- Clinical trials (including studies, evaluations, investigations) within **surgery, radio-oncology, nuclear medicine, interventional radiology** etc. (not supportive care).
 - Clinical investigations and evaluations according to EU-regulation 745/2017 on **medical devices** (MDR).
 - Prospective trials of **complex biomarker analysis with intent to treat**, (i.e. based on biomarker presence which is tested in direct association to the respective therapeutic trial(s), the enrolment of potentially eligible patients is pre-planned). Trials to be counted require a vote of the responsible ethics committee as well as informed consents of the enrolled patients. Note: Biomarker trials being integral part of a therapeutic study protocol but with a separate informed consent may also be counted. The patients for both parts of the trial can be counted separately in the respective trial categories.
 - **Supportive Care Trials:** Interventional clinical trials intended to treat side effects or complications as well as to improve the comfort and quality of life for the patient using drugs, sports, nutritional, dietary, behavioral psycho-oncological or other interventions.
 - **Screening, Diagnostic, Early Detection, Prevention Trials:**
 - Clinical trials directly testing the efficacy of devices, techniques, procedures; or tests for earlier or more accurate detection or diagnosis of disease, including trials on in vitro diagnostic medical devices (IVDR) according to EU-regulation 746/2017
 - Clinical trials for the modulation of cancer risk and inhibition of cancer progression using chemoprevention drugs, nutritional, dietary, behavioral, or other interventions.
 - **Epidemiologic/Outcome Trials, Observational Trials (including Observational Biomarker Trials):**
 - Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.
 - 'Patient-Reported Outcome' studies.
 - Prospective studies which aim at the correlation of markers (from patient samples, imaging) with the prognosis of disease or at the impact of markers for pathogenesis (retrospective investigation of pathological material is excluded).

For determining the difference between investigator-initiated and industry-initiated trials see **Enclosure 3**.

Please note that only prospective studies with a scientific research question (defined study end point) - which require a vote of the responsible ethics committee - are accepted (e.g. marketing trials may not be counted).

Further explanation: To be counted as a prospective trial/study, the relevant data regarding the study end point has to be collected prospectively. A vote of the responsible ethics committee for the specific planned investigations must exist. The vote has to be issued after the formulation of the study protocol / patient information but before recruitment of patients or collection of data or biomaterial. If the analysis of biomaterial is part of the trial or is performed in the context of the trial, the study can be counted as prospective.

Please provide the URL or QR-Code for your Trials Registry.

In Section III.F a table on patient enrolment per tumor entities (Table III.F) is requested. Please refer in the slide(s) to this Section (incl. page number). Optional explanations are also possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

G. Clinical Trials Infrastructure

Please provide the following information:

- Structure of your clinical trials office dedicated to cancer.
- List the services, the clinical trials office offers (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).
- Present the mechanism to close poorly recruiting trials.
- In case of a CCC Consortium, please address 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.
- Present information on the early clinical trials unit (ECTU) by using the following table:

Table II.G

Early Clinical Trials Unit					
CCC Site*	ECTU**		Number of beds/ treatment chairs	Number of Employees (VTE) dedicated to the ECTU (differentiate in physicians, study nurses, others) in 2024	Number of Cancer Patients treated in the ECTU in 2024
	Dedicated ECTU for Oncology	Special beds in regular wards			

*In case of a CCC Consortium

**Yes/No

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

H. Regional Network/Outreach Activities

H.1 Outreach to Local Hospitals and Physicians

Please provide the following information:

- Present the measures the center takes to promote innovative developments in your regional network.
- Overview of existing stable cooperations/collaborations/partnerships of the cancer center with local and regional hospitals, office-based oncologists and general practitioners by using the following table:

Table II.H.1

Categories of Cooperation in the Regional Network	
	Number of cooperation partners ¹
Shared SOPs	
Consultations/second opinion	
Tumor Boards ²	
Staff with shared affiliation	
Joint clinical trials activities ³	
Tumor documentation ⁴	

¹Only cooperation partners who are providers of medical services (e.g. hospitals, physicians in private practice) in the regional network and with whom a formal cooperation agreement is in place.

²Types of cooperation (examples): joint Tumor Boards; external patients are discussed in the CCC's Tumor Boards; experts of the CCC participate in Tumor Boards of regional partners.

³For types of cooperation: see Chapter II.H.2.

⁴Types of cooperation (examples): joint clinical cancer registry/tumor documentation with regional partners; reporting of patient numbers/treatment data of regional partners to the CCC; use of the same tumor documentation system; cooperation regarding quality management of documentation/sharing documentation standards.

- Provide a map of your regional network showing your (most important) cooperation partners and assign the respective categories of cooperation (see above).

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

H.2 Regional Network for Cancer Trials

A regional trials network should encompass agreements for conducting joint trial activities, especially concerning patient recruitment and a publicly available cancer trials registry with patient-oriented search options. Such a registry should list all cancer trials in the regional network(s) of a CCC open for patient recruitment at any one time in order to ensure that up-to-date information is available for each patient.

Please provide the following information:

- Concise presentation of the measures used to ensure that each patient in the regional network(s) has access to suitable clinical trial options.
- Present a map showing the regional partners within the clinical trial network(s). This map should also indicate which categories of cooperation in the field of clinical trials are applicable for the respective partners, e.g.:
 - Joint patient recruitment policy
 - Agreements regarding joint/complementary trials and/or referrals for patient enrolment
 - Joint trials registry (open trials in the network)
 - Is patient recruitment of the regional partners reported to the CCC?
 - Services of the CCC (GCP training, flying study nurses etc.)
- Optional: If the respective data are available, please provide trial and enrolment numbers in the regional network by using the following table:

Table II.H.2.1

Cancer Trials in the regional network of the CCC (in 2024)			
Types of Prospective Trials ¹	Number of open trials in 2024 in the regional trials network(s) of the CCC ²	Number of cancer patients newly enrolled by the CCC in 2024 ^{3,5,6}	Number of cancer patients newly enrolled by network partners in 2024 ^{3,4,5}
Phase I-III			
Surgery, Radiotherapy, Interventional Radiology, Nuclear Medicine, Medical Devices			
All other prospective cancer trials			

¹For explanations, see footnotes to Table II.F

²List only trials which were open for patient recruitment in 2024 in your regional network(s) as presented in the map under H.2. When trials or trial-related procedures/treatments take place at more than one location, the trial must only be counted once.

³Patients treated within a trial that is conducted at the CCC as well as at regional partners must only be counted once.

⁴Trial-related procedures/treatments take place at the collaborating partner hospital/practice.

⁵Please note that numbers shown in column 2 and 3 are not restricted to patients but may also include healthy volunteers (e.g. in case of prevention or screening trials).

