

# FAQs

## Catalogue of Requirements for the Visceral Oncology Centres

of the German Cancer Society (*Deutsche Krebsgesellschaft - DKG*)

**Chairs of the Certification Committee:** Prof. Dr. J. Mayerle, Prof. Dr. S. Post

Within the framework of the certification procedure, questions regularly crop up which require an explanation of the Technical and Medical Requirements. This document contains answers to the questions which the centres can refer to when implementing, and the experts can refer to when assessing the Technical and Medical Requirements.

### Version FAQ and Catalogue of Requirements (CR)

Version status FAQ: 14.09.2023

The FAQs in this document refer to the following documents which are now in force:

|   |              |            |
|---|--------------|------------|
| Catalogue of Requirements<br>Viszeral   | Version N1   | 14.09.2023 |
| Catalogue of Requirements<br>Colorectal | Version N1   | 14.09.2023 |
| Indicator Sheet Colorectal              | Version N1.1 | 14.09.2023 |
| Indicator Sheet Pancreas                | Version N1.1 | 14.09.2023 |
| Indicator Sheet Stomach                 | Version N1.1 | 14.09.2023 |
| Indicator Sheet Liver                   | Version N1.1 | 14.09.2023 |
| Indicator Sheet Esophagus               | Version N1.1 | 14.09.2023 |
| Indicator Sheet Anal Cancer             | Version N1.1 | 14.09.2023 |

## Overview of FAQs

### Catalogue of Requirements

| Section CR                                |        | Requirement   | Last update |
|---|--------|---|-------------|
| 1.2 Interdisciplinary cooperation         | 1.2.0  | Pancreas: Number of primary cases                   | 03.05.2023  |
| 1.2 Interdisciplinary cooperation         | 1.2.0  | Stomach: Number of primary cases                    | 22.04.2021  |
| 1.2 Interdisciplinary cooperation         | 1.2.0  | Esophagus: Number of primary cases                  | 10.07.2018  |
| 1.2 Interdisciplinary cooperation         | 1.2.9  | Therapy deviation                                   | 09.04.2021  |
| 1.4 Psycho-oncology                       | 1.4.1  | Psycho-oncology – qualifications                    | 24.10.2018  |
| 1.4 Psycho-oncology                       | 1.4.2  | Psycho-oncology – Offer and access                  | 28.08.2023  |
| 1.7 Study management                      | 1.7.6  | Proportion study patients                           | 16.08.2022  |
| 1.8 Nursing care                          | 1.8.5  | Colorectal: Stomatherapy – Staff                    | 30.11.2018  |
| 1.8 Nursing care                          | 1.8.6  | Colorectal: Stomatherapy – Definition of tasks      | 28.08.2019  |
| 1.9 General service areas                 | 1.9.2  | Nutritional counselling                             | 03.05.2023  |
| 2.1 Consulting hours                      | 2.1.5  | Colorectal: Height localisation rectum              | 26.11.2020  |
| 5.2 Organ-specific surgical therapy       | 5.2.4  | Pancreas: Surgical expertise pancreas               | 22.04.2021  |
| 5.2 Organ-specific surgical therapy       | 5.2.4  | Stomach: Surgical expertise stomach (primary cases) | 22.04.2021  |
| 5.2 Organ-specific surgical therapy       | 5.2.4  | Liver: Surgical expertise                           | 22.04.2021  |
| 5.2 Organ-specific surgical therapy       | 5.2.4  | Esophagus: Surgical expertise esophagus             | 22.04.2021  |
| 5.2 Organ-specific surgical therapy       | 5.2.10 | Stomach: Expertise for each endoscopic surgeon      | 22.04.2021  |
| 10 Tumour documentation / Outcome quality | 10.3   | Cooperation with cancer register                    | 05.10.2017  |

