**Catalogue of Requirements for**

**Colorectal Cancer Centres**

All of the requirements for Colorectal Cancer Centres (CrCC) are laid down in this catalogue. The certification of

Colorectal Cancer Centres is based on the fulfilment of these requirements.

**Developed by the DKG (German Cancer Society) Certification Committee for Colorectal Cancer** **Centres**

**Chairmen** Prof. Dr. J. Mayerle, Prof. Dr. C. Reißfelder

**Members (in alphabetical order):**

|  |
| --- |
| ABO - Working Group on Imaging in OncologyACO - Working Group Surgical OncologyADDZ - [Working Group of DKG-Certified CRCC Centres](http://www.ag-darmzentren.com/)ADT - Working Group of German Tumour CentresAET - Hereditary Tumour DiseasesAGORS - Working Group Rehabilitation and Social MedicineAGSMO - Working Group in Supportive measures in oncologyAIO - Working Group on Internal OncologyAOP - Working Group on Oncological PathologyAPM - Working Group on Palliative MedicineARO - Working Group on Radiological OncologyASO - Working Group on Social Work in OncologyASORS - Working Group for Supportive Care in Oncology, Rehabilitation and Social MedicineAUO - Working Group on Urological OncologyBDI - Professional Association of German InternistsBDP - Professional Association of German PathologistsBDVST - Professional Association of German Radiation TherapistsBNG - German Association of Practising GastroenterologistsBNHO - Professional Association of Haematologists and OncologistsBVGD - Gastroenterology AssociationCAO - Working Group on Surgical OncologyCAO-V - Working Group on Surgical Oncology – Visceral SurgeryDeGIR - German Society of Interventional RadiologyDEGRO - German Society for Radiation OncologyDGAV- German Society for General and Visceral SurgeryDGCh - German Society for SurgeryDGHO - German Society for Haematology and OncologyDGK - German Society for ColoproctologyDGN - German Society for Nuclear MedicineDGP - German Society for Palliative MedicineDGP - German Society of PathologyDGPRÄC - German Society of Plastic, Reconstructive and Aesthetic SurgeonsDGVS - German Society for Digestive and Metabolic DiseasesDRG - German Radiological SocietyDVSG - German Association for Social Work in Health CareGerman ILCOJoint Project on Familial Colorectal CancerKOK - Conference of Oncological Nursing and Paediatric Nursing careology / Association of DietitiansOPH - Working Group Oncology PharmacyPRIO - Working Group on Prophylaxis and Integrative Medicine in OncologyPSO - Working Group on Psychological OncologyRepresentative of the S3 Evidence-Based Guideline Anal CancerRepresentative of the S3 Evidence-Based Guideline Colorectal Cancer VDOE/VDD - Professional Association of Oecotrophology |

**Valid from 14.09.2023**

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| This Catalogue of Requirements is binding for all audits from 1 January 2024. All changes to the previouslyapplicable versions of this Catalogue (of the audit years 2023) are highlighted in green.The following was incorporated:* S3 Guideline “Diagnosis and Treatment of the Colorectal Carcinoma”
* S3 Guideline “Diagnosis, Treatment and Follow up of Anal Canal and Cancers of the perianal Skin

The Catalogue of Requirements is based on the TNM classification of malignant tumours, 8th edition 2017, the ICD classification ICD-10-GM 2023 (DIMDI) and the OPS classification OPS 2023 (DIMDI). |

**Information on the Colorectal Cancer Centre**

**Centre scope**

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|  |  | Colorectal |  | Anal cancer |
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Certification for anal cancer is only possible in combination with a certification as a Colorectal Cancer Centre.

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| Colorectal Cancer Centre (CrCC) |  |
| Director of the Centre |  |
| Coordinator of the Centre |  |

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|  |  |  | This CoR is valid for |
|  |  |  |  |  |  |
| Clinical site 1 (hospital/clinical site) |  |  |  |  |  |
|  |  |  |  |  |  |
| Clinical site 2 (hospital/clinical site) |  |  |  |  |  |
| only in the case of cooperating CrCCs |  |  |  |  |  |

**QM system certification**

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| --- | --- | --- | --- | --- |
| QM system certification |  | yes |  | no |

**Network/ main cooperation partners**

The (main) cooperation partners of Colorectal Cancer Centres are registered with the certification institut OnkoZert in a "master data sheet" (*"Stammblatt"*). All the information contained therein is published on [**www.oncomap.de**](http://www.oncomap.de). The Centre must report all new and also all invalid cooperations. All other updates (changes in management, contact data etc.) must be corrected in the “master data sheet and must be regularly updated prior to the annual surveillance audit. This master data sheet can be requested from OnkoZert.

**Compilation/Update**

The electronically generated questionnaire serves as the basis for certification of the CrCC. The correctness and completeness of the information contained therein have been verified.

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| The data on outcome quality relate to the calendar year: |  |
|  |  |
| Date on which the questionnaire was compiled /updated: |  |

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	1. Medical oncology
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Annexes to the questionnaire (separate Excel document)

Data Sheet - Colorectal (Excel-Template)

Data Sheet - Anal Cancer (Excel-Template)

| 1. General information on the Colorectal Cancer Centre**1.1** **Structure of the network** |
| --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.1.1 | 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 | Main cooperation partners and cooperation partners can be part of a clinic or also be independent practices.partners can be part of a clinic or also be independent practices. Main cooperation partnersVisceral surgery (only Anal Cancer: with additional qualification in Proctology according to the model further training regulations (MWBO) or EBSQ coloproctology), gastroenterology, radiotherapy, haematology/oncology, pathology, radiology (only LCC: interventional radiology) Cooperation partnersPsycho-oncology, social work, stomatherapy (only colorectal), nutritional counselling, physiotherapy, genetics, pain therapy and self-help group, palliative medicine, diabetology (only pancreas), for Anal Cancer additional: plastic surgery, gynaecology |  |  |
| 1.1.3 | Cooperation agreementsA 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 Catalogue of Requirements (not every service provider has to be a cooperation partner as well). The cooperation partners are to be listed in the "Master Data Sheet" (administration by OnkoZert).If the cooperation partners of a Centre work under a funding body or at a clinical site, 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
* Declaration of willingness to cooperate on internal/external audits
* Undertaking to comply with the relevant DKG criteria and the annual submission of the relevant data
* Upholding of medical confidentiality
* Participation in continuing education/specialty training programmes and public relations work
* Declaration of consent to be publicly identified as part of the Centre (e.g. homepage)
* 24/7 reachability of main clinical cooperation partners in VC: surgeons, gastro-enterologists, radio-oncologists, radiologists
 |  |  |
|  | Tumour board(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 | Presentation of the CentreThe overall structure of the Centre is to be presented and made public (e.g. Internet). This also encom-passes giving the names of all internal/external coop-eration partners with the following details:- Name, address of cooperation partner- Cooperation partner with tel./email |  |  |
| 1.1.5 | Strategy planning/ReportingIt 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
 |  |  |

| **1.2** **Interdisciplinary cooperation**  |
| --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.2.0 | Number of primary cases |  |  |
| - Colorectal -CR CC5.2.4 | CR CC5.2.4 Surgical expertise Centre* 30 colon cancer
* 20 rectal cancer