⁶Numbers can be extracted from table II.F

- Please present the development of trials activity in your regional network(s) from 2021 to 2024.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

I. Community Outreach

A Comprehensive Cancer Center must define the community or region that it serves and maintain productive outreach efforts like programs on promoting cancer prevention and early detection, on preventing cancer through community education or on encouraging behaviors that foster healthier lifestyles.

Please provide clearly arranged information on your community outreach programs including numbers of participants.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

J. Multidisciplinary Care

J.1 Multidisciplinary Structures

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 evidence-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 evidence-based standard operating procedures is expected. 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.

Furthermore, a CCC is expected to provide a considerable portfolio of activities/structures in the area of multidisciplinary care which goes beyond the requirements for the certification as an Oncology Center (e.g. best-practice and evidence-based diagnosis and treatment of rare tumors and complex oncological diseases, specialized consultations and specialized tumor boards, services for cancer survivors like survivorship care plans and consultations, etc.). A CCC should also offer non-standard services in oncology nursing like transitional care ('Brückenpflege') or oncology nursing consultation ('Pflegesprechstunde') etc.

Please provide the following information:

- Organogram/flowchart to show the current multidisciplinary structures of your CCC. Thereby you should make clear, how it is ensured, that patients with specific tumor entities not covered by the certification(s) of 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 include also information about the number of FTE positions of specialized oncology nurses, Advanced Practice Nurses (B.Sc, M.Sc.) as well as patient managers/patient navigators ('Lotsen') which support your cancer patients during diagnostics, treatment and after-care.
- Information on the tumor boards at your center by using the following table:

Table II.J.1

Tumor Boards		
Name of Tumor Board/ Scope	Frequency of meeting	Total Number of Tumor Board Recommendations in 2024*

*Provide the total number of Tumor Board (TB) recommendations in 2024 (a patient can appear more than once, if he/she had more than one TB discussion and received more than one recommendation).

- Information on the mechanism in your tumor boards identifying eligible patients for clinical trials.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

J.2 Central Building/Entry Portal

A central entry portal is an integral part of the core activities of a Comprehensive Cancer Center. Please provide the following information:

- Plan of the hospital/university campus indicating the building(s) in which core activities of the cancer center are conducted.
- If there is no central building and/or no central entry portal: Are there plans to establish these structures? Give brief information on how the center concentrates its core activities.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

K. Tumor Documentation/Clinical Cancer Registry and Information Technology

A CCC must have state-of-the-art information technology (IT) structures which support the whole spectrum of the center's activities from quality controlled multidisciplinary care to research by providing:

- clinical information system
- electronic medical patient-records
- local clinical cancer registry
- trials registry/access to information about clinical trials/study management
- tumor board documentation system
- electronic clinical pathways/care plans
- biobank IT system
- quality assurance/controlling
- data warehouse

In addition, integration of AI-based methods into patient care (including ethical, organizational, and technical readiness for the responsible and scalable adoption of internal and external AI solutions) is gaining increased importance for CCCs.

Please provide graphical presentations/flow charts addressing the following points:

- How are these systems interlinked with each other and linked to the hospital information system?
- If your center has already developed or is developing strategies for AI implementation for the patients' benefit, please present information.
- How are the cooperating partners within the regional network linked to your IT systems?
- In case of a CCC Consortium, please also refer on how the individual partner sites are interconnected regarding their IT systems.
- How does your center ensure interoperability with national initiatives/data networks (e.g. MII, DKTK, DNPM, nNGM), especially with regard to consent management, use/access regulations, data integration centers, CCP bridgehead infrastructure and pseudonymization.

Optional explanations are also possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

L. Palliative Care

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 guideline for palliative medicine of the German Guideline Program in Oncology ('S3-Leitlinie Palliativmedizin für Patienten mit einer nicht heilbaren Krebserkrankung') as well as of the 'Best Practice in Palliative Care' as worked out by the German CCC Network (**Enclosure 4**) is expected.

A CCC is expected to provide further programs/activities in the area of palliative care/medicine which go beyond the requirements for the certification as an Oncology Center (e.g. professorship for palliative medicine, research projects, innovative concepts in palliative care). In particular, a separate, closed-off palliative care unit at the Comprehensive Cancer Center (in case of a CCC consortium, at each site) must be in place and specialized palliative home care ('SAPV') for the patients must be ensured.

- **Please note:** A palliative care unit is a highly important component of the Comprehensive Cancer Center and should be located in the same building as the CCC, or at least within the same hospital complex in close proximity to the CCC. Please provide a plan of the hospital complex/university campus indicating the palliative care unit. If there is no palliative care unit at the CCC, are there plans to establish this structure on the hospital complex/university campus?

Please provide the following information:

- Table II.L

Palliative Care Structures at the Comprehensive Cancer Center*					
	Yes/No	Number of Beds**	Personnel, FTE (physicians, nurses, others)	Number of patients treated in 2024	Number of cancer patients treated in 2024
Palliative Care Unit***					
Multiprofessional Palliative Care Service***					
Palliative Outpatient Care Clinic ***					
Specialized Palliative Home Care (SAPV)***					
Chair for Palliative Medicine					

*In case of a CCC consortium, please indicate for each CCC site.

**Exclusively for patients with a need for palliative care

***As defined in **Enclosure 4**

- As well as the filled-in table, also present information on your research activities and innovative concepts in palliative care/medicine.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

M. Psychosocial Care/Self-Help Groups

The criteria for supportive care requested within the 'National Cancer Certification Program' ('Erhebungsbogen für Onkologische Spitzenzentren und Onkologische Zentren', Section 1.4-1.6), must be fulfilled. The implementation of the

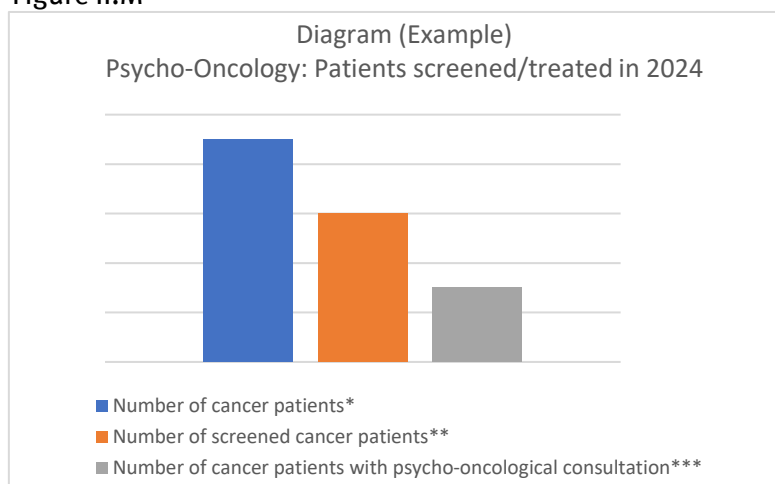
- German guideline for Psycho-Oncology of the German Guideline Program in Oncology ('S3-Leitlinie Psychoonkologische Diagnostik, Beratung und Behandlung von erwachsenen Krebspatient*innen'),
- 'Best Practice for Psycho-Oncological Screening in Comprehensive Cancer Centers' (**Enclosure 5a**) and
- 'Best Practice for Psycho-Oncological Care in Comprehensive Cancer Centers' (**Enclosure 5b**)

are expected. Furthermore, a CCC is expected to provide programs/activities in the area of psychosocial oncology which go beyond the requirements for the certification as an Oncology Center (e.g. research projects, survivorship programs, innovative psycho-oncological concepts).

