Comprehensive Cancer Care Networks (CCCNs)

Standard for Colorectal and Pancreatic Cancer Care Networks

Developed in the context of iPAAC from the working group of Work Package 10

Prologue

This standard sets out the requirements to be met by Comprehensive Cancer Care Networks (CCCN) which will be piloted in the scope of the Joint Action “Innovative Partnership Action Against Cancer” financed by the European Commission.

This document summarizes the tumour-specific requirements for colorectal and pancreatic care within a Comprehensive Cancer Care Networks

The document is to be used in conjunction with the “Supporting Document Standard for CCCN”

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Valid from 01 January 2021

This Set of Standards (SoS) is binding for all peer reviews from 1 January 2021. All changes to the previously applicable versions of this Set of Standards are marked in yellow.

Information on the CCCN

Network's area of application:

☐ Colorectal

☐ Pancreas

Clinical site (clinic/place) _____

Director of the Centre _____

Centre Coordinator _____

Network/Main cooperation partners

The Network's cooperation partners are registered in a master data sheet.

Preparation / Update

The data on outcome quality refer to the calendar year. ☐

Preparation/update date of the document ☐

Table of Contents

Legend: "black" relevant for all organs
"pink "only relevant for "colorectal"
"red" only relevant for "pancreas"
"grey" chapters which are not relevant for specific tumour entity. NB: all tumour entities have the same table of content; not all chapters are relevant for all tumour entities

1. General information on the Centre

1.1 Network structure

Section	Requirements	Explanatory remarks of the Centre
1.1.1 - All -	The names of the persons holding the following positions are to be given: • Director of the Centre (max. 2 directors/Centre, of whom 1 named contact) • Centre Coordinator Centre Coordinator – tasks • Coordination internal/external audits • Monitoring of Technical and Medical Requirements and ensuring compliance with them • Communication interface • Steering/monitoring of cross-specialty activities	
1.1.2 - All -	Main cooperation partners and cooperation partners can be part of a clinic or also be independent practices. Main cooperation partners Visceral surgery, gastroenterology, radiotherapy, medical oncologist, pathology, radiology Cooperation partners Psycho-oncology, social work, stoma-therapy (only colorectal), nutritional counselling, physiotherapy, genetics, pain therapy and self-help group, palliative medicine, diabetology (only pancreas)	
1.1.3 - All -	Cooperation agreements A cooperation agreement is to be entered into with cooperating treatment partners. Documentation must be provided that they meet the appropriate Technical and Medical Requirements of the Standard (not every service provider has to be a cooperation partner as well). The cooperation partners are to be listed. If the cooperation partners of a Centre work under a funding body or at a clinic location, written agreements are not necessary (nonetheless the implementation of the following points must be ensured). The following points are to be regulated: • Competences and responsibilities • Description of the treatment processes of relevance for the Centre bearing in mind the interfaces • Obligation to implement indicated Guidelines • Description of cooperation on tumour documentation	

1. General information on the Centre

1.1 Network structure

Section	Requirements	Explanatory remarks of the Centre
	• Declaration of willingness to cooperate on internal/external audits • Undertaking to comply with the criteria of the set of Standards and the annual submission of the relevant data • Upholding of medical confidentiality • Participation in specialty training programmes and public relations work • Declaration of consent to be publicly identified as part of the Centre (e.g. homepage)	
- All -	Tumour Board/conference (only to the extent that participation is required under "1.2 Interdisciplinary cooperation") • Binding participation • Ensuring availability of specialist for the specialty to which binding participation applies • Participation and consensus provisions in the case of more than 1 cooperation partner for each specialty (see also provisions "Interdisciplinary cooperation")	
1.1.4 - All -	Presentation of the Centre The overall structure of the Centre is to be presented and made public (e.g. Internet). This also encompasses giving the names of all internal/external cooperation partners with the following details: - Name, address of cooperation partner - Cooperation partner with tel./email	
1.1.5 - All -	Strategy planning/Reporting It is recommended to conduct an annual review on the management level in which the following aspects, for instance, are examined: • Goal definition/assessment, where appropriate new orientation of goals • Consideration of audit results (internal/external) • Human resources for Centre management (Centre Coordinator) • Public relations work/Patient information • Tumour documentation/Outcome quality	
1.1.6 - All -	Further/additional training • A qualification plan for the cooperation partners as described in 1.1.1 is to be submitted in which the qualification measures planned for the coming year are described. • At least 1 unit of colorectal and pancreatic cancer care network specific further/additional training per staff member (duration > 0.5 days), to the extent that the staff	

1. General information on the Centre

1.1 Network structure

Section	Requirements	Explanatory remarks of the Centre
	member performs tasks relevant to the quality of the tumour specific network	
1.1.7 - All -	On-the-job training concept The process of familiarising new members of staff must follow a specified on-the-job training concept	
1.1.8 - All -	Accessibility/obligation to be on call A specialist in radiation therapy and urology must be present during working hours and have 24/7 on-call duty outside of working hours (including weekends and holidays), if necessary via cooperation	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	