### Indicator Sheet (=Excel-Vorlage)

|        | Indicator   | Last update |
|--------|---|-------------|
| 6      | Pancreas: Patients enrolled in a study  | 29.09.2022  |
| 7a / b | Pancreas: Endoscopy complications   | 14.07.2016  |
| 15     | Pancreas: Pathology reports   | 14.07.2016  |
| 7      | Stomach: Patients enrolled in a study   | 29.09.2022  |
| 3a     | Liver: Post-surgical presentation in tumour board   | 03.04.2019  |
| 3b     | Liver: Post-intervention presentation in tumour board   | 03.04.2019  |
| 7      | Liver: Patients enrolled in a study.  | 29.09.2022  |
| 10     | Liver: mRECIST/EASL classification according to TACE/TAE  | 03.04.2019  |
| 11b    | Liver: Complications after percutaneous radiofrequency ablations (RFA) + microwave ablation (MWA) | 05.10.2017  |
| 12a    | Liver: Number of complex surgical interventions   | 03.04.2019  |

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| 8 | Esophagus: Patients enrolled in a study            | 23.11.2021 |
| 3 | Anal Cancer: Psycho-oncological Distress Screening | 16.08.2022 |
| 5 | Anal Cancer: Patients enrolled in a study          | 29.09.2022 |

Interpretations regarding the indicators colorectal are not shown in this document, as the FAQs for this organ are stored in the specification document.

Download: <http://www.xml-oncobox.de/de/Zentren/DarmZentren>

Color legend „black“ .... relevant for all organs

Only relevant for „Colorectal“

Only relevant for „Pancreas“

Only relevant for „Stomach“

Only relevant for „Liver“

Only relevant for „Esophagus“

Only relevant for „Anal Cancer“

## FAQs - Catalogue of Requirements Visceral

### 1.2 Interdisciplinary cooperation

| Section      | Requirements   |  |  |
|--------------|--|--|--|
| 1.2.0        | Number of primary cases  |  |  |
| -Pan-creas - | <p>The Centre must treat 25 patients annually with a primary diagnosis of pancreatic cancer (ICD-10 C 25).</p> <p>Definition:</p> <ul style="list-style-type: none"> <li>• Patients and not stays or surgical procedures</li> <li>• Adenocarcinomas, neuroendocrine carcinomas are counted. IPMNs (intraductal papillary mucinous neoplasms) are not counted.</li> <li>• Histological/cytological findings must be available (biopsy or resection) from primary tumour or metastasis with concomitant presence of a pancreatic tumour in medical imaging.</li> <li>• Patients with initial disease (incl. primary M1) who are presented at the centre or the tumour board and receive essential parts of the therapy there</li> <li>• The time of counting is the time of the histological confirmation of diagnosis</li> <li>• Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not included.</li> </ul>  | <p><a href="#">FAQ (05.10.2017)</a><br/>Does carcinosarcoma of the pancreas count as a primary case?</p> <p>Answer:<br/>Yes.</p> <p><a href="#">FAQ (03.05.2023)</a><br/>Can solid pseudopapillary neoplasia of the pancreas (Frantz tumour) be counted as a primary case?</p> <p>Answer:<br/>Solid pseudopapillary neoplasms of the pancreas (Frantz tumours) do not count as primary cases, but can be considered for surgical expertise in the case of surgical treatment.</p>  |  |
| - Stomach -  | <p>The Centre must treat 30 patients annually with a primary diagnosis of an adenocarcinoma of the stomach and of the esophagogastric junction (ICD-10 C, 16.0<sup>1</sup>, 16.1-16.9). If the Centre is not certified as an esophageal cancer centre at the same time, the ICD-10 C 15.2 and 15.5 and 16.02<sup>2</sup> can be included in the scope of the stomach cancer centre.</p> <p>Definition:</p> <ul style="list-style-type: none"> <li>• Patients and not stays or surgical procedures</li> <li>• Histology / cytology report must be available (biopsy or resection).</li> <li>• Patient with initial disease</li> <li>• The time of counting is the time of the histological confirmation of diagnosis</li> <li>• Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not included.</li> </ul> <p><sup>1</sup> Tumours, whose centre is &gt; 2 cm from the esophagogastric junction, are classified as gastric carcinomas even if the esophagogastric junction is affected.</p> <p><sup>2</sup> Tumors that involve the esophagogastral junction and their center within the prox. 2 cm of</p> | <p><a href="#">FAQ (06.07.2020)</a><br/>Does squamous cell carcinoma in the lower third (C15.5) or abdominal portion (C15.2) of the esophagus count towards the Gastric Cancer Centre?</p> <p>Answer:<br/>ICD-10 C 15.2 and 15.5 can only be included in the scope of the gastric cancer centre if it is an adenocarcinoma (no recognition of squamous cell carcinoma) and there is no certified oesophageal cancer centre. In the case of a parallel certified gastric and Esophageal Cancer Centre, ICD-10 C 15.2 and C 15.5 only count for the Esophageal Cancer Centre.</p> <p><a href="#">FAQ (14.07.2016)</a><br/>Are patients with a GIST also recognised as primary cases?</p> <p>Answer:<br/>Patients with a GIST are not recognised as primary cases. GIST is a different tumour entity and should not be confused with adenocarcinomas of the stomach. The S3</p> |  |