 Primary case definition, see last page of this Catalogue of Requirements | Data sheet colorectal(Excel template) |  |
| - Anal - | Number of primary cases The centre must treat 12 patients per year with a primary diagnosis of Anal Cancer.Definition:* Anal Cancer: C21.1
* Cancers of the perianal skin: C44.50 ~~in conjunction with surgical procedure (5-485\* or 5-49\*\*) or radio-chemotherapy (target area code 5.1/5.2 OBDS for radiation) or radiotherapy (target area code 5.1/5.2 OBDS (Germany: Basic Oncology Data Set)~~
* Patients and not stays and no operations
* Patients with first disease (incl. primary M1)
* Counting time is the time of histological confirmation of diagnosis
* Patients who are only presented for a second opinion or only on a consultative basis are not taken into account.
 | Data sheet anal (Excel template) |  |
| 1.2.1 | Cycle/Participants tumour boardA tumour board 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
* Haematology/Oncology
* Pathology
* Radiology (LCC: interventional 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 (palliative medicine, psycho-oncology, etc.) are to be invited. If the haematologist/oncologist is unable to attend the tumour board, he/she may be represented by the specialist responsible for chemotherapy who complies with the requirements in Section 6.2. |  |  |
| 1.2.2 | General requirements tumour board Several cooperation partnersIf 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 boardIf web tumour board 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 board with no imaging material are not an option. |  |  |
| 1.2.3 | Indicator Presentation tumour boardPretherapeutic case presentationPost-operative case presentationAll pretherapeutic/post-operative cases are to be presented at the tumour board in line with the respective indicator definition. If no presentation is made, clear reasons must be given in the patient’s medical record. |  |  |
|  | Presentation tumour boardPatients with a rectal carcinoma should be presented again in the tumour board after termination of neoadjuvant therapy and in the case of full clinical remission in order to discuss the indication of a Watch &Wait strategy. |  |  |
| 1.2.4 | Recurrence/metastasis* 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 | Demonstration imaging materialPatient-related imaging material must be available at the tumour board and suitable technical equipment must be provided for the presentation of this material. |  |  |
| 1.2.6 | Preparation tumour board* The main patient and treatment data are to be compiled in writing beforehand and made available to the participants at the tumour 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 | 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 documenta-tion system.
* The outcome of the tumour board is to be recorded in the tumour documentation system.
 |  |  |
| 1.2.8 | Participation tumour board as continuing education Participation tumour board as continuing educationFor the following functions/professional groups, a one-time mandatory participation in the tumour board is to be made possible (refresher every 3 years):* Assistant staff (MTA, MTRA, ...) from the fields of radiology and radiotherapy
* Social services and psycho-oncology staff
* Participation in the tumour board is recognised as continuing education for the aforementioned functions/professional groups.
 |  |  |
| 1.2.9 | Therapy deviation* The therapeutic procedure should be oriented to-wards 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 | Supportive therapy and symptom relief* The options for supportive/palliative inpatient therapy must be described (process description/algorithm).
* A specialised pain therapist must be available. The process for pain therapy (algorithm) must be described and documented cases must be provided for the assessment period.
* Access to nutritional counselling (in accordance with section 1.9) must be described and documented cases must be provided for the assessment period
* Access to psycho-oncological and psychosocial counselling as well as pastoral care must be described.
* In the case of implementation via cooperation partners, a cooperation agreement must be concluded for the aforementioned requirements.
 |  |  |
| 1.2.11~~1.2.10~~ | Morbidity/mortality conference* The conference can be staged on the same date as the tumour board.
* 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.
 |  |  |
| 1.2.12~~1.2.11~~ | Quality circles* Tasks, circle of participants and contents of the quality circles are to be laid down.
* Conferences are to be held at least four times a year.
* A list of participants is kept.
* The quality circles must produce clear results (ac-tions, 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 continuing education
* Interdisciplinary case reviews
* Structural improvements to the Centre
* Public relations

 * At the time of initial certification one quality circle must have taken place.
 |  |  |
| 1.2.13~~1.2.12~~ | Continuing education* Continuing education events are to be staged for the network of the Visceral Oncology Centre at least twice a year (where appropriate also after the morbidity & mortality conferences/quality circles).
* Contents/results and participation are to be record-ed. A continuing education plan is to be presented.
 |  |  |
| 1.2.14~~1.2.13~~ | Events of the CentreEach main cooperation partner must participate in at least two of the Centre's events. The following are recognised:* Quality circles
* Morbidity/mortality conference
* Continuing education
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| **1.3** **Cooperation referrers and providers of aftercare treatment** |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.3.1 | Cooperating referrersAn up-to-date list is to be kept of the cooperating referrers. The referrers are to be informed about cooperation within the Centre with regard to the following details: Obligations of the Centre:* Referrers are entitled to attend the tumour board when their patients are presented.
* Referrers are to be given the opportunity to present patients in the tumour board.
 |  |  |
| 1.3.2 | ContactsThe Centre's contacts are to be given to the referrers in line with their function (e.g. telephone number, email). This can be done with the required publication of the cooperation partners. |  |  |
| 1.3.3 | Provision of documentsThe co-attending physicians are to be given the following information in a timely manner (individual docu-ments and/or summaries in the medical report):* Histology
* Tumour board minutes / treatment plan
* Surgical report (optional)
* Changes to therapy

 Timeline for the provision of the necessary information to the co-attending physicians < 2 weeks |  |  |
| 1.3.4 | Feedback systemFor the co-attending physicians a written standard operating procedure (SOP) for the recording, processing and feeding back of the general and case-related concerns/questions/complications is to be put in place. |  |  |
| 1.3.5 | 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 recog-nised.
* The referrer satisfaction survey must be available for the first time for the first surveillance audit (1 year after initial certification).
 |  |  |
| 1.3.6 | Continuing educationEvents for the exchange of experience and continuing education events are to be proposed at least twice a year by the Centre. Contents/results and participation are to be recorded. |  |  |

| **1.4** **Psycho-oncology**  |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.4.1 | Psycho-oncology – qualifications* Qualified psychologists / Master in Psychology, which qualifies for a scientifically recognised psychotherapy procedure or
* physicians
* Diploma/master's degree in social pedagogy qualifying for a scientifically recognised psychotherapy

 with at least 1 psychotherapeutic specialty training: behavioural therapy, psychodynamic psychotherapy (analytical psychotherapy and psychotherapeutic depth psychotherapy), systematic therapy, neuropsychological therapy (for psychological disorders caused by brain injuries), interpersonal therapy (IPT; for effective disorders and eating disorders), EMDR for the treatment of post-traumatic stress disorders, hypnotherapy for addictions and psychotherapeutic treatment for somatic disorders and psycho-oncological continuing education (recognised by the German Cancer Society - DKG). Licence to practise: At least 1 person in the psycho-oncological team of the network (inpatient or outpatient) must be licensed (psychological or medical psychotherapist). Protection of the status quo for all those who are currently recognised and those who have started a psycho-oncological specialty training by 31.12.2019 recognised by the German Cancer Society - DKG.The representatives of other psychosocial professional groups can be accepted on presentation of the above-mentioned psycho-oncological qualifications. For this, a case-by-case examination is required. The assumption of psycho-oncological tasks by the social services, self-help groups or pastoral care is not sufficient. They supplement psycho-oncological care. The process of patient care in the centre (screening, evaluation of screening results, care) must be demonstrated in the audit based on examples. |  |  |
| 1.4.2 | Psycho-oncology – Offer and accessEach patient must be offered the option of psycho-oncological counselling in a timely manner in the vicinity. The offer must be made in a low-threshold manner.Documentation and evaluationIn order to identify the need for treatment, screening of the level of mental stress is mandatory (see: Indicator "Psycho-oncological distress screening) and document the results. The proportion of patients overburdened in the screening of distress has to be shown. |  |  |
|  | Psycho-oncological counsellingPsycho-oncological care, especially for patients with high distress scores in the distress screening, should be presented. |  |  |
| 1.4.3 | Psycho-oncology resourcesNeeds-based at least 1 psycho-oncologist with the above qualifications is available to the Centre (name is to be given). |  |  |
| 1.4.4 | PremisesA suitable room is to be provided for psycho-oncological patient consultations. |  |  |
| 1.4.5 | Organisation planIf psycho-oncological care is provided by external cooperation partners or for several clinical sites and clinic facilities, the performance of tasks is to be laid down in an organisation plan that contains details, inter alia, of the availability of resources and local presence. |  |  |
| 1.4.6 | Psycho-oncology – tasksThe psycho-oncological care of patients is to be offered at all stages of care (diagnosis, inpatient, post-inpatient). Goals and tasks of care:* Diagnostic clarification after positive screening
* Prevention/treatment of resulting psychosocial problems
* Activation of personal coping mechanisms
* Maintenance of quality of life
* Consideration of social environment
* Organisation of further outpatient care through cooperation with outpatient psycho-oncological service providers
* Public relations (patient event or the like)
 |  |  |
| 1.4.7 | The following are also recommended:* Provision of supervision, initial and continuing education courses for staff
* Twice yearly discussions between psycho-oncologists and the nursing and medical areas
* Regular written and, where appropriate, oral feedback on psycho-oncological activities to the medical staff (e.g. through a referral report or documentation in the medical record)
* Regular participation in ward conferences and tumour boards
* Close cooperation with the social services
* Interface/exchange with self-help and pastoral care
* The psycho-oncologists should present their work at least twice a year at the tumour boards.
 |  |  |
| 1.4.8 | Continuing education/specialty trainingAt least 1 dedicated continuing education/specialty training session a year for each staff member (at least 1 day a year) |  |  |