1.2 Multidisciplinary cooperation

Section	Requirements	Explanatory remarks of the Centre
1.2.1 - Colorectal -	The Centre should manage at least 100 colorectal cancer cases a year (primary colorectal cancer, locally advanced or recurrent disease, metastatic disease) The Centre must operate • 30 patients annually with a primary diagnosis of colon carcinomas (ICD-10 C18,19,20,) • 20 patients annually with a primary diagnosis of rectal carcinomas (ICD-10 C25)	
- Pancreas -	The Centre must treat 25 patients annually with a primary diagnosis of pancreatic cancer (ICD-10 C 25). Definition: • Patients and not visits/stays at the CCCN or surgical procedures are to be counted • Adenocarcinomas, neuroendocrine carcinomas are counted. IPMNs (intraductal	

	papillary mucinous neoplasms) are not counted. • Histological/cytological findings must be available (biopsy or resection) from primary tumour or metastasis with concomitant presence of a pancreatic tumour in medical imaging. • Patients with initial disease • The time of counting is the time of the histological confirmation of diagnosis • Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not included.	
1.2.2 - All -	Cycle/Participants tumour board A tumour conference must be held at least once a week. For the following specialties participation by specialists in the tumour board is mandatory: • Visceral surgery • Gastro-enterology • Radiotherapy • Medical oncologist • Pathology • Radiology Metastases: In the case of organ metastases, a surgeon with the corresponding specialisation and specific expertise is to be consulted. Depending on the indication, other participants (nursing, palliative medicine, psycho-oncology, etc.) are to be invited.	
1.2.3 - All -	General requirements tumour board Several cooperation partners If several cooperation partners are named for a specialty, then the presence of one representative is sufficient as long as the formalised exchange of information between the partners is in place (e.g. via quality circles). Independently thereof, each cooperation partner must take part in the tumour board at least once a month. Web/online tumour board If web tumour boards are used, it must be possible to transmit the sound and documents presented. It must be possible for each main cooperation partner to present its own documents/imaging material. Telephone tumour boards with no imaging material are not an option.	
1.2.4	Recurrence/metastasis	

- Colo-rectal -	• Surgical responsibilities for metastasis resection are to be laid down (in particular liver, lung) where appropriate by means of cooperation. • Therapeutic approaches (curative and palliative) for metastasis surgery and radiotherapy (e.g. stereotactic irradiation of brain tumours) are to be laid down in the descriptions of the procedures. • Patients with primary unresectable liver metastasis should be regularly presented during systemic therapy for evaluation in the tumour board.	
1.2.5 - All -	Demonstration imaging material Patient-related imaging material must be available at the board and suitable technical equipment must be provided for the presentation of this material.	
1.2.6 - All -	Preparation tumour board • The main patient and treatment data are to be compiled in writing beforehand and made available to the participants at the board. A pre-appraisal of suitable study patients is to be undertaken. • All patients with recurrences and/or metastases, who have entrusted the Centre with their care, are to be presented.	
1.2.7 - All -	Minutes of the tumour board • The results of the tumour board consist, *inter alia*, of a written, interdisciplinary treatment plan ("Minutes tumour board"). • The minutes of the tumour board must be available at all times in a secure manner to all main cooperation partners and can, at the same time, constitute the medical report. • The "minutes of the tumour board" should be automatically generated from the tumour documentation system. • The outcome of the tumour board is to be recorded in the tumour documentation system.	
1.2.8 - All -	Participation tumour board as further training For the following functions/professional groups, participation in the tumour board is to be made possible: • Assistant staff (Medical Technical Assistan (MTA), Medical Technical Radiology Assistan (MTRA), etc. ...) from the fields of radiology and radiotherapy • Staff members social services and psycho-oncology • Specialist oncology nurse and at least 2 nurses for each treatment unit • Participation in the tumour board is recognised as further training for the aforementioned functions/professional groups.	

1.2.9 - All -	Therapy deviation • The therapeutic procedure should be oriented towards the treatment plans or recommendations of the tumour board. • If any deviations from the original therapy plan or deviations from the Guidelines are observed, they must be recorded and evaluated. Depending on the cause, avoidance measures are to be taken. • If therapy is not started or terminated prematurely at the patient's request (despite an existing indication), this must also be recorded.	
1.2.10 - All -	Morbidity/mortality (MM) conference • The conference can be staged on the same date as the tumour conference. • A list of participants is kept. • Conferences are to be held at least twice a year. • Cases with a special course of the disease or a course that needs to be improved are to be discussed. Patients who died post-surgery/post-intervention must definitely be discussed. • Minutes are to be taken of conferences.	
1.2.11 - All -	Quality circles • Tasks, circle of participants and contents of the quality circles are to be laid down. • Conferences are to be held at least three times a year. • A list of participants is kept. • The quality circles must produce clear results (actions, decisions) which seem likely to bring about a major further development of/improvement in the Centre. • The outcome of the quality circles is to be recorded. Possible topics: • Analysis of outcome quality (benchmarking) • Interdisciplinary further training • Interdisciplinary case reviews • Structural improvements to the Centre • Public relations At the time of initial certification one quality circle must have taken place.	
1.2.12 - All -	Further training • Further training events are to be offered for the network of the Oncology Centre at least twice a year (where appropriate also after the MM conferences/quality circles). (Topics could be for example: presentation of new guideline recommendations, new surgery techniques and so on)	

	• Contents/results and participation are to be recorded. A further training plan is to be presented.	
1.2.13 - All -	Events of the Centre Each main cooperation partner must participate in at least two of the Centre's events. The following are recognised: • Quality circles • Morbidity/mortality conference • Further training	
1.2.14	Treatment plan/minutes of the tumour board • In principle, therapeutic procedures should be in accordance to the treatment plans and/or recommendations by the tumour board. Any deviations from the recommended therapy plan must be presented to the tumour board and must be documented in the patient´s record.	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	