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|              | <p>the esophagogastral junction (proportion Siewert type I / Siewert type II) is counted as esophageal carcinoma.</p>  | <p>guideline on gastric cancer does not cover the tumour entity GIST.</p> <p><u>FAQ (05.10.2017)</u><br/>The findings usually report cm from the dentition. Does the abdominal portion of the esophagus begin below the diaphragm?</p> <p>Answer:<br/>Yes. Tumours involving the oesophagogastric junction and centred within the proximal 2 cm of the oesophagogastric junction. (Siewert type I/ Siewert type II proportion) are counted as oesophageal carcinomas.</p> <p><u>FAQ (05.10.2017)</u><br/>Do distal oesophageal carcinomas that do not extend into the oesophagogastric junction count as primary cases or are only AEG tumours and gastric carcinomas considered?</p> <p>Answer:<br/>Tumours whose centre is &gt; 2 cm from the oesophagogastric junction are classified as gastric carcinomas, even if the oesophagogastric junction is included</p> <p><u>FAQ (10.07.2018)</u><br/>Which carcinomas of the gastro-esophageal junction (= AEG tumours) are assigned to the stomach and which to the esophagus?</p> <p>Answer:<br/>According to the clinical classification Siewert I-III, Siewert I and II carcinomas are assigned to the esophagus, carcinomas type Siewert III to the stomach (prior to neoadjuvant therapy determination by endoscopist required).</p> <p><u>FAQ (22.04.2021)</u><br/>May a "mixed adeno-neuroendocrine carcinoma" and an "adenosquamous carcinoma (8244/3)" and an "adenosquamous carcinoma of the stomach (8560/3)" be counted as a primary case for the Gastric Cancer Centre.</p> <p>Answer:<br/>Yes, provided that a proportion of adenocarcinoma can be detected, counting as a primary case is possible.</p> |  |
| - Esophagus- | <p>The Centre must treat 40 patients annually with the diagnosis of a high-grade dysplasia (HYIEN, HGD) or an invasive squamous cell carcinoma or an esophageal adenocarcinoma (= Centre cases).</p> | <p><u>FAQ (10.07.2018)</u><br/>Which carcinomas of the gastro-oesophageal junction (= AEG tumours) are assigned to the stomach and which to the esophagus?</p>  |  |