Wherever available, the support by patient organizations and self-help groups must be implemented in patient care. Information about possible support from self-help groups must be made available to each patient immediately after a cancer diagnosis. This should be included in SOPs and accordingly implemented in patient care.

Please provide the following information:

- Figure II.M



* Total newly diagnosed + patients with recurrence and metastasis (Total from Table II.A.2.2)

** Number of patients screened for psychological distress

*** Number of cancer patients who had at least one consultation with a psycho-oncologist (face-to-face consultations by psycho-oncologists who are qualified in accordance with the Best Practice Psycho-oncological Care guidelines; minimum 25 min.)

In addition to the information in the figure, also please provide the following information:

- Clearly arranged information on structure and activities in psycho-oncology (personnel FTE, research projects, survivorship programs, innovative psycho-oncological concepts).
- Clearly arranged information on social support/reintegration services of your center that go beyond the requirements of the certification as an Oncology Center.
- Graphical presentation how patient organizations and self-help groups are integrated/supported at your center.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

N. Patient Engagement/Involvement

Structured patient participation is an important feature of a Comprehensive Cancer Center. Patient representatives have to be involved in boards/committees responsible for the conceptual design and assessment of patient care. In addition, there is growing importance of involvement of patient representatives in research projects/clinical trials. Providing training opportunities for patient representatives to enable them to adequately fulfil their diverse tasks is recommended. Furthermore, a patient advisory board should be in place. Implementation of a patient coordinator position fulfilling a linking role between the professional members of the center and the patient representatives is recommended.

Please provide a graphical presentation how patient involvement is already implemented or is planned to be implemented at your center. If applicable, please show examples how your center has implemented patient engagement in research.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

O. Training Programs

A CCC is expected to have activities/programs for multidisciplinary training of physicians, physician scientists, scientists, nurses and related professions of the cancer center as well as for staff of the regional network.

Please provide information on the Center's training programs by using the following table:

Table II.O

Training program*	Number of successful participants of the CCC in 2024	Number of successful participants of regional partners in 2024
Examples: Programs for MD, PhD, physicians, undergraduate, oncology nursing, academic nursing, study nurses etc.		
...		

*Please list only programs where the cancer center is involved. Do not refer to 'standard' or 'routine' education/training. In case of a CCC-consortium please highlight joint programs.

Optional explanations are possible in Section III. If you take advantage of this, please refer in the slide(s) to Section III (chapter, page No.).

Section III.: Further Information

For selected funding criteria you are requested to present in this section a few pre-defined Tables/Figures. Additionally, you have the opportunity here to present further in-depth information of the data presented in the central slide set (Section II). In each case, please refer to the corresponding slide.

Wherever possible, use tables, lists or figures, charts or diagrams and avoid extensive prose text.

A. Basic Information/Size of the Center

A.1 Catchment Area

Additional explanations/information can be given (optional).

A.2 Size of the Center / Patient Numbers

Table III.A.2

Number of Patients in 2024 per anatomic cancer site (detailed list of anatomic cancer sites according to the 'National Cancer Certification Program')		
	Newly diagnosed ¹	Newly diagnosed + patients with recurrence and metastasis ²
<i>Tumor Entities covered by a certification within the 'National Cancer Certification Program'³</i>		
Colorectal		
Anal Cancer		
Pancreas		
Gastric		
Liver/Biliary Tract		
Oesophagus		
Other gastrointestinal tumors (neuroendocrine tumors of the gastrointestinal tract, tumors of the small intestine)		
Endocrine malignancies (incl. thyroid, adrenal gland, paraganglia, pituitary gland, parathyroid, neuroendocrine tumors)		
Haematological systemic disease:		
Leukemias		
Lymphomas		
Multiple Myeloma		
Others		
Breast		
Gynaecological tumors (cervix, uterus, ovaries incl. BOT, vulva, vaginal tumors, STIC)		
Skin (invasive malignant melanoma)		
Prostate		

Penis		
Testicles		
Kidney		
Urinary bladder		
Sarcoma (incl. GIST)		
Head/neck tumors (upper aerodigestive tract, oral cavity, throat, larynx, salivary glands)		
Neuro-oncological tumors		
Lung		
Mesothelioma		
Pediatric Tumors (Patients < 18 y.)		
<i>Tumor Entities not covered by a certification within the 'National Cancer Certification Program'⁴</i>		
Others		
thereof Entity Y (optional)		
TOTAL		

¹Newly diagnosed: Patients with initial diagnosis treated at the center. Please list here the 'Primary Cases' according to the definition as in 'National Cancer Certification Program'.

²Newly diagnosed + patients with recurrence and metastasis. Please list here the 'Centre Cases' according to the definition as in 'National Cancer Certification Program' (primary cases + patients with (locoregional) recurrence + patients with secondary distant metastasis). In contrast to the National Cancer Certification Program, 'Centre Cases' can also be listed for Hematological systemic disease.

³Encompasses all entities, that may be certifiable within the 'National Cancer Certification Program' independent of whether a center is certified for all of these possible entities.

⁴Tumor Entities not covered by a certification within the 'National Cancer Certification Program': Please show here (rare) tumor entities for which your cancer center has specific competence which are not certifiable within the 'National Cancer Certification Program'.

Additional explanations/information can be given (optional).

A.3 Fields of Specific Competence in Oncology

Additional explanations/information can be given (optional).

A.4 Participation in national or CCC-Network wide Initiatives

Additional explanations/information can be given (optional).

A.5 Local Funding of the CCC

Additional explanations/information can be given (optional).

A.6 Third-Party Funding

Additional explanations/information can be given (optional).

B. Leadership and Organizational Structure

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

Please provide CV(s) with photo, research focus, and the most important publications (max. 10) of the Cancer Center Director and the Deputy Director(s).

Additional explanations/information can be given (optional).