1.3	Cooperation referrers and aftercare	
Section	Requirements	Explanatory remarks of the Centre
1.3.1 - All -	Referrer satisfaction survey • Every three years a referrer satisfaction survey must be conducted. The results of this survey are to be evaluated and analysed. A cross-department survey can be recognised. • The referrer satisfaction survey must be available for the first time for the first surveillance audit	*See also 1.3 SoS CCCN*

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	

1.4	Psycho-oncology	
Section	Requirements	Explanatory remarks of the Centre
1.4.1 - All -	Psycho-oncology A psycho-oncologist is available for the Centre	*See also 1.4 SoS CCCN*

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	

1.5	Social work and rehabilitation	
Section	Requirements	Explanatory remarks of the Centre
1.5.1 - All -	Social services A social worker is available for the Centre	*See also 1.5 SoS CCCN*

Self-		Yes	

As-sess-ment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Mostly	
		Partially	
		No	
		Not applicable	

1.6	**Patient participation and empowerment**	
Sec-tion	Requirements	Explanatory remarks of the Centre
1.6.1 - All -	Patient surveys: A concept for a patient survey must be developed	
1.6.2 - All -	Patient information (general) Patient information must be provided. Including information and presentation of the CCCN with all cooperation partners and treatment options	
1.6.3 - All -	Discharge consultation: Each patient is given a discharge consultation (short documentation/check list) in which at least the following topics are addressed: • Therapy planning • Individual aftercare plan (where appropriate handing over of an aftercare pass) Oncology nurse specialist should be present and confirm if the patient has all relevant information and that the after-care plan is assured	
- Pan-creas -	• Information on possible secondary diseases (e.g. diabetes) and the related risks (e.g. hy-poglycaemias)	
1.6.4 - All -	Patient information (case-related): The patient is given the following documents: • Medical report / discharge letter (including details tumour conference / treatment plan) • Aftercare plan / aftercare pass • where applicable, study documents It is recommended that patients are given a cen-tral /structured folder for the documents. The pro-cedure for the provision of patient information is to be standardised.	
1.6.5 - All -	Complaint management A regular system of complaint management must be in place.	
1.6.6 - All -	Self-help groups/patient support groups The self-help groups/patient support groups, with which the CCCN actively cooperates, are to be named. If possible, the self-help group/patient support groups should consider the specific needs of visceral oncology patients (keyword - affected by the same condition).	

1.6	Patient participation and empowerment	
Section	Requirements	Explanatory remarks of the Centre
	• Written agreements are to be entered with the self-help groups. These agreements should be updated at least every 5 years and should encompass the following points: • Access to self-help groups at all stages of treatment (first diagnosis, hospitalisation, chemotherapy, after-care…) • Announcement of contact data of self-help groups e.g. in-patient brochure, website) • Possibility to display information brochures of the self-help groups • Regular provision of premises at the CCCN for patient consultations • Quality circle with participation of representatives from psycho-oncology, self-help groups, social services, spiritual counselling, nursing care and medicine. • Personal discussions between self-help groups and the CCCN for the purposes of jointly staging or coordinating actions and events. The results of the discussions are to be documented. • Participation of all medical staff in events of the self-help group	
1.6.7 - All -	Self-help groups The self-help groups, with which the CCCN actively cooperates, are to be named.	•
1.6.8 - All -	Information/dialogue with patient: Adequate information must be provided about diagnosis and therapy planning and a dialogue is to be entered into. This includes *inter alia*: • Presentation of alternative treatment concepts • Offer of and aid in obtaining second opinions • Discharge consultation as a standard procedure A general description is to be given of the way in which information is provided and the dialogue organised. This is to be documented for each patient in medical reports and minutes/records.	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	

1.7	Research and Clinical Trials	
Sec-tion	Requirements	Explanatory remarks of the Centre
1.7.1 - All -	Access to studies It must be possible for patients to access studies. The studies conducted at the Centre must be listed and published, for instance on the Centre's homepage (including short description of the study).	*See also 1.7 SoS CCCN*
1.7.2 - All -	Proportion of study patients at least 5% of primary cases Only the introduction of patients into studies with a positive vote of the ethics committee is counted as study participation	

Self-As-sess-ment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	

List of the studies

List of studies - colon/rectum [1)]

Responsible cooperation partner [2)]	Name of the study	Centre patients Recruited in 2020 [3)]
Numerator Indicator No. 6 "Study rate"		

List of studies - pancreas [1)]

Responsible cooperation partner [2)]	Name of the study	Centre patients Recruited in 2020 [3)]
Numerator Indicator No. 6 "Study rate"		

1) The list of studies must be processed. It is not possible to refer to the Standard of the CCCN document.
2) Responsible cooperation partners: Study unit/specialty unit running the study (e.g. department for radio-oncology, joint haematology/oncology practice Dr. Smith; …) Designation cooperation partners identical to details on www.oncomap.de, if listed
3) Only those study patients can be counted who are listed as Centre patients in the Centre and were included in the study in 2020 (no double counting of study patients in more than 1 Centre).