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|  | <p>of which at least 20 patients with a primary diagnosis<br/>(ICD-10 C15, 16.0<sup>2</sup>, D00.1 (HGD, HGIEN))<br/>Definition primary diagnosis:</p> <ul style="list-style-type: none"> <li>• Patients and not stays or surgical procedures</li> <li>• Patient with initial disease (incl. primary M1)</li> <li>• The time of counting is the time of the histological/imaging confirmation of diagnosis</li> <li>• Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not included.</li> </ul> <p><sup>2</sup> Tumours that affect the esophagogastric junction and whose centre is within the prox. 2 cm of the esophagogastric junction (proportion Siewert type I/Siewert type II), are counted as esophageal carcinomas.</p> | <p>Answer:<br/>According to the clinical classification Siewert I-III, Siewert I and II carcinomas are assigned to the esophagus, carcinomas type Siewert III to the stomach (prior to neoadjuvant therapy determination by endoscopist required).</p> |
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#### 1.4 Psycho-oncology

| Section                  | Requirements   |  |
|--------------------------|--|--|
| <p>1.4.1<br/>- All -</p> | <p>Psycho-oncology – qualifications</p> <ul style="list-style-type: none"> <li>• Qualified psychologists / Master in Psychology, which qualifies for a scientifically recognised psychotherapy procedure or</li> <li>• physicians</li> <li>• Diploma/master's degree in social pedagogy qualifying for a scientifically recognised psychotherapy</li> </ul> <p>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).</p> <p>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).</p> <p>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.</p> <p>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.</p> | <p>FAQ (24.10.2018)<br/>Can the further training "Systemic Therapist" be recognised as psychotherapeutic further training?</p> <p>Answer:<br/>The further training "Systemic Therapy" can be recognised.</p> |

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|                  | <p>The assumption of psycho-oncological tasks by the social services, self-help groups or pastoral care is not sufficient. They supplement psycho-oncological care.</p> <p>The process of patient care in the centre (screening, evaluation of screening results, care) must be demonstrated in the audit based on examples.</p>  |  |  |
| 1.4.2<br>- All - | <p>Psycho-oncology – Offer and access<br/>Each 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.</p> <p>Documentation and evaluation<br/>To identify treatment needs, screening of mental strain must be undertaken (see Indicator "Psycho-oncological distress screening") ) and the outcome is to be documented. The proportion of patients with excessive stress in the distress screening should be presented.</p> <p>Psycho-oncological counselling<br/>Psycho-oncological care, in particular for patients with excessive stress in the distress screening, must be presented.</p> | <p><u>FAQ (28.08.2023)</u><br/>How should the proportion of patients with higher levels of distress in the distress screening and further psycho-oncological care be presented?</p> <p>Answer: It must be shown how many screened patients had an above-threshold test.</p> <p>The processes of psycho-oncological care must be described; the number of counselling sessions carried out should be recorded.</p> <p>A separate FAQ document on psycho-oncology (Catalogue of Requirement and Indicators) is expected to be published in early 2024.</p> |  |

## 1.7 Study management

| Section          | Requirements   |   |  |
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| 1.7.6<br>- All - | <p>Proportion study patients</p> <ol style="list-style-type: none"> <li>Initial certification: At the time of initial certification <math>\geq 1</math> patients must have been included in studies (guidance value: <math>\leq 6</math> months prior to certification)</li> <li>after 1 year: at least 5% of the primary case number</li> </ol> <p>The requirement applies to each tumour entity.</p> <p>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.</p> <p>All study patients can be taken into account when calculating the study rate (share study patients based on the Centre's primary case number).<br/>General preconditions for the definition of the study quota:</p> <ul style="list-style-type: none"> <li>Patients can be counted 1x per study, time: date of patient consent.</li> <li>Patients in a palliative and adjuvant situation can be counted, no limitations regarding stage of disease.</li> <li>Patients for colorectal prevention studies can be counted.</li> </ul> | <p><u>FAQ (05.10.2017)</u><br/>Does the requirement of "1 patient at initial certification" also apply to the modules of the Visceral Oncology Centre?</p> <p>Answer:<br/>If no patient is included in studies at the initial certification of the pancreas, stomach, liver and esophagus modules, the centre must prove its activity for study inclusion and at the same time fulfil the study quota for the colorectal cancer centre. A certificate can only be granted under certain conditions (reduced validity). By the 1st surveillance audit, 1 patient per module must be included in studies.</p> <p><u>FAQ (16.08.2022)</u><br/>Can negatively screened study patients be counted?</p> <p>Answer:<br/>Patients who have signed a consent form for screening for study participation can be counted for the numerator of the respective study indicator, even if study participation of the patient is not possible due to the results of screening examinations carried out with special diagnostics (no routine diagnostics).</p> |  |