B.2 Overview of the Organizational Structure of the Cancer Center

If your center is part of initiatives with comparable or similar goals in the fields of translational/clinical research like the extended National Center for Tumor Diseases (NCT) and/or the German Cancer Consortium (DKTK): how does your CCC integrate such activities?

Additional explanations/information can be given (optional).

C. Research Activity/Translational Oncology

Table III.C

List of the most relevant peer-reviewed oncology-related publications from the last 5 years			
Nr.	Citation	Current Impact Factor	Field/Category of Research
Research Program 1: Title			
1.	First author (et al.), year, journal, volume, page		e.g. Basic Research
2.			e.g. Clinical Translation, Therapeutic Intervention
3.			e.g. Outcomes Research, Follow up
...			
Research Program 2: Title			
...			
Research Program X: Title			
...			

List the most relevant peer-reviewed oncology-related publications from the last 5 years resulting from the most important research programs of the cancer center (**altogether max. 25; max. 35 for CCC Consortia**). Please cite in chronological order (recent first). Only published or accepted manuscripts may be cited within the list; manuscripts at any other stage (e.g. planned, submitted, under revision, conditionally accepted, forthcoming, etc.) will not be acknowledged. In case of a CCC Consortium, please **highlight joint publications** of consortium partners.

Additional explanations/information can be given (optional).

D. Research Infrastructure

D.1 Structures promoting interdisciplinary/translational research activities

Additional explanations/information can be given (optional).

D.2 Innovative Technology Platforms

Additional explanations/information can be given (optional).

D.3 Tumor-/biobank(s)

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

Additional explanations/information can be given (optional).

E. Access to Innovation (Molecular Diagnostics/Precision Medicine/Immunotherapy/Early Clinical Trials)

E.1 Innovative Diagnostics and Clinical Therapy Programs

Additional explanations/information can be given (optional).

E.2 Early Clinical Trials

Additional explanations/information can be given (optional).

F. Clinical Trials Activity

Table III.F

Number of cancer patients newly enrolled ¹ in prospective clinical cancer trials (in 2024) per anatomic cancer sites										
Tumor Entity/ Anatomic Cancer Site	Medicinal Product Trials				Non-Medicinal Product Trials					
	Phase I, I/II	Phase II	Phase III	Phase IV	Surgery, Radiotherapy, Interventional Radiology, Nuclear Medicine	Medical Devices	Biomarker trials with direct therapeutic intention	Supportive Care	Screening/ Diagnostic/ Early Detection/ Prevention	Epidemiologic/ Observational/ Outcome/ Observational Biomarker
<i>Tumor Entities covered by a certification within the 'National Cancer Certification Program'²</i>										
Colorectal										
Anal Cancer										
Pancreas										
Gastric										
Liver/Biliary Tract										
Oesophagus										
Other gastrointestinal tumors (neuroendocrine tumors of the gastrointestinal tract, tumors of the small intestine)										
Endocrine malignancies (incl. thyroid, adrenal gland, paraganglia, pituitary gland, parathyroid, neuroendocrine tumors)										
<i>Haematological systemic disease</i>										
Leukemias										
Lymphomas										
Multiple Myeloma										
Others										
Breast										
Gynaecological tumors (cervix, uterus, ovaries incl. BOT, vulva, vaginal tumors, STIC)										
Skin (invasive malignant melanoma)										
Prostate										

Penis										
Testicles										
Kidney										
Urinary bladder										
Sarcoma (incl. GIST)										
Head/neck tumors (upper aerodigestive tract, oral cavity, throat, larynx, salivary glands)										
Neuro-oncological tumors										
Lung										
Mesothelioma										
Pediatric Tumors (Patients < 18 y.)										
<i>Tumor Entities not covered by a certification within the 'National Cancer Certification Program'^{1,3}</i>										
Entity I										
Entity II										
...										
<i>Multiple Entities⁴</i>										
TOTAL										

¹A patient is considered to be newly enrolled in 2024, if he/she has signed the informed consent in 2024 and has actively participated in the trial. A patient can only be counted once, unless he/she was on more than one trial protocol. Please note, that numbers shown under 'Non-Medicinal Product Trials' may also include healthy volunteers e.g. in case of prevention or screening trials.

²Encompasses all entities, that may be certifiable within the 'National Cancer Certification Program' independent of whether a center is certified for all of these possible entities.

³Tumor Entities not covered by a certification within the 'National Cancer Certification Program': Please show here (rare) tumor entities for which your cancer center has specific competence which are not certifiable within the 'National Cancer Certification Program'.

⁴Multiple entities: patients who were recruited in 'multiple entity trials', where a differentiation into specific entities is not possible, can be included here. All tumor entities can be included whether they are covered by a certification within the 'National Cancer Certification Program or not.

Categories of Trials:

Medicinal Products ('AMG'):

- **Phase I, I/II:** Clinical trials on medicinal products for human use according to EU-regulation 536/2014, phase I and I/II. Interventional and minimal-interventional clinical trials can be included.
- **Phase II:** Clinical trials on medicinal products for human use according to EU-regulation 536/2014, phase II (including Phase II/III trials). Interventional and minimal-interventional clinical trials can be included.
- **Phase III:** Clinical trials on medicinal products for human use according to EU-regulation 536/2014, phase III (including Phase III/IV trials). Interventional and minimal-interventional clinical trials can be included.
- **Phase IV:** Clinical trials according to EU-regulation 536/2014, phase IV (including non-interventional and clinical studies).

'Non-Medicinal Product Trials':

- Clinical trials (including studies, evaluations, investigations) within **surgery, radio-oncology, nuclear medicine, interventional radiology** etc. (not supportive care).
- Clinical investigations and evaluations according to EU-regulation 745/2017 on **medical devices** (MDR).

- Prospective trials of **complex biomarker analysis with intent to treat**, (i.e. based on biomarker presence which is tested in direct association to the respective therapeutic trial(s), the enrolment of potentially eligible patients is pre-planned). Trials to be counted require a vote of the responsible ethics committee as well as informed consents of the enrolled patients. Note: Biomarker trials being integral part of a therapeutic study protocol but with a separate informed consent may also be counted. The patients for both parts of the trial can be counted separately in the respective trial categories.
- **Supportive Care Trials:** Interventional clinical trials intended to treat side effects or complications as well as to improve the comfort and quality of life for the patient using drugs, sports, nutritional, dietary, behavioral psycho-oncological or other interventions.
- **Screening, Diagnostic, Early Detection, Prevention Trials:**
 - Clinical trials directly testing the efficacy of devices, techniques, procedures; or tests for earlier or more accurate detection or diagnosis of disease, including trials on in vitro diagnostic medical devices (IVDR) according to EU-regulation 746/2017.
 - Clinical trials for the modulation of cancer risk and inhibition of cancer progression using chemoprevention drugs, nutritional, dietary, behavioral, or other interventions.
- **Epidemiologic/Outcome Trials, Observational Trials (including Observational Biomarker Trials):**
 - Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.
 - 'Patient-Reported Outcome' studies.
 - Prospective studies which aim at the correlation of markers (from patient samples, imaging) with the prognosis of disease or at the impact of markers for pathogenesis (retrospective investigation of pathological material is excluded).