1.8 Nursing care		
Section	Requirements	Explanatory remarks of the Centre
1.8.1 - All -	Specialised oncological nurses At least one active oncological nurse must be involved at the Centre.	*See also 1.8 SoS CCCN*
1.8.2 - Colorectal -	Stoma therapy Staff • Qualifications of management in stoma therapy • Availability of qualified stand-ins must be ensured • Members of staff have to be named • If stoma therapy services are provided externally, a cooperation agreement must be concluded.	
1.8.3 - Colorectal -	Stomatherapy – Definition of tasks • Pre-inpatient or pre-operative and post-inpatient instructions, counselling and training of patients and their relatives. • Participation in pre-operative marking (or regulated exchange of experience) • Where appropriate, holding of stoma consulting hours	
1.8.4 - Colorectal -	Stomatherapy – Equipment / infrastructure • Own premises • Possibilities presentation of demonstration material • Storage opportunities for material for stoma care • the infrastructure where the stoma consultation takes place should have a room with private toilet and mirror	
1.8.5 - Colorectal -	Stomatherapy – Exchange surgery • Regulated information for surgeon particularly in the case of infections, need for surgical corrections, ...)	
1.8.6 - Colorectal -	Stomatherapy – documentation of therapy • Documentation in inpatient patient record (documents of the stoma therapists alone not sufficient) • Stoma pass for patients	
1.8.7 - Colorectal -	Stoma-therapy – follow-up Further care after discharge is to be described including provision of information for patients. Follow-up after surgery should be performed in these intervals: 1 week / 2 weeks / 1 month/ 3 month / 6 month / every year	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice.	Yes	
		Mostly	

	• Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Partially	
		No	
		Not applicable	

1.9 General service areas

Section	Requirements	Explanatory remarks of the Centre
1.9.1 - All -	Pastoral care • Pastoral care in the Centre is to be ensured • Patients must be given the option of care (need is to be actively identified)	
1.9.2 - All -	Nutritional counselling • Nutritional counselling must be a component of the Colorectal and Pancreatic Network services	
1.9.3 - All –	Pharmaceutical care qualification Qualified clinical pharmacist	
1.9.4 - All -	Offer and access If required, the pharmacist is to provide doctors, nursing staff and patients with information and advice (proof required).	
1.9.5 - All -	Pharmacy – task profile Objectives and tasks of pharmaceutical care and support: • Daily centralised quality-assured production of the active ingredients needed for intravenous tumour therapy • Monitoring of stability and compatibility of therapy regimens • Plausibility analysis of dosage taking into account individual patient laboratory parameters, liver and kidney function and drug interaction with concomitant medication • Support for risk assessment, staff instruction, decontamination, extravasation and disposal of cytostatic drugs • Correct reception, storage, production or preparation, distribution and disposal of the experimental drugs • Giving of information and advice to doctors, nursing staff and patients by pharmacist if necessary	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice.	Yes	
		Mostly	

	• Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Partially	
		No	
		Not applicable	

2. Organ-specific diagnostics
2.1 Consultations

Section	Requirements	Explanatory remarks of the Centre
2.1.1 - All -	Special consulting hours colorectal/pancreatic At least 1 per week	
2.1.2 - All -	Waiting times special consulting hours • < 2 weeks waiting time for a consulting hours appointment • < 60 minute waiting time during consulting hours	
2.1.3 - Colorectal -	Clarification tumour dignity 100% clarification dignity already prior to radical surgical procedure (Reasons for deviations are to be given)	
2.1.4 - Colorectal -	Spread diagnosis Within one week the following tests must be undertaken: • Abdominal ultrasound • X-ray (lung) • CEA test If necessary (again within 1 week) • Other x-ray examinations • CT/MRI; PET-CT (optional) • Scintigraphy • Urological examination • Gynaecological examination	
2.1.5 - Colorectal -	Qualification rectum diagnosis Details expertise per treatment unit for: • Rectal endosonography • Rigid rectoscopy • Chromoendoscopy • Proctology	
2.1.6 - Colorectal -	Stenosis In the case of a non-passable coloscopic stenosis, a renewed full coloscopy must be undertaken post-operatively for 100% of all patients within 3-6 months. The unit responsible for performing (monitoring appointments) the coloscopy must be clearly defined.	
2.1.7	Prevention / screening for asymptomatic population	

2. Organ-specific diagnostics
2.1 Consultations

Section	Requirements	Explanatory remarks of the Centre
- Colorectal -	• External or in-house programmes for counselling risk groups, lifestyle and nutritional recommendations (information events, information material...) • Activities to increase attendance of coloscopy check-ups and FOBT	
2.1.8 - Colorectal -	Genetic counselling Cooperation with genetic counselling is to be regulated in a cooperation agreement. Cooperation must be proven by way of documented cases during the current assessment period.	
2.1.9 - Colorectal -	Identification and procedure for risk groups (familial and elevated risk) Risk persons are to be identified and documented when recording their medical history on admission. They have the following characteristics in particular: • age < 50 years • prior colorectal carcinoma or endometrial carcinoma • one or more colorectal carcinomas in close family members • Endometrial urothelial, small intestine or gastric carcinoma in close family members	•
- Colorectal -	The algorithms for the genetic diagnostic procedure and molecular-pathological clarification in the case of suspected HNPCC and medical history sheets for the identification of risk persons to clarify the familial and hereditary risk and an information letter about elevated risk of disease onset and recommended early detection tests for close family members can be downloaded on http://www.krebsgesellschaft.de/deutsche-krebsgesellschaft-wtrl/deutsche-krebsgesellschaft/zertifizierung/erhebungsboegen/organkrebszentren.html in the section colorectal cancer.	
- Pancreas -	Spread diagnosis / diagnostic confirmation Within one week the following tests must be undertaken: • Abdominal ultrasound • Endosonography upper gastrointestinal tract (Proof of competence: at least 30 endosonographies/examining physician/year) • Endoscopic ultrasound fine needle biopsy in the abdomen (not only pancreas punctures required) (Proof of competence: at least 10/ examining physician/year) • Multidetector CT • MRI with MRCP	