| **1.5**  **Social work and rehabilitation**  |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.5.1 | Qualifications social services:* Social workers/social pedagogues
* Individual case examinations according to the specifications of the professional society are possible
* Additional qualification: Experience in the medical/oncological field
 |  |  |
| 1.5.2 | Social services - resources:For the counselling of patients in the centre, there is at least 1 social worker available for 400 counseled patients (not cases) of the centre (= primary cases, secondary metastases, recurrences). The personnel resources can be provided centrally; an organisational plan must be available. |  |  |
| 1.5.3 | Offer and accessEvery patient must be offered the possibility of counselling by the social service in all phases of the disease, locally and promptly (proof required). The offer must be made without any barriers. |  |  |
| 1.5.4 | The number of patients who received counselling from the social services is to be recorded and evaluated. |  |  |
| 1.5.5 | Premises:A suitable room must be provided for social counselling work. |  |  |
| 1.5.6 | Organisation planThe performance of tasks is to be regulated by means of an organisation plan, in which, among other things, the availability of resources and the local presence can be identified. |  |  |
| 1.5.7 | Tasks of the psychosocial counselling:Contents of counselling: using the DVSG catalogue of services and the expert standards PEOPSA (Psychosocial Initial Counselling of Oncological Patients by Social Work)* Identification of social, economic and mental health emergencies
* Start of medical rehabilitation measures
* Advice on social law and economic issues (e.g. severely disabled persons' legislation, wage replacement benefits, pension, benefit requirements, co-payments, and many other issues)
* Support for submitting applications
* Advice on outpatient and inpatient care treatment options
* Referral to support schemes and specialised services, nursing care services
* Support for professional and social reintegration
* Cooperation with service funding agencies and service providers, specialist services
* Discharge management
* Intervention in emergencies
* Placement in palliative care concepts and hospice care (outpatient/inpatient)
 |  |  |
| 1.5.8 | Further tasks:* Public relations and networking
* Participation in multiprofessional case reviews, supervision, continuing education
* Offering continuing education/ information events for other disciplines of the Centre and/or patients
* Multiprofessional cooperation particularly with physicians, nursing staff, physiotherapists, psycho-oncologists, pastoral services, self-help groups inter alia
 |  |  |
| 1.5.9 | Documentation and evaluationThe activities of the social services must be documented (e.g. CareSD, KIS) and evaluated. |  |  |
| 1.5.10 | Continuing education/specialty training* At least 1 dedicated continuing education/specialty training session a year for each staff member (at least 1 day a year)
* Offer supervision
 |  |  |

| **1.6** **Patient involvement** |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.6.1 | Patient surveys:* At least every 3 years all Centre patients are given the opportunity over a period of at least 3 months to take part in a patient survey.
 |  |  |
|  | The "return rate patient survey" should be higher than 50%. |  |  |
| 1.6.2 | Evaluation patient survey* Responsibility for the evaluation is to be specified.
* The evaluation must encompass the patients of the Centre.
* A recorded evaluation is to be made and presented during the audit.
* Actions are to be laid down on the basis of the evaluation.
* The evaluation can be considered in connection with a quality circle.
 |  |  |
| 1.6.3 | Patient information (general)* The Centre should give a full presentation of itself and its treatment options (e.g. in a brochure, patient folder, homepage).
* The names of the cooperation/treatment partners are to be given with details of the contact. A description is to be given of the treatment on offer.
* The presented treatment offering must encompass: Rehabilitation/post-hospital rehabilitation, self-help, treatment measures and alternatives
* Information provided: for instance patient guidelines and/or S3 Guidelines of the Oncology Guidelines Programme
 |  |  |
| 1.6.4 | 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)
 |  |  |
| -Anal- | * Information on the procedure for assessing the success of therapy after curative radiochemotherapy
* Assessment of therapy success by digital-rectal examination and proctoscopy 11 weeks, 18 weeks and 26 weeks after the start of radiochemotherapy.
 |  |  |
| 1.6.5 | Patient information (case-related):The patient is given the following documents:* Medical report / discharge letter (including details tumour board / treatment plan)
* Aftercare plan / aftercare pass
* where applicable, study documents