Please note that only prospective studies with a scientific research question (defined study end point) - which require a vote of the responsible ethics committee - are accepted (e.g. marketing trials may not be counted).

Further explanation: To be counted as a prospective trial/study, the relevant data regarding the study end point has to be collected prospectively. A vote of the responsible ethics committee for the specific planned investigations must exist. The vote has to be issued after the formulation of the study protocol/patient information but before recruitment of patients or collection of data or biomaterial. If the analysis of biomaterial is part of the trial or is performed in the context of the trial, the study can be counted as prospective.

Additional explanations/information can be given (optional).

G. Clinical Trials Infrastructure

Additional explanations/information can be given (optional).

H. Regional Network/Outreach Activities

H.1 Outreach to Local Hospitals and Physicians

Additional explanations/information can be given (optional).

H.2 Regional Network for Cancer Trials

Additional explanations/information can be given (optional).

I. Community Outreach

Additional explanations/information can be given (optional).

J. Multidisciplinary Care

J.1 Multidisciplinary Care

Additional explanations/information can be given (optional).

J.2 Central Building/Entry Portal

Additional explanations/information can be given (optional).

K. Tumor Documentation/Clinical Cancer Registry and Information Technology

Additional explanations/information can be given (optional).

L. Palliative Care

Additional explanations/information can be given (optional).

M. Psychosocial Care/Self-Help Groups

Additional explanations/information can be given (optional).

N. Patient Engagement/Involvement

Additional explanations/information can be given (optional).

O. Training Programs

Additional explanations/information can be given (optional).

Section IV.: Formal Documents

This section will be checked by the Offices of the Deutsche Krebshilfe and will not be forwarded to the reviewers. Therefore, please provide a separate file containing the following documents.

1. Requested Funding

Provide the table from Section I.3 together with 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.

2. Oncology Center Certificate

Copy of your current Oncology Center Certificate (in case of a CCC Consortium, please provide the certificate for each CCC site)

3. Bylaws

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

4. Statements of Support

Statements of support by department and institute directors participating in the Cancer Center.

5. Declaration

Please disclose 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'.

6. Data Privacy Statement

Please add the signed Data Privacy Statement (**Enclosure 6**: 'Hinweise zur Verarbeitung Ihrer personenbezogenen Daten').

7. Miscellaneous

Here you can provide further documents, if applicable.

Final Note:

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.

Enclosure 1

Counting of Patients in Surgical Oncology on the Basis of OPS Codes

Surgical Therapy	OPS Codes
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 2024.

*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

Integration of palliative care into CCCs funded by the German Cancer Aid

Best Practice Recommendations (<i>Update 2025</i>)
Timing of Palliative Care integration
Patients within a CCC shall be offered palliative care immediately after receiving a diagnosis of an incurable cancer, regardless of whether they are receiving tumor-specific therapy.
Palliative care unit
A palliative care unit is an essential requirement at a CCC to ensure a high quality of care for tumor patients.
A palliative care unit shall be an organizationally and structurally distinct, independent unit.
A palliative care unit shall have 8 to 12 beds.
Palliative care specialists shall be available for CCC patients 24 hours a day, 7 days a week.
Inpatient palliative care consultation team
A multiprofessional inpatient palliative care consultation team is a necessary component of a CCC and shall be available. Its purpose is to provide advice and support to tumor patients being cared for in other departments and their relatives.
A multiprofessional inpatient palliative care consultation team at a CCC shall consist of at least three staff members and should incorporate professionals from medicine, nursing, and at least one other profession providing treatment to patients. The team shall be available during typical working hours.
Information on the availability of the inpatient palliative care consultation team shall be accessible in all departments.
Outpatient clinic and day services
In addition to existing palliative care structures, the CCC shall offer outpatient palliative care consultations. This service should be offered at least twice a week by appointment only.
Patients shall also have access to specialist palliative care as part of the day-care services offered by all specialist departments treating tumor patients.
Oncologists should inform patients and family caregivers about the possibility to include palliative care specialists during consultation hours when required or helpful.
Information on palliative care shall be clearly displayed in the waiting area of outpatient departments that treat tumor patients.
Regional Networks
Specialized outpatient palliative care (SAPV) shall be provided either in-house or in collaboration with regional and supra-regional providers of SAPV.

In the case of an external cooperation with a SAPV service, a written cooperation agreement shall be in place.
A CCC shall ensure cooperation with a hospice.
For CCC patients with incurable cancer, hospice support shall be provided by qualified volunteers.
Involvement of specialist palliative care (SPC) in decision-making processes within a CCC
The CCC's steering committees shall include specialists in palliative medicine to promote interdisciplinary cooperation.
Advance directives and powers of attorney (previously 'Documentation')
Regardless of the stage of the patient's disease, doctor-patient consultation shall include questions about whether a health care proxy and / or a living will have been drawn up.
The existence of a health care proxy and / or living will shall be recorded centrally in electronic form and made available to all co-treating professionals in the CCC.
Treatment pathways for patients at the end of life
The CCC shall have a policy for ensuring the quality of the care provided to patients in their dying phase.
A treatment pathway for dealing with end-of-life situations should include the following elements: steps for assessing the situation of seriously ill patients in a multi-professional team, documentation of decision-making, an information brochure for relatives, and instructions to be followed after death.
Research
To promote interdisciplinary research projects in a CCC, specialist palliative care shall be incorporated into the CCC's research structures.
The palliative care department's research output should be subject to regular evaluation.
Teaching
Each CCC shall have a policy for supporting and promoting research and teaching in the field of palliative care; this should include a chair for palliative care.
Each CCC shall provide a range of lectures and classes in palliative care, which should be subject to annual evaluation.
Continuing professional development (CPD) and training
Each CCC shall have a CPD policy which enables members of all professions involved in patients' treatment to gain a basic qualification in general palliative care.
Emergency department staff should receive invitations to attend in-house training on the care and counseling of patients with incurable diseases. This has the purpose of raising staff awareness of decisions pertaining to palliative care or intensive care.
Tumor boards
Within a CCC, the need for specialist palliative care (SPC) should be documented when registering with the tumor board, and these patients should then be represented by specialists on the tumor board.