2. Organ-specific diagnostics
2.1 Consultations

Sec-tion	Requirements	Explanatory remarks of the Centre
	• Interventional ERCP (Proof of competence: at least 50/examining physician/year) • X-ray (lung)	
	If necessary (again within 1 week): • Other X-ray examinations • CT/MRI; PET-CT (optional) • Scintigraphy	

Self-As-sess-ment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	

2.2 Diagnostics

Sec-tion	Requirements	Explanatory remarks of the Centre
2.2.1 - Colo-rectal -	Qualification of coloscopy diagnosticians • Specialist for internal medicine and gastroen-terology or surgery	
- Colo-rectal -	At least 2 specialists (in the practice-based sector 1 specialist with corresponding cross-over staff provision) • The names of the specialists are to be given. Experience examining physician: • Coloscopies: 200 patients annually Polypec-tomies: 50 patients annually	•
- Colo-rectal -	Authorisation of new examining physicians in the last 3 years at least 200 coloscopies and 50 poly-pectomies.	
- Colo-rectal -	Each coloscopy and polypectomy is to be per-formed / supervised by an examining physician who has the above-mentioned experience.	
2.2.2 - Colo-rectal -	Performance coloscopy • Signed declared consent • Patient monitoring Pulse oxymetry Documentation using surveillance sheet after examination with sedation • Photo documentation Completeness of the examination	

2.2 Diagnostics

Section	Requirements	Explanatory remarks of the Centre
	(ileocecal valve, cecal pole, terminal ileum) Polyp removal points (before - after) • Aftercare recommendation Timing control coloscopy	
- Colorectal -	• Complication rate therapeutic Coloscopies • Full elective coloscopies	
2.2.3 - Colorectal -	Requirements coloscopy • Full coloscopy with biopsy of each suspected spot including a rectal examination	
2.2.4 - Colorectal -	Outpatient polyp removal • Possibilities of stypsis • Recording of complications • Procedure for handing over non-removable polyps in office-based practices to the inpatient departments of the Centre. - Names of contacts - Definition passing on of information	
2.2.5 - Colorectal -	Pathology report for adenoma • Distinction between low-grade versus high-grade intraepithelial neoplasms • Details of completeness of removal Pathology report for carcinoma in adenoma • Scale of in-depth infiltration (sm-/pT category) • Degree of histological differentiation (grading) • Presence or lack of lymph vessel invasion (L classification) • Evaluation of resection margins (R classification) • Low-risk/high-risk classification	
2.2.6 - Colorectal -	Presentation in the tumour conference Each carcinoma in the adenoma must be presented in the tumour conference.	
2.2.7 - Colorectal -	Communication of results polypectomy In-person discussion/information about malignant findings (not on the phone) by coloscopy unit	
2.2.8 - Colorectal -	Infrastructure/work environment • Emergency equipment Available emergency equipment and written action plan for emergencies • Preparation, sterilisation and traceability of instruments	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice.	Yes	
		Mostly	

	• Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Partially	
		No	
		Not applicable	

Experience examining physician colorectal - coloscopies/polypectomies

Coloscopy unit (practice/clinic department)	Title, name, first name	Centre [1] from … to	Number coloscopies ≥ 200 patients a year	Number poly-pectomies ≥ 50 patients a year

1) Period normally the previous calendar year (=indicator year); deviations e.g. in staff fluctuation, appointment of examining physicians for less than one year; in the event of unclear fulfilment 1 examining physician can also be listed twice for 2 periods (e.g. previous calendar year and current year up to date of submission of Standard)

3. Radiology

Sec-tion	Requirements	Explanatory remarks of the Centre
3.1 - All -	Specialists • At least 1 radiology specialist • Cross-cover provision of staff with the same qualification is to be documented in writing. • The names of the specialist and cross-cover staff are to be given.	*See also chapter 3 SoS CCCN*
3.2 - All -	Procedures available in radiology: • conventional X-ray • spiral-CT • MRI (field strength at least 1.5 Tesla)	
3.3 - All -	Standard operating procedures (SOPs) for radiol-ogy The imaging techniques are to be described and checked once a year to ensure they are up to date.	