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|  | <ul style="list-style-type: none"> <li>Patients who are taking part in several studies simultaneously can be counted several times.</li> <li>Patients in the follow-up of a study are no longer included in the study rate.</li> </ul> | <p>FAQ (03.05.2023)<br/>Can patients referred to a Centre for Personalised Medicine (CPM) for the purpose of complex diagnostics, interdisciplinary consultation and individual therapy recommendations who participate in a study there be counted towards the study quota of the sending centre?</p> <p>Answer:<br/>Yes, in this case the study inclusion can be counted by both the sending centre and the CPM. The other requirements for study inclusion apply in accordance with the Catalogue of Requirements.</p> |  |
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## 1.8 Nursing care

| Section                             | Requirements  |   |  |
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| <p>1.8.5</p> <p>- Colo-rectal -</p> | <p><b>Stomatherapy – Staff</b><br/>Qualification head of stomatherapy<br/>Qualified representative is to be ensured.<br/>Name of staff member is to be given.<br/>If stomatherapy is administered externally, a cooperation agreement is to be entered into.</p> <p>Recognised training stomatherapy:</p> <ul style="list-style-type: none"> <li>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:<br/>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).</li> </ul> | <p>FAQ (30.11.2018):<br/>To whom does the protection of the status quo for the recognised training courses in stomatherapy apply? To the ostomy therapist or to the centre where the ostomy therapist works?</p> <p>Answer:<br/>This is a personal grandfathering that applies to all ostomy therapists who completed or began their training in ostomy therapy before 01.01.2019 according to the criteria valid until 31.12.2018.</p> |  |
| <p>1.8.6</p> <p>- Colo-rectal -</p> | <p><b>Stomatherapy – Definition of tasks</b></p> <ul style="list-style-type: none"> <li>Pre-inpatient or pre-operative and post-inpatient instructions, counselling and training of patients and their relatives.</li> <li>Participation in pre-operative marking (or regulated exchange of experience)</li> <li>Where appropriate, holding of stoma consulting hours</li> </ul>  | <p>FAQ (28.08.2019):<br/>Does the preoperative marking of the stoma always have to be done by stoma therapy?</p> <p>Answer:<br/>No. The marking of the stoma position can also be done by the surgeon. However, it must be ensured that the marking of the stoma position takes place preoperatively at least for elective operations with stoma creation.</p>  |  |



## 1.9 General service areas

|                      | Requirements  |  |
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| 1.9.2<br><br>- All - | <p>Nutritional counselling</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• Cooperation is to be regulated in a cooperation agreement</li> <li>• Qualified deputisation must be ensured.</li> <li>• Need for nutritional counselling is to be actively identified and carried out for each patient. This is especially true during the post-operative phase. The process must be documented in the patient records.</li> <li>• An SOP for nutrition management should be set out in writing.</li> </ul> | <p><u>FAQ (03.05.2023)</u><br/>Do nutritionists also fulfil the qualification requirements of a nutritionist?</p> <p>Answer:<br/>No. Proof of a degree in nutritional science is required.</p> |

## 2.1 Consulting hours

| Section                      | Requirements   |   |
|------------------------------|--|---|
| 2.1.6<br>- Colo-<br>rectal - | <p>Height localisation rectum</p> <ul style="list-style-type: none"> <li>• Rigid rectoscopy or MRI examination can be used for height localisation.</li> <li>• The height localisation must be specified in the report.</li> </ul> | <p>FAQ (26.11.2020):<br/>How is the height localisation of a rectal cancer by MRI examination?</p> <p>Answer:<br/>For this, the distance between the distal end of the tumour and the anrectal junction must be indicated. The anal verge (in contrast to rigid rectoscopy) is less suitable as a measuring point for height localisation by MRI due to the lower reliability of the measurement.</p> |