Primary care
The CCC shall systematically inform GP practices and involve them in care planning at the start of specialized inpatient care and prior to discharge into specialized outpatient palliative care (SAPV).
General practitioners of all patients with incurable cancers, shall be informed upon their discharge about aspects of their case with relevance to palliative care, such as the aims of their treatment and any advance directives that are in place. Appropriate ways of conveying this information might include a discharge letter, transfer sheet, or handover telephone call.
Policies for ensuring the quality of support for family caregivers
Each CCC shall have a policy for ensuring the quality of the support for family caregivers of patients with incurable cancers.
<p>These policies should include the following aspects:</p> <ul style="list-style-type: none"> - Structured assessment of the burdens and needs of family caregivers during the course of the disease, - Provision and mediation of support services to family caregivers, - Provision of information materials, e.g. on support services for relatives, disease-specific materials, palliative and hospice care, services for the grieving.
Family caregivers: Assessment of burden and support needs
Relatives of patients with incurable cancer should have their stress levels and support needs assessed throughout the course of the illness. This includes concerns experienced by children and adolescents in this role.
For relatives of patients with incurable cancer, standardized self-assessment questionnaires for relatives (such as CARE-Pal*) should be used in addition to personal interviews to assess stress levels and support needs.
Family caregivers of patients with incurable cancer shall receive support from the patient's treatment team in accordance with their needs. Multiprofessional teams incorporating professionals from the fields of specialist palliative care, psycho-oncology, specialist nursing, social work, case management, spiritual and pastoral care, outpatient hospice services, etc., shall provide specific support as required. Children and young people should be offered easily accessible, age-specific and age-appropriate support.
Providing information to family caregivers and involving them in care
Family caregivers of patients with incurable cancer shall receive information on palliative care and on support services for family caregivers, regardless of whether the patient is receiving tumor-specific therapy.
Where the patient consents to this, family caregivers of patients with incurable cancer shall receive information on treatment decisions and the planning of treatment and care and should be able to participate actively in doctor-patient conversations. Digital means of communication should be used for this purpose where necessary and appropriate.
Integration of palliative care in basic oncological screening procedures
<p>Screening to identify a need for SPC shall be a component of the oncological screening of patients with incurable and progressive disease.</p> <p>The primary criterion or the integration of SPC shall be the stress situation of the patient. The stress experienced by relatives can also be a criterion. A limited life expectancy due to illness alone is not a sufficient criterion for the integration of SPC.</p>
Patients with a potentially curable disease may also require specialist palliative care.

Screening: creating and managing internal processes
Oncologists and specialist palliative care professionals in CCCs shall agree on and implement a central CCC-wide process for identifying patients with a need for SPC.
This process should encompass:
a) ...criteria for identifying which patients should receive screening for SPC needs and the points during the course of disease at which screening should take place.
b) ... the selection of a screening tool, e.g., based on the toolbox** or the Standard Operating Procedure (SOP) for Oncological Basic Screening***, including the definition of specific criteria (cut-off) for further in-depth assessment by the specialist palliative care team.
c) ...determining which professionals will assume responsibility for the conduction and analysis of the screening and the in-depth assessment of patients whose initial screening is positive, and for taking decisions on whether specialist palliative care should become part of the patient's care.
d) ...alternative screening approaches in case the selected screening tool is not applicable to all patients (for example, the patient is unable to complete a self-report questionnaire).
Choice of screening tools
Patient-reported outcome measures (PROMs; patient questionnaires), scores/lists of criteria completed by healthcare professionals, and/or routine data may serve as potential screening tools.
CCCs shall choose a screening tool that <ul style="list-style-type: none"> - is able to ascertain the patient's needs and the burden affecting them - has been validated for the identification of SPC needs, meaning that criteria for the interpretation of results (such as cut-offs) are available - meets the general standards for test criteria in medicine (reliability, objectivity, etc.).
In-depth assessment for patients whose initial screening is positive
For patients who test positive in the screening, an in-depth assessment by specialist palliative care services shall clarify the extent of the burden and the need for palliative care. Regardless of this decision, general palliative care shall continue.
Palliative care specialists shall conduct the in-depth assessment of patients with incurable cancer.
The assessment shall take place in dialogue with patients and/or family caregivers.
The assessing professionals shall seek to acquire additional information with the specific purpose of identifying remits and responsibilities for the patient's care; such information might include details of the causes and progression of symptom burden and distress or of support/treatment already in place.
Referral decisions on responsibility shall take account of local conditions and circumstances, such as the resources available in specialist and general oncological palliative care.

*Ullrich, A., Bergelt, C., Marx, G., Daubmann, A., Benze, G., Heine, J., Dickel, Lisa-Marie ... Oechsle, K. (2024). The CAREPAL-8: a short screening tool for multidimensional family caregiver burden in palliative care. *BMC Palliative Care*, 23(1), doi: <https://doi.org/10.1186/s12904-024-01480-w>

**Müller, E., Gahr, S., Schnabel, A., Müller, M. J., Sölder, P., Tewes, M., Roch, C. (2024). Screening auf Bedarf an spezialisierter Palliativversorgung. *Die Onkologie*, 1-7, doi: <https://doi.org/10.1007/s00761-024-01574-3>

***<https://www.onkozert.de/informationen-zertifizierung/hinweise-downloads/onkologisches-basiscreening/>

Enclosure 5a

Best Practice: Psycho-Oncological Screening at Comprehensive Cancer Centers (CCC)

Working Group Psycho-oncology within the network of Oncology Centers of Excellence

INTRODUCTION

One of the oncological care goals of German health policy, as agreed in the National Cancer Plan, is that patients with cancer receive appropriate psycho-oncological care when needed. Distress screening is one of the tools used to achieve this.

RECOMMENDATIONS

1. Suitable screening methods
 - 1.1 Based on the S3 guideline on psycho-oncology [1], the following screening methods are recommended, among others:
 - Distress Thermometer (DT) [2]
 - Questionnaire on the stress of patients with cancer (QSC) [3]
 - Hospital Anxiety and Depression Scale (HADS) [4]
 - Patient Health Questionnaire (PHQ) [5,6].Information on the quality criteria and evidence for individual instruments can be found in the S3 guideline.
 - 1.2 The desire for psycho-oncological support should be regularly assessed during screening. The following wording can be used, for example:
 - Would you like psychological/psycho-oncological support during your stay at our clinic/center?
 - Would you like to contact the psycho-oncological service regardless of your stress levels?
 - Would you like to take the opportunity for a psychosocial consultation?
2. Timing of screening
 - 2.1 All patients shall be screened for psychosocial distress at the time of diagnosis of an oncological disease. Furthermore, they shall be asked whether they would like psycho-oncological support.
 - 2.2 Screening should be repeated regularly, especially in the event of changes in the disease situation and changes in the treatment concept, such as the transition from curative to palliative treatment.
3. Responsibilities for distress screening
 - 3.1 The primary care unit, i.e. the specialist clinic (e.g. outpatient clinic, ward), is responsible for determining psychosocial distress (distress screening) and the desire for psycho-oncological support.
 - 3.2 Each care unit (e.g. outpatient clinic, ward) appoints a person responsible for organizing the screening and a deputy (e.g. specialist oncology nurse, case manager).