Self-As-sess-ment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once.	Yes	
		Mostly	
		Partially	
		No	

	• Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Not applicable	

4. Nuclear medicine

5. Surgical oncology

5.1 Trans-organ surgical oncology

5.2 Organ-specific surgical therapy

Section	Requirements	Explanatory remarks of the Centre
5.2.1 - All -	Post-operative care Care in the following areas is to be laid down in a standard operating procedure (SOP): • Intensive care (incl. e.g. artificial respiration, tracheotomy etc.) • Physiotherapy • Post-operative pain management • Return to normal food intake	*See also chapter 5 SoS CCCN*
5.2.2 - All -	Surgeons Basic qualification surgeon The basic qualification is specialist for visceral surgery according to country specific requirements	
- Colorectal -	• or specialist for general surgery with the European qualification EBSQ Coloproctology	
- Pancreas	• or specialist for general surgery with the European qualification EBSQ Hepato-Pancreatico-Biliary Surgery (HPB)	
- All -	• All patients of the Centre must be operated on directly by one of these surgeons or under his/her supervision (second surgeon).	
- All -	• Assistant operation Recognition as assistant operation only possible if this is done as part of training (no parallel recognition of cases with 2 surgeons).	
- Colorectal -	Colorectal surgeons • The names of at least 2 colorectal surgeons are to be given. Expertise for each colorectal surgeon (primary cases) 15 colon carcinomas a year 10 rectal carcinomas a year Authorisation of new colorectal surgeons in the previous 3 years cumulative at least 20 rectal and at least 30 colon carcinomas (proof of competence based on surgical reports).	Names listed in the table "Colorectal surgeons" (at the end of this section)

5.2 Organ-specific surgical therapy

Section	Requirements	Explanatory remarks of the Centre
Colorectal -	Expertise senior colorectal surgeon (primary cases) • On appointment 45 colon carcinomas and 30 rectal carcinomas in the previous 5 years • On extension Valid qualification certificate 5 years; requirement for extension 45 colon carcinomas and 30 rectal carcinomas in the previous 5 years	
- Pancreas -	Pancreas surgeon • The names of at least 2 pancreas surgeons are to be given (pancreas surgeon can also be colorectal surgeon) Expertise of each pancreas surgeon • 10 pancreatic resections a year Authorisation of new pancreas surgeons • In the previous 3 years cumulative at least 20 pancreatic resections	Names given in the table "Pancreas surgeons" (at the end of this section)
5.2.3 - All -	Emergency treatment • Emergency treatment (e.g. bowel obstruction, bleeding) is to be laid down in a standard operating procedure (SOP). • Shift planning for qualified staff (roster/on call rota)	
- Colorectal -	Surgically removed lymph nodes The right oncological decision is to operate (*inter alia* at least 12 lymph nodes). Any deviation from this is to be discussed with the pathologist.	
- Pancreas -	The right oncological decision is to operate (*inter alia* at least 12 **regional** lymph nodes.) Any deviation from this is to be discussed with the pathologist.	
5.2.4	Surgical expertise CCCN	
- Colorectal -	Surgical expertise colorectal • 30 patients annually with a primary diagnosis of colon carcinomas (ICD-10 C18,19,20,) • 20 patients annually with a primary diagnosis of rectal carcinomas (ICD-10 C25)	See data sheet colorectal
- Pancreas -	Surgical expertise pancreas	See data sheet pancreas
	At least 20 pancreatic resections / year	
	At least 12 surgical primary cases with pancreatic resection / year	
	Definitions **Primary case** • Adenocarcinomas, neuroendocrine carcinomas are counted; IPMN's (intraductal papillary mucinous neoplasms) are not counted; for full definition see SoS 1.2.1 **Surgical primary cases**	

5.2 Organ-specific surgical therapy

Section	Requirements	Explanatory remarks of the Centre
	• Only ICD-10 C25 (Adeno-Ca, neuroendocrine carcinoma, NO IPMN) in connection with partial resection of the pancreas, (total) pancreatectomy **Pancreas resections** • benign + malignant ICDs, also IPMNs; only the type of surgery is relevant (= pancreas left, pancreas head section, total pancreatectomy; partial resection of the pancreas, (total) pancreatectomy)	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	

Table "Colorectal surgeons"

Title, name, first name	Period [1)] from … to	Number surgical procedures [2)] colon ≥ 15	Number surgical procedures [2)] rectum ≥ 10	Clinical site/clinic [3)]

Table "Pancreas surgeons"

Title, name, first name	Period [1)] from … to	Number surgical procedures pancreas ≥ 10	Clinical site/clinic [3)]

1) Period normally the previous calendar year (=indicator year); deviations e.g. in staff fluctuation, appointment of surgeons for less than one year; in the event of unclear fulfilment 1 surgeon can also be listed twice for 2 periods (e.g. previous calendar year and current year up to date of submission Standard)
2) There is no annual expertise requirement for senior colorectal surgeons
3) What is relevant for multi-site Centres or for the case that a surgeon regularly works in several clinical sites/clinics as a surgeon (surgical expertise is to be detailed for each clinical site/clinic)