It is recommended that patients are given a central /structured folder for the documents. The procedure for the provision of patient information is to be standardised. |  |  |
| 1.6.6 | Event for patientsThe Centre is to stage an information event for patients and/or interested persons at least once a year.(can be considered together with 1.6.9)If patient events are (co-)financed by industry, this fact, including potential conflicts of interest of the speakers, must be revealed. The Centre must exclude any direct influence on patients by industry representatives. |  |  |
| 1.6.7 | Complaint managementAn official procedure for complaint management is in place. Patients are given feedback. Complaints are taken into account in the improvement process. |  |  |
| 1.6.8 | Self-help groupsThe self-help groups, with which the Cancer Cen-tre actively cooperates, are to be named. If possible, the self-help group should consider the specific needs of visceral oncology patients (keyword - affected by the same condition). |  |  |
| 1.6.9 | Self-help groupsSelf-help can be active in the field of patient involvement, psychosocial support and as an interest group. And, where appropriate, in the audit in these areas.The self-help groups, with which the Cancer Centre actively cooperates, are to be named. Written agreements with the self-help groups are to be entered into which cover the following points: * Access to self-help groups at all stages of treatment (initial diagnosis, hospitalisation, chemotherapy, ...);
* Provision of contact data of self-help groups (e.g. in patient brochures, homepage of the VC)
* Options to display information brochures of self-help groups
* Regular provision of rooms at the VC for patient consultations
* Quality circles with the participation of representatives of psycho-oncology, self-help groups, social services, pastoral care, nursing care and medicine
* Personal discussions between the self-help groups and the Centre with a view to jointly staging or mutually agreeing on actions and events. The results of the discussions are to be recorded.
* Involvement of medical staff in the events of the self-help group
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| **1.7** **Study management** |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.7.1 | Access to studiesIt 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). |  |  |
| 1.7.2 | Study managerThe name of the investigator in charge of the study is to be given. Study assistance* The name of a study assistant is to be included in the "study organisation chart" for "each active study unit".
* He/she can work in a parallel manner for several "units conducting studies".
 |  |  |
| 1.7.3 | Study assistance – qualifications Professional trainingContinuing education courses (e.g. MTA, nurse/health care assistant, physician's assistant) TrainingSpecial training for the study assistance function must be documented (guidance value: several day course).At the time of initial certification at least one registration for a course must be available. The course is to be completed within one year. During training the investigator / study manager must compensate for qualification deficits. |  |  |
| 1.7.4 | Study assistant - TasksThe range of tasks is to be laid down in writing (via position/function descriptions) and can encompass, inter alia, the following contents:* Conduct of studies together with the investigator in charge of the studies
* Patient care during the study and aftercare
* Organisation, coordination of diagnosis, laboratory, sample dispatch and test medication
* Collection and documentation of all data of relevance for the studies
* Preparation of and support for audits and authority inspections
* The activity of the study assistant can be combined with other activities like tumour documentation.
 |  |  |
| 1.7.5 | Cooperation study assistant – investigatorDirect availability of investigator or study manager for the study assistant is to be ensured (Documentation, for instance, about regular exchange). |  |  |
| 1.7.6 | Proportion study patients 1. Initial certification: At the time of initial certifi-cation ≥ 1 patients must have been included in studies (guidance value: ≤ 6 months prior to certification)2. after 1 year: at least 5% of the primary case number The requirement applies to each tumour entity. | Data sheets (Excel templates)Colorectal / Anal |  |
|  | Only the inclusion of patients in studies with an ethical vote counts as study participation (non-interventional/diagnostic studies and prevention studies are also recognised). Exclusive biobank collections are excluded. All study patients can be taken into account when calculating the study rate (share study patients based on the Centre's primary case number).General preconditions for the definition of the study quota:* Patients can be counted 1x per study, time: date of patient consent.
* Patients in a palliative and adjuvant situation can be counted, no limitations regarding stage of disease.
* Patients for colorectal prevention studies can be counted.
* Patients who are taking part in several studies simultaneously can be counted several times.
* Patients in the follow-up of a study are no longer included in the study rate.
 |  |  |
| 1.7.7 | Standard operating procedures (SOPs):The SOPs including responsibilities are to be laid down for the launch/initiation of new studies and the conduct of studies for each "active unit". This encompasses for instance:* Selection of new studies including release decision
* Internal announcement of new studies (update study list, ...)
* Study organisation (special features care study patients, documentation, ...)
* Type of announcement of study results (e.g. MA, patients)
 |  |  |
| 1.7.8 | Study assignmentBefore study participation can be recommended to a patient, there must be a patient-based discussion beforehand in the interdisciplinary tumour board. |  |  |

**List of the studies**

List of studies - colon/rectum 1)

|  |  |  |  |
| --- | --- | --- | --- |
| Responsible cooperation partner 2) | Name of the study | Centre patients | Patients total |
| Recruited in the indicator year ~~in~~~~2022~~ 3) | Totalrecruitedincl. previous years | Recruited in the indicator year ~~in~~~~2022~~) | Totalrecruitedincl. previous years |
| !! Details optional !! |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
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|  |  |  |  |  |  |
|  | Numerator Indicator No. 6 "Study rate" |  |  |  |  |

The list of accredited studies that can, therefore, be calculated for the study rate is depicted in [www.studybox.de](http://www.studybox.de/).

List of studies - Anal Cancer

|  |  |  |  |
| --- | --- | --- | --- |
| Responsible cooperation partner 2) | Name of the study | Centre patients | Patients total |
| Recruited in the indicator year ~~in~~~~2022~~ 3)) | Totalrecruitedincl. previous years | Recruited in the indicator year ~~in~~~~2022~~  | Totalrecruitedincl. previous years |
| !! Details optional !! |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  | Numerator Indicator No. 5 "Study rate" |  |  |  |  |

1) The list of studies must be processed. It is not possible to refer to the Catalogue of Requirements of the Oncology Centre.

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 ~~2022~~ the indicator year (no double counting of study patients in more than 1 Centre, exception CPM see FAQ).

| **1.8** **Nursing care** |
| --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.8.1 | Specialised oncological nurses* At least 1 specialist oncology nurse must be actively employed on day duty.
* Oncological nurses are to be designated by name.
* In inpatient areas where patients are cared for, the activity of an oncology nurse must be verified. The performance of duties/representation must be regulat-ed and documented in writing.

 The precondition for recognition as a specialist oncology nurse is* specialty training specialist oncology nurse in line with the respective federal state regulations
* or with the Model Federal State Ordinance of the German Hospital Federation (Deutsche Krankenhausgesellschaft e.V.)
* or advanced practice nurse (master title) plus 2 years’ practical professional experience (equivalent to a full-time position) in the Colorectal Cancer Centre or Visceral Oncology Centre
 |  |  |
| 1.8.2 | Responsibilities/Tasks* Specialised assessment and management of strains, symptoms and side-effects
* Individual derivation of interventions from nursing standards
* Conduct and evaluation of nursing and therapeutic measures
* Establishment of individual patient-based need for counselling
* The need for specialised counselling is to be defined already in the nursing concept of the Colorectal Cancer Centre.
* Ongoing provision of information to and counselling of patients (and their family members) throughout the entire course of the disease
* Conduct, coordination and documentation of structured counselling sessions and instructions to patients and their family members. Depending on the concept these activities may also be carried out by other long-serving specialist nurses with oncological expertise.
* Participation in the tumour according to chapter 1.2)
* Initiation of and participation in multi-professional case discussions/nursing visits. The objective is to find solutions in complex nursing situations. Criteria for the selection of patients are to be laid down. At least 12 case discussions/nursing visits are to be documented for each year and Centre.

 Superordinate activities:* A nursing concept is to be developed and implemented in which the organ-specific aspects of oncological nursing care are taken into account in the Visceral Oncology Centre.
* Drawing up of specialised, in-house standards on the basis of (if possible) evidence-based guidelines (e.g. S3-LL Supportive).
* Offer of consultation with/supervision by colleagues
* Networking between oncology nurses in a joint quality circle and participation in the quality circle in the Visceral Oncology Centre
* Interdisciplinary exchange with all professional groups involved in treatment
* Responsibility for implementing the requirements for specialist nurse responsible for carrying out chemotherapy (see Section 6)
 |  |  |
| 1.8.3 | On-the-job trainingThe process of familiarising new members of staff must follow a specified oncological on-the-job training concept. |  |  |
| 1.8.4 | Continuing education* A plan for the continuing education of the nurs-ing staff is to be submitted in which the training measures for the forth-coming year are set out.