4. Conducting the distress screening
 - 4.1 The screening can be carried out either electronically or in written form (paper-pencil).
 - 4.2 The person conducting the screening at the specialist clinic explains the purpose of the distress screening to the patient, and hands over the screening documents or electronic device and collect them again. Patients also have the option of not providing any information.
 - 4.3 The indication for psycho-oncological care of the patient is given if the determined threshold value is reached or exceeded (\geq) in the screening procedure used and/or the patient expresses a desire for psycho-oncological support.
 - 4.4 If the indication is given, contact is established with the psycho-oncological service of the CCC. This request can be made automatically or initiated by medical professionals or, after referral, by other professional groups (e.g. nursing staff).
5. Responsibilities for documentation
 - 5.1 The person conducting the distress screening shall document the issuance and return of the screening forms/tablets in a suitable location.
 - 5.2 The result of the screening (value obtained and preference) has to be documented by the responsible person in the hospital information system (HIS). Screenings that cannot be performed (e.g. due to patient characteristics) and the patient's refusal to undergo screening have to be documented as well.
6. Variables for clinical documentation
 - 6.1 The relevant screening results, such as the date of the screening, screening value, cut-off exceeded yes/no, request for support yes/no, consultation request yes/no (if this is not done automatically), are recorded in the HIS by the person performing the screening in the specialist unit on a patient-specific basis.
7. Hardware requirements for documentation
 - 7.1 Computer-based distress screening requires the programming or purchase of software and hardware for conducting the surveys (e.g. tablet computers). Software from an external provider can usually only be integrated into a hospital's IT structure with considerable effort, meaning that both sides have to allocate resources for programming interfaces. The necessary interfaces are: I) provision of patient data from the HIS, II) storage of the screening findings in the digital patient file, and III) notification of the psycho-oncological service in the event of supra-threshold screening results and/or at the patient's request.
 - 7.2 When conducting paper-based screening and documenting the screening results, it has to be noted that in this case, the person in charge of the screening is not only responsible for issuing the screening documents, ensuring prompt and reliable returns, and evaluating, interpreting and entering the data, but also, where necessary, for initiating psycho-oncological treatment so that adequate care can be provided.

8. Regular evaluations and reports

8.1 Depending on the intended use, reports on the number of patients screened can cover different time periods.

8.2.1 An annual summary of the data must be compiled for annual reports and in preparation for the OnkoZert audit. Any fluctuations that become apparent can and shall be interpreted over the course of the year.

8.2.2 Quarterly reports serve as feedback to the departments in which screening is used.

8.2.3 Monthly reports are useful for internal controlling and provide information about any need for readjustment by the group of people responsible for screening.

8.3 The reports include key figures that refer to a defined period and defined treatment units (e.g. an organ cancer center, the entire CCC or the respective location). In addition to absolute frequencies, relative frequencies should also be reported for key figures. These refer to:

- Number of patients with oncological treated,
- Number of patients who underwent distress screening,
- Number of patients who reached or exceeded the cut-off point of the screening procedure used for clinically significant psycho-oncological impairment,
- Number of patients who expressed a desire for psycho-oncological support in the distress screening.

CONCLUSION

Psycho-oncological care for patients with cancer is now standard practice in multi-professional, high-quality, patient-oriented cancer medicine. An essential part of this is screening for psychosocial distress as a prerequisite for evidence-based psycho-oncological care.

Original Publication (in German):

Stengel et al.: Best Practice - psychoonkologisches Screening an Comprehensive Cancer Centers. Forum, 2021. **36**: p. 278–283. (<https://doi.org/10.1007/s12312-021-00944-x>)

Enclosure 5b

Best Practice: Recommendations for Psycho-Oncological Care in a Comprehensive Cancer Center (CCC) funded by the German Cancer Aid

Working Group Psycho-Oncology within the Network of Oncology Centers of Excellence

INTRODUCTION

A best practice (BP) recommendation for conducting and implementing distress screening at Comprehensive Cancer Centers (CCCs) in Germany was published by this working group [1]. This paper now expands on this initial recommendation with a statement on psycho-oncological care at CCCs in Germany, which was developed in a multi-stage process. Requirements for needs-based, high-quality psycho-oncological care during the various phases of the disease are outlined and structural requirements are clarified.

RECOMMENDATIONS

Statement 1: Psycho-oncology should be implemented as a functional area with an independent operating concept (financial plan, organizational structure, room plan, processes/SOPs, interfaces and cooperation structures with the specialist disciplines involved in patient care). [87.5% agreement, consensus]

Statement 2: As basic quality criterion, if there is an indication for co-treatment, it should be documented whether and how often contact with the psycho-oncological service has taken place – ideally with specification of the duration. [96.8% agreement, strong consensus]

Statement 3: Psycho-oncological care should be provided on an interdisciplinary, multi-professional and cross-sectoral basis. [96.8% agreement, strong consensus]

Statement 4: Psycho-oncological services should be easily accessible and local (outreach) – also using digital support. [96.8% agreement, strong consensus]

Statement 5: Psycho-oncological services should be aimed at patients and their relatives and should also include services for treatment teams. [96.8% agreement, strong consensus]

Statement 6: Psycho-oncological interventions shall be offered in all sectors of care and phases of the disease. [100.0% agreement, strong consensus]

Statement 7: Conventional face-to-face services can be supported and expanded by eHealth interventions, where appropriate and desired by patients. [93.6% agreement, consensus]

Statement 8: In order to further develop psycho-oncological care, novel, innovative treatment and care approaches shall be developed, empirically tested and presented to the public. [100.0% agreement, strong consensus]

Statement 9: The quality of outcomes in psycho-oncological care should be assessed continuously, multidimensionally and across sectors. [100.0% agreement, strong consensus]

Statement 10: Patients who have been screened as mentally distressed and/or express a desire for psycho-oncological support shall receive a support offer from the psycho-oncological service. [100% agreement, strong consensus]

CONCLUSION

Evidence-based psycho-oncological care requires a high level of quality in terms of structure, process and results.