6. Medical oncology / systemic therapy

6.1 Medical oncology

6.2 Organ-specific systemic therapy

Section	Requirements	Explanatory remarks of the Centre
6.2.1 - All -	Physicians' qualifications Medical oncologist or specialist for internal medicine and gastroenterology or specialist for radiotherapy The radio-oncologist can perform chemotherapy in conjunction with radio-chemotherapy concepts. The name of one representative with the above-mentioned qualification is to be given. The specialists named here must actively carry out the medicinal tumour therapy. The delegation of responsibilities to physicians without the above-mentioned qualification is not possible.	*See also chapter 6 SoS CCCN*
6.2.2 - All -	Specialised Nurses Requirements for the specialised nurse responsible for administering chemotherapy: • At least 1 year of professional experience in oncology • 50 chemo therapy applications/annually (estimations possible for initial certification, proof must be provided in the following years in the audits)	
6.2.3 - All -	On call/reachability medical staff • 24-hour outside normal working hours including weekends and public holidays • During 24-hour reachability access to therapy data must be possible.	
6.2.4 - All -	Case numbers per treatment unit Calculation method: chemotherapy per patient (consisting of several cycles or applications) In the event of a shortfall, expertise cannot be documented via cooperation (must be documented for each individual treatment unit). At least 200 chemotherapy sessions a year **or**	
- Colorectal -	at least 50 patients with a specific indication (colon/rectum)	
- Pancreas -	at least 20 patients with a specific indication (pancreas)	
6.2.5 - All -	Basic diagnosis laboratory Basic diagnosis including emergency laboratory must be possible 24 h. If laboratory is not staffed 24 h, written rules/agreement for 24 h emergency laboratory are required.	
6.2.6 - All -	Basic diagnosis medical imaging	

6.2 Organ-specific systemic therapy

Section	Requirements	Explanatory remarks of the Centre
	Cooperation for ultrasound and radiological emergency and routine diagnosis If medical imaging is not staffed 24 h, written rules/agreement for 24 h emergency diagnosis is required.	
6.2.7 - All -	Systemic therapy regimens • The drawing up of / changes to existing therapy regimens must be undertaken by means of regulated release. • Prior to release or changes to therapy regimens, the expert opinion of pharmacists can be sought. • The therapy regimens are to be protected from any unauthorised changes. • The therapy regimens are comparable between the outpatient and inpatient units. Therapy plans • All systemic therapy must be planned on the basis of a therapy regimen. • The therapy plans are to be checked and released.	
6.2.8 - All -	Cytostatic preparation • Production is undertaken with due consideration of statutory provisions in a pharmacy. If it is not part of the facility, a care agreement must be entered into. • It must be possible to speak to the pharmacy during the period in which therapy is administered. 24-hour on-call service is required for inpatients. Standard operating procedures (SOPs) are to be drawn up for production.	
6.2.9 - All -	Standard operating procedures (SOPs) • The SOP for medicinal oncological therapy is to be described for all phases (start, conduct and conclusion of therapy). • Supportive measures in accordance with the guidelines are to be described for the individual therapy concepts and documented in detail for each patient.	
6.2.10 - All -	Standards comorbidities and secondary diseases Standards are to be drawn up for the treatment of comorbidities and secondary diseases, in particular for the treatment of extravasation, infections and thromboembolic complications.	
6.2.11 - All -	Emergency treatment Available emergency equipment and written action plan for emergencies	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice.	Yes	
		Mostly	

	• Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Partially	
		No	
		Not applicable	

7 Radiotherapy

Section	Requirements	Explanatory remarks of the Centre
7.1 - All -	Specialists. • At least two specialists • Specialists are to be designated by name	*See also chapter 7 SoS CCCN*
7.2 - All -	Medical physicist • At least one medical physicist must be available in the department on workdays • Medical physicists and their backups are to be designated by name • A back-up plan must be formulated in writing	
7.3 - All -	Accessibility/obligation to be on call A specialist in radiation therapy must be present during working hours and have 24/7 on-call duty outside of working hours (including weekends and holidays), if necessary via cooperation	
7.4 - All -	Required technical equipment and radiation treatment plan/techniques • One accelerator with >= 6 MV photons with at least 6-15 MeV electrons • Description of the technical equipment • A contingency plan (tandem solution) formulated in writing Radiation treatment planning: • Therapy simulator or virtual simulation • Planning CT • 3D radiation treatment planning system	
7.5 - All -	Waiting time • Period between patient's first contact and the initial presentation: < 10 Days • Period between the initial presentation and beginning of treatment, provided there are no medical reasons to the contrary: < 4 weeks • The actual overall treatment time should not exceed the prescribed overall treatment time by more than 10%. Interruptions in radiotherapy for medical reasons or by the patient constitute exceptions • The waiting periods are to be surveyed by random sampling and statistically assessed (recommendation: assessment period 4 weeks per year).	
7.6 - All -	Consultation hours	

7 Radiotherapy

Section	Requirements	Explanatory remarks of the Centre
	• It must be ensured that every patient is presented to a physician before the beginning of a radiation treatment series • At least one additional contact with a physician must be documented at the radiotherapy facility during a radiation treatment series	
7.7 - All -	Documentation/tumour monitoring • The doses that are prescribed are to be recorded according to the guidelines. A documented reason must be given for deviations from the prescribed dose. • Support measures in keeping with the guidelines are to be described for individual therapy concepts and documented in detail in relation to the individual patient.	
7.8 - All -	Simultaneous chemoradiotherapy The procedure for sequential/simultaneous chemoradiotherapy has to be described. If the radiation oncologist does not perform the simultaneous chemoradiotherapy him/herself, the responsibilities for the treatment of side effects, interruptions of radiotherapy, dose specification and dose reductions must be clearly defined beforehand. The joint treatment plan must also be signed by a specialist in radiotherapy in every case. Treatment documentation: Blood-count checks and laboratory tests must be documented by the radiation oncologist during radiochemotherapy.	
7.9 - All -	Palliative radiotherapy • In cases of palliative radiotherapy, the intention of the therapy (local control or solely to alleviate symptoms) must be documented. • Palliative medical measures, as well as the development of symptoms and adverse effects, must be described especially in relation to therapy concepts intended to alleviate symptoms and documented in relation to the individual patient. • Simultaneously administered pharmacotherapy (e.g. pain or tumour-specific therapy) must be documented.	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once.	Yes	
		Mostly	
		Partially	
		No	

	• Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Not applicable	

8. Pathology

Section	Requirements	Explanatory remarks of the Centre
8.1 - All -	Specialists • At least 2 qualified specialists for pathology • The specialists are to be designated by name Specialists (director and at least 1 other specialist).	*See also chapter 8 SoS CCCN*
8.2 - All -	Number of cases: Pathological Institute At least 15,000 histological (incl. cytological) examinations per year (case numbers, documentation via journal entry number) •	
Colorectal	At least 50 examined colon/rectum biopsies At least 50 examined colon/rectum specimens	
- Pancreas -	Every year at least 12 pancreatic surgery histologies	
8.3 - All -	Procedures that must be available • Immunohistochemical examinations • In-situ hybridisation • Molecular pathology These special services can only be delegated to pathological institutes. The institutes should have a recognised QM system or a valid accreditation or be able to document successful participation in round robin tests.	
8.4 - All -	Frozen section analysis (cryosection) • The technical and organisational prerequisites for frozen section analysis must be fulfilled. • An operational cryostat must be available • Virtual slide telepathology is not acceptable	
8.5 - All -	Retention time • Archiving of paraffin blocks ≥ 10 years, • Retention of wet tissue ≥ 4 weeks. • Cryopreservation should also be possible	
8.6 - All -	Parameters for frozen sections Time required and time measured from arrival in pathology (in min.) to announcing the result (benchmark max. 30 minutes) Evaluation of time needed: min./max./range figure	
8.7 -Colorectal-	Pathology reports Pathology reports for the macroscopic report and the microscopic examination must contain 100% of the information required by the guideline. The following information is required: • Site • Tumour type acc. to WHO classification • Tumour invasion depth (pT classification)	

8. Pathology

Section	Requirements	Explanatory remarks of the Centre
	• Status of the regional lymph nodes (pN classification) • Number of lymph nodes analysed • Number of lymph nodes affected • Grading • The pathologist must always indicate the resection edges and the minimum safety distance (quality indicator derived from the guideline); (deviations must be explained). • R classification • Lymph/blood-vessel invasion • TME quality (quality indicator derived from the guideline)/CRM quality • Degree of tumour regression in the case of neoadjuvant therapy (optional).	
- Pancreas -	Mandatory information pathology report • Status of the resection area with regard to the remaining part of the pancreas and the circumferential resection margins (marked in Indian ink) • R0 narrow/wide • Lymph vessel invasion • vein invasion • perineural sheath invasion	
8.8 - All -	Time until histological result • Biopsy specimens/polyps: max. 3 working days • Surgical specimens max. 5 working days	
8.9 colorectal	Lymph nodes At least 12 lymph nodes must be examined in the surgical specimen	
- Pancreas	At least 12 regional lymph nodes in the surgical specimen are to be examined.	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	

9. Palliative care, Hospices and Home Care

Section	Requirements	Explanatory remarks of the Centre
9.1 - All -	Palliative care	*See also chapter 9 SoS CCCN*

9. Palliative care, Hospices and Home Care

Section	Requirements	Explanatory remarks of the Centre
	Cooperation agreements with providers of specialised in- and outpatient palliative care, hospices and palliative wards must be documented	
9.2 - All -	Supportive therapy and symptom alleviation in the palliative situation • The options of supportive/palliative inpatient therapy are to be described (SOP/algorithm). • A pain management therapist must be available. The pain management SOP (algorithm) is to be described and confirmed using documented cases for the assessment period. • Access to nutritional counselling is to be described and confirmed using documented cases for the assessment period. • Access to psycho-oncological and psychosocial care and pastoral care is to be described. • If provided by cooperation partners, a cooperation agreement is to be entered into for the above requirements.	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	

10. Tumour documentation and Patient Registry

Section	Requirements	Explanatory remarks of the Centre
10.1 - All -	Tumour documentation system A system of tumour documentation that contains patient data for a period of at least 3 months must be in place at the time of initial certification	*See also chapter 10 SoS CCCN*
10.2 - All -	Period covered by the data The full data are to be presented for the respective last calendar year.	
10.3 - All -	Documentation officer The name of at least 1 documentation officer is to be given , name/function: Tasks documentation officer: • Ensuring and monitoring the timely, full, complete and correct transfer and quality of the patient data that are relevant for certification by all cooperation partners to the cancer registry.	

10. Tumour documentation and Patient Registry

Section	Requirements	Explanatory remarks of the Centre
	• Motivation of trans-sectoral cooperation with participating specialty units in the cancer registry (pathology reports, radiotherapy and medicinal treatments). • Qualification and support for the staff involved in data collection • Regular analysis of evaluations particularly over the course of time.	

Self-Assessment	• Yes – the chapter has been implemented on a wide scale, and the Deming cycle has been completed twice. • Mostly – the chapter has been implemented in critical places, the Deming cycle completed once. • Partially – the chapter has been only partly implemented, or only recently introduced and not evaluated. • No – the chapter has not been implemented • Not Applicable (rare).	Yes	
		Mostly	
		Partially	
		No	
		Not applicable	

Annex **Key Figures (see details in attached and corresponding Excel sheets)**