At least one specific continuing education course per staff member and year (at least 1 day per year) if the staff member performs tasks relevant to the quality of the centre. |  |  |
| 1.8.5 | Stomatherapy – StaffQualification head of stomatherapy Recognised training stomatherapy:• The following continuing education courses run by the FgSKW (Expert association for stoma, continence and wound) as nursing care experts for stoma, continence and wound encompassing 720 continuing education hours or other comparable continuing education courses. The following protection applies to stomatotherapists who were named in the centers before 01/01/2019:Length of continuing education at least 400 hours plus practical units (contents like “Curriculum nursing expert stoma, continence, wound” of the FgSKW excluding sections incontinence and wound). A qualified replacement must be guaranteed. Members off staff must be named. If stomatherapy services are provided externally, a cooperation agreement must be entered into. |  |  |
| 1.8.6 | 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
 |  |  |
| 1.8.7 | Stomatherapy – Equipment / infrastructure* Own premises
* Possibilities presentation of demonstration material
* Storage opportunities for material for stoma care
 |  |  |
| 1.8.8 | Communication with other specialties* Formalised interprofessional information exchange with surgeons, radio-oncology and oncology
 |  |  |
| 1.8.9 | Stomatherapy – documentation of therapy* Documentation in inpatient patient record (documents of the stoma therapists alone not sufficient)
* Stoma pass for patients
* OPS coding of stoma systems (analogue to discharge letter) in the stoma passport
 |  |  |
| 1.8.10  | Stomatherapy – continuing education/specialty training* Regular training for nurses in inpatient units and relevant specialty units
* Regular continuing education for all other professional groups involved and for patients and their relatives
* Active support for the work of the self-help organisations through professional further training schemes
* Regular own participation in continuing education courses in professional and extracurricular areas
 |  |  |

| * 1. **General service areas**
 |
| --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.9.1 | 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 | Nutritional counselling* Qualified nutritional counselling (carried out by dietitians / ecotrophologists/nutritionists or specialist with additional training in nutritional medicine) must be an integral part of the Centre
* Cooperation is to be regulated in a cooperation agreement
* Qualified deputisation must be ensured.
* Need for nutritional counselling is to be actively identified and carried out for each patient. This is especially true during the post-oprative phase. The process must be documented in the patient records.
* An SOP for nutrition management should be set out in writing.
 |  |  |
|  | Further and continuing training for the above-mentioned nutritionists* At least 1 specific training programme per employee per year
 |  |  |
|  | Screening for malnutrition and therefore ~~T~~the metabolic risk (nutritional risk) should be recorded at the latest on inpatient admission for, if possible, all tumour patients using e.g. Nutritional Risk Screening (NRS), for instance in line with Kondrup 2003 ~~(measures same as S3-LL)~~.The measures should be analogue to the tumour entity-specific S3 GL.The ~~A~~ subsequent, process-guided nutritional consultation / therapy (e.g. German Nutrition Care Process) should be demonstrated accordingly and documented in the discharge letter.~~If patients are hospitalised for more than 10 days, the screening should be repeated weekly.~~ |  |  |

| 2. Organ-specific diagnostics**2.1** **Consulting hours** |
| --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 2.1.1 | General contents of the consultation at the clinical sites* Identification of risk groups and individualised prevention planning
* Planning clarification of dignity
* Therapy planning, aftercare
 |  |  |
| 2.1.2~~2.1.1~~ | Special consulting hours colorectal* Basis for staging? (Participating physician, personal authorisation, institute authorisation, polyclinic authorisation)
* At least 1 x week
 |  |  |
| 2.1.3~~2.1.2~~ | Waiting times special consulting hours* < 2 weeks waiting time for a consulting hours appointment
* < 60 minute waiting time during consulting hours
 |  |  |
| 2.1.4~~2.1.3~~ | Clarification tumour dignity100% clarification dignity already prior to radical surgical procedure(Reasons for deviations are to be given) |  |  |
| 2.1.5~~2.1.4~~ | Diagnostics for stagingWithin one week the following tests must be un-dertaken:* 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
 |  |  |
| 2.1.6~~2.1.5~~ | Rectum diagnosis Access to the following procedures shall be ensured* Rectal endosonography
* Rigid rectoscopy
* Chromoendoscopy
* Proctology
 |  |  |
| Height localisation rectum* Rigid rectoscopy, the flexible endoscopy or MRI examination can be used for height localisation.
* The height localisation as well as the used method must be specified in the diagnostic report.
 |  |  |
| 2.1.7~~2.1.6~~ | StenosisIn 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. |  |  |
| 2.1.8~~2.1.7~~ | Prevention / screening for asymptomatic population* 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
 |  |  |
| 2.1.9~~2.1.8~~ | List with co-attending physicians / screening net-work * An up-do-date internal list with co-attending phy-sicians and members of the screening network is to be kept (differentiated presentation of co-attending physicians/screening).
 |  |  |
| 2.1.10~~2.1.9~~ | Genetic counsellingCooperation with genetic counselling is to be regulated in a cooperation agreement. Cooperation must be proven by way of docu-mented cases during the current assessment pe-riod. The "Centres for Familial Colorectal Cancer" listed by German Cancer Aid (Deutsche Krebshilfe) are particularly suited for this. (<http://www.hnpcc.de/>). |  |  |
| 2.1.11~~2.1.10~~ | Identification and procedure for risk groups (familial and elevated risk)Risk persons are to be identified and documented in line with the risk classification in the S3 Guidelines 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 cancer in close family members
* Endometrial urothelial, small intestine or gastric carcinoma in close family members
 |  |  |
| 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. |  |  |
| 2.1.12~~2.1.11~~ | Individual care plan * In the case of identified risk persons individual care planning must be undertaken in line with the S3 Guidelines.

 Procedure in the event of suspected Lnych syndromeIn the SOP for confirming/ruling out Lynch syndrome, the following points are to be borne in mind:* Responsibility for identifying risk persons
* Responsibility for organising the primary immunohistochemical MSI examination and further analyses thereafter
* Responsibility for MSI testing
* Responsibility for passing on information to patients
* Responsibility for referral for genetic counselling/testing
 |  |  |
| 2.1.13~~2.1.12~~- Anal - | Special Proctology Consultation hours* At least 1 x per week
* Waiting times for special consultations: < 2 weeks waiting time for a consultation appointment, < 60 minutes waiting time during consultation hour

 Dispersion DiagnosticsThe following examinations are obligatory within 1 week:* Proctoscopy
* Endosonography anorectal

 If necessary (also within 1 week)* CT/MRI; PET-CT (optional)
* Gyn. Examination

 Anal Cancer diagnosticsAccess to the following procedures must be ensured:* Rectal Endosonography
* Rigid Rectoscopy
* Proctoscopy

 Identification and procedure for high-risk groups:Persons at risk are to be identified, documented and, if necessary, screened as part of the admission history. Risk groups are in particular HIV-positive patients and women with HPV-related genital dysplasia. |  |  |

| **2.2**  **Diagnostics** |
| --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 2.2.1 | Qualification of diagnosticians performing colonoscopy* Specialist in internal medicine and gastroenterology
* Specialist in visceral surgery
* Surgeons and internists with a qualification in colonoscopy or colonoscopy authorisation by the responsible health insurance fund
 |  |  |
|  | At least 2 specialists (in the practice-based sector 1 specialist with corresponding cross staff provision)* The names of the specialists are to be given.

 Experience examining physician:* Coloscopies: 200 patients annually
* Polypectomies (only loop): 25 patients annually
 |  |  |
|  | Authorisation of new examining physicians in the last 3 years at least 200 coloscopies and 50 polypectomies (only loop). |  |  |
|  | Each coloscopy and polypectomy is to performed/supervised by an examining physician who has the above-mentioned experience. |  |  |
|  | AssistanceRecognition as an assistant is possible if this is done as part of the training (no parallel recognition of cases with 2 named examiners) |  |  |
| 2.2.2 | Performance coloscopy* Signed declared consent
* Patient monitoring

Pulse oxymetryDocumentation using surveillance sheet after examination with sedation* Photo documentation

Completeness of the examination(ileocecal valve, cecal pole, terminal ileum)Polyp removal points (before - after)* Aftercare recommendation
* Timing control coloscopy
 |  |  |
| 2.2.3 | Complications* Reference to possible complications after coloscopy (information material)
* Recording / evaluation complication rates
 |  |  |
| 2.2.4 | Requirements coloscopy* Full coloscopy with biopsy of each suspected spot including a rectal examination
* Comparison with the results of the referrer
 |  |  |
| 2.2.5 | 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 Colorectal Cancer Centre.