Original Publication (in German):

Dinkel et al.: Best Practice: Empfehlungen zur psychoonkologischen Versorgung in einem von der Deutschen Krebshilfe geförderten Comprehensive Cancer Center. Forum, 2024. 39: 294–301. ([https:// doi.org/ 10.1007/ s12312- 024- 01351-8](https://doi.org/10.1007/s12312-024-01351-8))

Enclosure 6

Data Privacy Statement ('Hinweise zur Verarbeitung Ihrer personenbezogenen Daten')

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Im Rahmen der Antragsbearbeitung verarbeiten wir Ihre Daten nach Artikel 5 und Artikel 6 Abs. 1 (a, f); Abs. 4 DSGVO. Dabei handelt es sich zum Beispiel um:

- Vorname, Name akademischer Grad, Geburtsdatum
- Vollständige Bezeichnung der Institution
- Postanschrift
- Telefon- und Faxnummer, E-Mail-Adresse usw.

Wir möchten Sie ausdrücklich darauf hinweisen, dass Ihre personenbezogenen Daten für wissenschaftliche und historische Forschungszwecke oder für statistische Zwecke gespeichert werden. Außerdem werden Ihre Unterlagen an externe Gutachterinnen und Gutachter zur Prüfung weitergeleitet. Um eine mögliche Doppelförderung auszuschließen, behält sich die Stiftung Deutsche Krebshilfe das Recht vor, Anfragen an andere Fördereinrichtungen unter Angabe der Namen der Antragstellenden und des Projekttitels zu stellen. Weiterhin möchten wir Sie darüber informieren, dass wir über bewilligte Förderprojekte sowohl in unserem Jahresbericht als auch auf unserer Homepage Auskunft geben werden. Hierfür ist es wichtig, dass Sie uns am Ende dieses Merkblattes mit Ihrer Unterschrift auch Ihre Einwilligung bekunden. (DSGVO Art. 6 Abs. 1 und Abs. 4; BDSG § 49). Wir möchten Sie ebenfalls auf Ihr Widerspruchsrecht hinweisen gemäß DSGVO Art. 21 Abs. 4 und Abs. 6.

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Ort, Datum

Unterschriften der Antragstellenden

Enclosure 7

Guidelines for the Creation of Maps displaying the Catchment Area of the CCC

Patients to be counted for the creation of the maps mentioned below (Figures II.A.1.1, II.A.1.2, II.A.1.3) are defined as follows:

Number of all cancer patients in 2024 matching one of the following criteria: reported to the state clinical cancer registry, follow up, second opinion, tumor board, trials participation. Each patient may only be counted once per year.

In the case of CCC Consortia, data do not have to be broken down into numbers for the individual CCC sites.

- Figure II.A.1.1 Population density in Germany

Map of Germany showing the population density in inhabitants per square kilometer (based on postal code areas).

Diese Karte wird von der Deutschen Krebshilfe zur Verfügung gestellt (bitte setzen Sie sich hierfür mit der Geschäftsstelle der Deutschen Krebshilfe in Verbindung; Kontakt: siehe Seite 54).

- Figure II.A.1.2: Patient's Place of Residence (Wohnorte der Patienten)

Map of Germany showing the catchment area of the center, colored by the range of numbers of the patients cared for at the center (bases on postal code areas). Each color represents 25 % of the patients.

Shape-Dateien zur Darstellung des Bundesgebietes, der Bundesländer und der Postleitzahlengebiete können bei der Deutschen Krebshilfe angefragt werden (bitte setzen Sie sich hierfür mit der Geschäftsstelle der Deutschen Krebshilfe in Verbindung; Kontakt: siehe Seite 60).

Anleitung zur Erstellung der Karte:

Die Karte (Figure II.A.1.2) beinhaltet die Grenzen der Bundesrepublik Deutschland, der einzelnen Bundesländer sowie die Grenzen der Postleitzahlengebiete (letztere mit Linienstärke 0). Die Postleitzahlengebiete werden absteigend nach der Summe aller Patienten (Köpfe) pro Postleitzahlengebiet sortiert.

Die Patientenzahlen der absteigend sortierten PLZ-Gebiete werden so lange aufsummiert, bis $\frac{1}{4}$ der zu zählenden Patienten (Definition siehe oben) erreicht ist, beginnend mit dem PLZ Gebiet, mit den meisten Patienten. Dieses PLZ-Gebiet werden mit der vorgegebenen Farbe #F9422F (Hex Code) hinterlegt. Analog wird mit jedem weiteren Viertel der CCC-Patienten verfahren. Die für die jeweiligen Viertel zu verwendende Farben sind in der nachfolgenden Tabelle aufgeführt.

Bitte fügen Sie Figure II.A.1.2 eine Legende mit den vorgegebenen Farben (siehe folgende Tabelle) und der jeweils zugehörigen 'Range of Patient Numbers' bei.

Farbe (Hex Code)	Range of Patient Numbers (Beispiel)
#F9422F	90-150
#8F87CB	30-89
#80D0F0	6-29
#D5D5D5	1-5

- Figure II.A.1.3: Proportion of Coverage (Versorgungsanteil)

Map of Germany colored by the number of patients cared for at the center in relation to a population of 100,000 inhabitants (based on postal code areas).

Eine Tabelle mit den Einwohnern pro Postleitzahlengebiet (basierend auf Zensus 2011) wird für die Erstellung von Figure II.A.1.3 benötigt und von der Deutschen Krebshilfe zur Verfügung gestellt (bitte setzen Sie sich hierfür mit der Geschäftsstelle der Deutschen Krebshilfe in Verbindung; Kontakt: siehe Seite 60).

Anleitung zur Erstellung der Karte:

Basierend auf den Patienten (Köpfe) pro 100,000 Einwohner des jeweiligen Postleitzahlengebietes* werden die zugehörigen Postleitzahlengebiete in der Karte entsprechend vorgegebener Patientenzahlenbereiche ('Range of Patients') eingefärbt.

*Berechnung:
$$\frac{\text{Anzahl der Patienten} \times 100\,000}{\text{Anzahl der Einwohner des PLZ-Gebiets}}$$

Bitte fügen Sie Figure II.A.1.3 eine Legende mit den vorgegebenen Farben unter Angabe der vorgegebenen 'Range of Patient Numbers/100,000 Inhabitants' bei.

Farbe (Hex-Code)	Range of Patient Numbers/100,000 Inhabitants (bitte bei der Deutschen Krebshilfe anfragen)
#012AD9	
#4467FE	
#90A5FE	
#E5EAFF	

Datenschutzrechtliche Aspekte sind zu berücksichtigen.

Note:

You have the opportunity to use a software tool which has been developed in the context of the 'ONConnect' joint application of the CCC network. The development of the tool was also supported by members of the Working Group 'Digital Oncology' of the CCC network. Prerequisite is, that you prepare a list of patient numbers per postal code area. Then, data import and processing/calculation is performed locally at your center by using the above-mentioned software tool. If you wish to use the software, please contact the offices of the Deutsche Krebshilfe (contact information: see page 60).

CONTACT

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