- Names of contacts- Definition passing on of information |  |  |
| 2.2.6 | 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
 |  |  |
| 2.2.7 | Presentation in the tumour boardEach carcinoma in the adenoma must be presented in the tumour board. |  |  |
| 2.2.8 | Communication of results polypectomyIn-person discussion/information about malignant findings (not on the phone) by coloscopy unit or GP |  |  |
| 2.2.9 | Infrastructure/work environment* Emergency equipment

Available emergency equipment and written action plan for emergencies* Preparation, sterilisation and traceability of instruments
* Compliance with the RKI recommendation for the preparation and sterilisation of flexible endoscopes (inter alia traceable batch documentation of preparation and sterilisation)
 |  |  |
| 2.2.10 | DiagnosticsThe MSI test should be carried out:* according to the GL algorithm for positive patient questionnaires with mainly hereditary CRC (GL CRC: "Algorithm: Genetic Diagnosis and Prevention")
* in patients between 50 and 60 years of age with MSI-suspected histology
* for mcRC, optional for the definition of the therapeutic strategy
* before adjuvant chemotherapy in stage II if indicated
 |  |  |
| 2.2.11- Anal - | Qualification Proctoscopy and Endosonography anorectal* Specialist in general or visceral surgery or
* Specialist in internal medicine and gastroenterology or
* Specialist in dermatology,

in each case with additional further training in Proctology according to the model further training regulations (MWBO) or European additional qualification EBSQ coloproctology  Requirement for pre-therapeutic documentation of findings:The tumour should be delimited about its location (indicated in lithotomy position (German: SSL)), maximum diameter, perianal and intraanal extension (in cm and positional relationship to the L. anocutanea and L. dentata), mobility and with regard to infiltration of other organs, especially the sphincter apparatus and, for women, the vagina. |  |  |

# 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 polypectomies (only loop)≥ 25 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 CR)

| 3. Radiology |
| --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 3.1 | Specialists* At least 1 radiology specialist
* Cover arrangements with the same qualification is to be documented in writing.
* Specialists and their cover staff are to be designated by name.
 |  |  |
| 3.2 | Radiology RTAs:At least 2 qualified RTAs must be available and their names given. |  |  |
| 3.3 | Radiology methods/ devices to be offered* conventional X-ray
* spiral-CT
* MRI (field strength at least 1.5 tesla) (only for Anal Cancer, multiparametric MRI, angulated on Anal Canal)
 |  |  |
| 3.4 | Standard operating procedures (SOPs) for radiologyThe imaging techniques are to be described and checked once a year to ensure they are up to date. |  |  |
| 3.5 | DiagnosisThe written report of the radiologists must be available to the co-attending physicians at the latest 24 h after the test. |  |  |
| 3.6 | Continuing education/specialty training* A training plan for medical and nursing staff is to be presented listing the planned training courses for the period of one year.
* At least 1 dedicated continuing education/specialty training course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre.
 |  |  |

|  |
| --- |
| 4. Nuclear medicine |
| Section | Requirements | Explanatory remarks of the Centre |  |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents. For the Visceral Oncology Centres this section does not specify any Technical and Medical Requirements. |  |  |

| 5. Surgical oncology**5.1** **General surgical oncology** |
| --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents. For the Visceral Oncology Centres this section does not specify any Technical and Medical Requirements. |  |  |

| **5.2** **Organ-specific surgical therapy** |
| --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 5.2.1 | Inpatient careDesignation of the wards (centralisation should be the goal when there are several wards) |  |  |
| 5.2.2 | Post-operative careCare 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
 |  |  |
| Discharge (in case of stoma therapy)* Further outpatient care after discharge in the case of stoma therapy must be described, including the provision of information for patients.
* Patients should be informed about post-resection syndrome (LARS - low anterior re-section syndrome) before the first operation.
* If possible, an outpatient consultation should be offered after stoma repositioning, in which, among other things, the LARS score is measured.
 |
| 5.2.3 | Surgical capacityAt least 1 operating theatre must be regularly available for surgical procedures. |  |  |
| 5.2.4 | Surgical expertise Centre |  |  |
|  | Surgical expertise colorectal* 30 surgical primary cases colon
* 20 surgical primary cases rectum

 If the number of primary rectal surgical cases falls below the threshold, patients listed in the Data Sheet as "Watch and Wait" can be added to the number of primary rectal surgical cases during surveillance and repeat audits. At least 17 primary surgical cases with rectal cancer must be proven.For the definition of primary cases, see the last page of this survey form. | Data sheet colorectal(Excel template) |  |
| - Anal - | Operative expertise Anal CancerDefinition of surgical resection: OPS 5-485\* or 5-49\*\*\*, each in combination with ICD C21 or C.44.50 | Data Sheet Anal Cancer(Excel template) |  |
| 5.2.5 | Colorectal surgeons2 colorectal surgeons must be named.Basic qualification is that of a specialist in visceral surgery with specialty training in special visceral surgery (from *Muster-WbO* 2003 [Model Training Ordinance] on, version dated 25 June 2010). The following are also recognised: qualification as a specialist in visceral surgery according to an older model training ordinance or with subspecialisation in visceral surgery according to an older model training ordinance or specialist in general surgery with the European EBSQ Coloproctology qualification. The qualifications of a specialist in general surgery or specialist in visceral surgery without specialty training according to *MWbO* 2010 or later are not recognised. |  |  |
|  |  |  |  |
|  | Expertise per colorectal surgeon (primary cases)15 colon carcinomas per year10 rectal carcinomas per year* Approval of new colorectal surgeonsAt least 20 rectal and at least 30 colorectal carcinomas cumulatively over the last 3 years as first (leading) surgeon (documented in surgical reports).
* AssistantsRecognition as an assistant is only possible in the context of training (no parallel recognition of cases if there are 2 colorectal surgeons).
* All patients in the CrCC must be operated on by one of these surgeons either directly or under his/her supervision (second surgeon).
 |  |  |
|  | Senior colorectal surgeon (optional/alternative)* Maximum 1 senior colorectal surgeon per Centre (not per clinical site)
* An application for assessment of qualification must be submitted to OnkoZert
* Centre is responsible for appointment (dependent on a positive qualification assessment by OnkoZert)
* Annual rotation is possible
 |  |  |
|  | Expertise of senior colorectal surgeon (primary cases)* In the case of appointment45 colon carcinomas and 30 rectal carcinomas in the last 5 years
* In the case of extensionQualification certificate valid for 5 years; requirement for extension is 45 colon carcinomas and 30 rectal carcinomas in the last 5 years
 |  |  |
| - Anal - | Anal Cancer SurgeonSpecialist in general or visceral surgery with addi-tional training in proctology according to the model further training regula-tions (MWBO) or additional European qualification EBSQ colo-proctology.At least 2 anal cancer surgeons must be named (anal cancer surgeon can also be a colon/pancreas/stomach/liver/oesophagus surgeon). |  |  |
| 5.2.6 | 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)
 |  |  |
| 5.2.7 | Lymph nodes |  |  |
|  | Surgically removed lymph nodesThe right oncological decision is to operate (inter alia at least 12 lymph nodes). Any deviation from this is to be discussed with the pathologist. |  |  |
| 5.2.8 | Induction of new staff membersSystematic, documented induction of new staff members is to be ensured, which imparts knowledge about the Oncology Centre's respective field of activity.* This induction must take place within three months of commencement of employment.
 |  |  |
| 5.2.9 | 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. |  |  |
| 5.2.10 | Continuing education/specialty training* A training plan for medical and nursing staff is to be presented listing the planned training courses for the period of one year.
* Every year at least 1 dedicated continuing education/specialty training session for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre.
 |  |  |

Table "Colorectal surgeons"

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Title, name, first name | Has basic qualification 1)yes/no | Senior colorectal surgeon 2)yes/no | Period 3)from … to | Number surgical procedures 4)colon ≥ 15 | Number surgical procedures 4)rectum ≥ 10 | Clinical site/clinic 5) |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

# Table “Anal surgeons”

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title, name, first name | Has basicqualification 1)yes/no | Period 3)from … to | Number of surgical procedures esophagus ≥ 10 | Clinical site/clinic 5) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. Precondition for basic qualification (in line with CR Section 5.2.5): specialist for visceral surgery with additional specialty training visceral surgery (from Model Specialty Training Ordinance 2003, status 25.06.2010). The following are deemed to be equivalent: specialist for visceral surgery or focus visceral surgery in line with older Model Specialty Training Ordinances. The following are likewise deemed to be equivalent: for the organ colon/rectum the specialist for general surgery with the European qualification EBSQ Coloproctology, for the organs pancreas and liver the specialist for general surgery with the European qualification EBSQ Hepato-Pancreatico-Biliary Surgery (HPB). The following qualifications are not recognised: specialist for general surgery or specialist for visceral surgery without specialty training in line with the Model Specialty Training Ordinance 2010 or later. For Anal Cancer: Specialist in general or visceral surgery with additional training in proctology according to the model further training regula-tions (MWBO) or European additional qualification EBSQ coloproctology.
2. Precondition senior colorectal surgeon (as specified in CR 5.2.5): positive qualification evaluation by OnkoZert and appointment by the Colorectal Cancer Centre (max. 1 senior colorectal surgeon per Centre)
3. 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 CR)
4. There is no annual expertise requirement for senior colorectal surgeons
5. 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. Medicinal Oncology / Systemic therapy**6.1** **Medical oncology** |
| --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents. For the Visceral Oncology Centres this section does not specify any Technical and Medical Requirements. |  |  |

| **6.2**  **Organ-specific systemic therapy** |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 6.2.1 | Physicians' qualificationsSpecialist for internal medicine and haematology and oncology or specialist for internal medicine and gastroenterology or specialist for radiotherapyThe 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. |  |  |
| 6.2.2 | Specialist nurse (outpatient/inpatient)Requirements for a specialist nurse who is responsible for administering chemotherapy:* at least 1 year's professional experience in oncology
* 50 chemotherapy administrations/year are to be documented (In the case of initial certification an estimate can be given, in the following years this must be documented in the audit).
* documentation of training in line with the recommendations of the Conference of Oncological Nursing and Paediatric Nursing Care (Konferenz Onkologischer Kranken- und Kinderkrankenpflege - KOK) (KOK recommended actions, administration of cytostatics by specialised nurses)
* active involvement in the implementation of the requirements to be met by emergency treatment and therapy of comorbidities and secondary diseases
* nursing counselling and/or education of patients is to be documented.
 |  |  |
| 6.2.3 | 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 | Case numbers per treatment unit* Calculation method: completed systemic / cytostatic / targeted therapy per patient (consisting of several cycles or applications, combined therapies count as one therapy). For therapies lasting over a year, the therapy started in the audit year counts. 1 therapy per patient = 1 therapy line per disease per patient.
* In the event of a shortfall, expertise cannot be documented via cooperation (must be documented for each individual treatment unit).

 At least 200 drug tumour therapy sessions (cytostatic therapies and / or targeted therapeutics and / or AB / immune therapies, no hormone therapies) a year **or** |  |  |
|  | at least 50 patients with a specific indication(colon/rectum) |  |  |
| 6.2.5 | Structural details per treatment unit* Number of therapy places outpatient
* Number of therapy places inpatient
 |  |  |
| 6.2.6 | Basic diagnosis laboratoryBasic 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. |  |  |
| 6.2.7 | Basic diagnosis medical imagingCooperation 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. |  |  |
| 6.2.8 | Treatment plan/tumour board minutes* The therapeutic procedure should be oriented towards the treatment plans or recommendations of the tumour board.
* The treatment plan/tumour board minutes must be available in the documentation for each patient.
* If there are any deviations from the recommended treatment plan, then they are to be presented at the tumour board.
 |  |  |
| 6.2.9 | 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.
 |  |  |
| 6.2.10 | Cytostatic preparation* Production is undertaken with due consideration of statutory provisions (inter alia Medicinal Products Act (AMG), GMP, GCP, Eudralex (Volume 10) 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.
 |  |  |
| 6.2.11 | 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.
 |  |  |
| 6.2.12 | Standards comorbidities and secondary diseasesStandards are to be drawn up for the treatment of comorbidities and secondary diseases, in particular for the treatment of paravasates, infections and thromboembolic complications. |  |  |
| 6.2.13 | Emergency treatmentAvailable emergency equipment and written action plan for emergencies |  |  |
| 6.2.14 | Case-related information/dialogue with patientAdequate information must be provided about diagnosis and therapy planning and a consultation is to be given. This includes inter alia:* Presentation of alternative treatment concepts
* Offer of and aid in obtaining second opinions
* Discharge consultation as a standard procedure

 Patient consultations are to be documented for each patient in medical reports or in other minutes/records. |  |  |
| 6.2.15 | Information therapy administration/planningAfter each administration of systemic therapy, the patient and/or the physician responsible for further treatment are given information about the current therapy status and the next steps (blood test, ...), e.g. via the aftercare pass. Preparation medical reportAfter the completion of systemic therapy (last administration) the physician responsible for further treatment or the co-attending physician is given the final report within 7 days. |  |  |
| 6.2.16 | Induction of new staff membersSystematic, documented induction of new staff members is to be ensured, which imparts knowledge about the Oncology Centre's respective field of activity.This induction must take place within three months of commencement of employment. |  |  |
| 6.2.17 | Continuing education/specialty training* A training plan for medical and nursing staff is to be presented listing the planned training courses for the period of one year.
* At least 1 dedicated continuing education/specialty training course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre.
 |  |  |

| **7** **Radio-oncology** |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 7.0 | The Technical and Medical Requirements to be met by radio-oncology are summed up in the "Catalogue of Requirements Radio-Oncology" in a cross-organ manner. Independently of the number of Organ Cancer Centres / Modules, which work with a radio-oncology unit, this "Cata-logue of Requirements Radio-Oncology" is only to be processed once and also only updated once per audit year (goal: no multiple presentations or on-site inspections within one audit year). The "Catalogue of Requirements Radio-Oncology" therefore constitutes an annex to this Catalogue of Requirements. Download cross-organ "Catalogue of Require-ments Radio-oncology" on <www.ecc-cert.org> and <www.onkozert.de>. |  |  |

| **8** **Pathology** |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 8.0 | The Technical and Medical Requirements to be met by pathology are summed up in the "Catalogue of Requirements Pathology" in a cross-organ manner. Independently of the number of Organ Cancer Centres / Modules, which work with a pathology, this "Catalogue of Requirements Pathology" is only to be processed once and also only updated once per audit year (goal: no multiple presentations or on-site inspections within one audit year). The "Catalogue of Requirements Pathology" therefore constitutes an annex to this Catalogue of Requirements. Download cross-organ "Catalogue of Requirements Pathology" on <www.ecc-cert.org> and <www.onkozert.de>. |  |  |

| **9.** **Palliative and hospice care** |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 9.1 | * Documentation is to be provided of cooperation agreements with service providers offering specialist outpatient and inpatient palliative care and inpatient hospices. Regional care concepts for the integration of palliative care are to be described on the basis of the treatment pathway for patients and family members from the S3 Guidelines Palliative Medicine (Figure 3, p. 174) with the names of all involved persons.
* A physician with additional specialty training must be available for consultations and tumour boards.
* The group of patients with incurable cancer is to be defined. They are to be informed in a timely manner about palliative medical support services (SOP).
* To identify the treatment requirement, it is necessary to carry out a screening to record symptoms and stress (see S3 guideline on palliative care)(e.g. MIDOS, iPOS).
* The access to palliative care can be offered in parallel to tumour-specific therapy. The procedure in the Centre is to be described in an SOP.
* The number of primary cases with incurable cancer is to be documented.
 |  |  |
| ~~9.2~~ | ~~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 (according to chapter 1.9) is to be described and confirmed using documented cases for the assessment period.~~
* ~~Access to psycho-oncological and psycho-social 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.~~

*The requirement was moved to chapter 1.2.10* |  |  |

| **10.** **Tumour documentation/Outcome quality** |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 10.1 | Requirements tumour documentation Tumour documentation, which contains the patient data for a minimum period of 3 months, must be in place at the time of initial certification. Name of the tumour documentation system in a cancer registry and/or Centre A data set must be used in line with the Uniform Oncological Basic Data Set and the modules of the Working Group of German Tumour Centres (ADT) and the Association of Population-based Cancer Registries in Germany (GEKID).The Centre must ensure that data are transferred to the competent cancer registry in a timely manner. Any existing regional laws for notification deadlines are to be complied with. |  |  |
| 10.2 | Period covered by the dataThe full data are to be presented for the respective last calendar year. |  |  |
| 10.3 | Cooperation with cancer register* Cooperation with the competent 65c cancer registry is to be documented on the basis of the cooperation agreement.
* The OncoBox is to be fed by the competent cancer registry. The full data are to be made available to the cancer register in an ongoing manner.
* The presentation of the Catalogue of Re-quirements and outcome quality should be ensured via the cancer registry to the extent that this information is of relevance for the cancer registry.
* As long as the competent cancer registry is unable to meet the requirements imposed, the Centre is to use additional or alternative solutions. The Centre is responsible in the case of a non-functioning external solution. If the responsible cancer registry is unable to provide the follow-up data, the cancer registry and centre should explain in writing why the data cannot be provided.
 |  |  |
| 10.4 | Documentation officerThe 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.
* 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.
 |  |  |
| 10.5 | Provision of resources:The required staff capacity should be made available (for instance 0.5 full-time position for 200 primary cases and 0.1 full-time position for 200 aftercare cases) to perform the documentation tasks and to record data (e.g. by a cancer registry). |  |
| 10.6 | The tumour documentation system must offer the following selection options:* Cohorts
* TNM classification or comparable classifications and prognosis factors
* Forms of therapy (surgical therapy, radiotherapy, hormone therapy, immunotherapy, chemotherapy)
* Date of recurrence/metastasis
* Deaths
* Follow-up status (latest update)
 |  |  |
| 10.7 | Indicators for outcome quality/scale of aftercare data: Kaplan-Meier curves:* Overall survival (OAS) for all patients in sub-groups by pT categories, stages
* metastasis-free survival for all patients and subgroups
* Progression-free survival or disease-free survival for all patients and subgroups
* Local recurrence rate for all patients and for subgroups
* Survival after progression (PDS)

 * At the start all cohorts are to be grouped together (3 years). In the case of larger patient numbers and outcome numbers, several cohorts can be evaluated separately.
* A table with patient numbers and survival data is a component of each Kaplan-Meier curve.
 |  |  |
| 10.8 | Data evaluation* The depiction of outcome quality (see point above) must be possible for re-certifications.
* The data in the tumour documentation system are to be evaluated at least once a year in line with the corresponding parameters.
* If benchmarking/an annual report is offered, the benchmarking results are to be taken into account in the analysis.
* Concrete actions are to be derived from the analysis.
* The discussion of results must be done in an interdisciplinary manner and in cooperation with the Centres in the network within the Visceral Oncology Centre.
 |  |  |
| 10.9 | Requirements for the follow-up of patients recorded in the matrix Outcome quality (valid from first surveillance audit after first re-certification) |  |  |  |  |
| Minimum requirement for successful recertification≥ 80 % |  | ≥ 80 % |  |
| Recertification or maintenance of certification only possible subject to conditions (e.g. reduced validity term, concept for increasing the return rate).60 – 79 % |  | 60 – 79 % |  |
| Certification was not reconfirmed or maintained.< 60 % |  | < 60 % |  |

**Data Sheet**

A structured EXCEL Data Sheet (= Excel template) is available to Centres to record the indicators and data on outcome quality. This EXCEL Data Sheet (=EXCEL template) also contains an automatic evaluation of data quality. Only those presentations of indicators are eligible for certification which are undertaken on the basis of this Data Sheet made available by OnkoZert. No changes may be made to the Data Sheet.

The Data Sheet can be downloaded from <http://ecc-cert.org/> and [www.onkozert.de](http://www.onkozert.de/).

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| **Period** | General information for processing the annex* The actual current values are to be given (no estimates).
* Data must normally refer to a calendar year.
* Data may be no older than 1 year (data from 2008 are not acceptable for an audit in 2011).
* if the "target values" are not achieved for one point, then an explanation is to be given at the corresponding spot in the Catalogue of Requirements
 | Definition period initial certifications* At the time of initial certification, the data must be available at least for a period of 3 months (an entire year is ideal); in the case of information on primary cases (CR 5.2.4), surgical procedures per surgeon (CR 5.2.5) and experience of examining physicians (CR 2.2.1), the data for an entire year are always needed
* If a full calendar year is not depicted, the period may be more than 4 full months beforehand (based on the certification date).
* The selected period must consist of full months (if possible select full quarters)
 |

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| **Primary case definition**- Colorectal – |  |  |
| Total primary cases for the Colorectal Cancer Centre are the sum of the types of primary cases given below.* Malignant diagnosis (adenocarcinoma) must be available
* Requirements tumour board, tumour documentation and aftercare are valid in full.

Types of primary cases* only endoscopic
* surgical
* palliative (not surgical)
* watch and wait (not surgical curative, not endoscopic)
 | Primary case definition (only endoscopic)* No additional surgical tumour removal
* Time of counting endoscopic removal

Primary case definition (surgical)* Malignant first diagnosis rectum (up to 16 cm from an cutaneous line)/colon
* Resecting surgical care (stoma installation alone is not sufficient)
* Transanal total wall excision
* Time of counting = date of surgical tumour removal

Primary case definition palliative (not surgical)* No surgical tumour removal planned
* Time of counting is date of histology report

Primary case definition watch and wait* Watch and wait patients have newly diagnosed rectal carcinomas which are not initially going to undergo surgical treatment after radiotherapeutic and/or chemotherapeutic pre-treatment in the case of full clinical remission. When these patients undergo secondary surgery in the event of tumour recurrence or for other reasons, they count as surgical primary cases.
* Time of counting is date of histology report
 | The following, *inter alia*, are not recognised as surgical primary cases:* Anal cancer
* Palliative bypass surgery
* High-grade intraepithelial neoplasms
* Palliative stoma installation
* Neoadjuvant chemotherapy (tumour has still to be removed surgically)
* Port implantation(tumour has still to be removed surgically)
* Recurrence
* Metastasis surgery
 |