## 5.2 Organ-specific surgical therapy

| Section      | Requirements  |   |  |
|--------------|---|---|--|
| 5.2.4        | Surgical expertise Centre   |   |  |
| - Pan-creas- | <p><b>Operative Expertise Pankreas</b></p> <ul style="list-style-type: none"> <li>At least 20 pancreatic resections/year</li> <li>At least 12 surgical primary cases pancreatic cancer/year</li> </ul> <p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>Primary cases counted: adenocarcinomas, neuroendocrine carcinomas; <b>not</b> counted IPMNs (intraductal papillary mucinous neoplasms); for full definition see CR 1.2.0</li> <li>Surgical primary cases Only ICD-10 C25 in combination with OPS: 5-524*, 5-525* = adenocarcinoma, neuroendocrine carcinoma, <b>NO</b> IPMNs</li> <li>Pancreatic resections Benign + malignant ICDs, also IPMNs; only type of surgical procedure is relevant (=left resection of the pancreas, pancreatic head resection, total pancreatectomy; OPS: 5-524*, 5-525*)</li> </ul> | <p><a href="#">FAQ (05.10.2017)</a></p> <p>Do all 3 of the following criteria have to be fulfilled or only one of them for a certificate to be granted/renewed?</p> <ul style="list-style-type: none"> <li>25 patients with a primary diagnosis of pancreatic carcinoma (ICD-10 C 25.-) (CR1.2.0)</li> <li>20 pancreatic resections / year (CR5.2.4)</li> <li>12 primary surgical pancreas cases (CR5.2.4)</li> </ul> <p>Answer:<br/>In accordance with the "Evaluation guideline for primary cases/case numbers", the 25 patients with a primary diagnosis of pancreatic carcinoma and the 20 pancreatic resections must be proven for the certificate to be granted/renewed.</p> <p><a href="#">FAQ (22.04.2021)</a></p> <p>What is the counting date for the survey of surgical expertise?</p> <p>Answer:<br/>The date of surgery is decisive.</p> |  |

## 5.2 Organ-specific surgical therapy

| Section     | Requirements   |  |  |
|-------------|--|--|--|
| - Stomach - | <p><b>Surgical expertise stomach</b></p> <ul style="list-style-type: none"> <li>At least <math>\geq 20</math> surgical resections stomach/AEJ (abdominal gastrectomies, sub-total stomach resections and/or transhiatal/abdominothoracic extended gastrectomies in patients with gastric cancer or AEJ) independent of the primary case status</li> </ul> <p><b>Definition surgical resection stomach/AEJ:</b></p> <ul style="list-style-type: none"> <li>ICD-10 C16.0<sup>1</sup>, 16.1-16.9, OPS: 5-425*, 5-426*, 5-435* to 5-438*</li> </ul> <p>If the centre is not certified as an esophageal cancer centre at the same time, resections according to ICD-10 C15.2 and 15.5 and 16.02<sup>2</sup> can be included (see also Chapter 1.2.0).</p> <p><sup>1</sup> Tumours, whose centre is <math>&gt; 2</math> cm from the esophagogastric junction, are classified as gastric carcinomas even if the esophagogastric junction is affected.</p> | <p><a href="#">FAQ (14.07.2016)</a></p> <p>Can ESD and laparoscopic resections (sleeve-resection 5.434.51) be counted as surgical primary cases?</p> <p>Answer: No.</p> <p><a href="#">FAQ (22.04.2021)</a></p> <p>What is the counting date for the survey of surgical expertise?</p> <p>Answer: The date of surgery is decisive.</p> |  |

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|  | <p><sup>2</sup> Tumors that involve the esophagogastral junction and their center within the prox. 2 cm of the esophagogastral junction (proportion Siewert type I / Siewert type II) is counted as esophageal carcinoma.</p>  |  |  |
| - Liver -                              | <p><b>Surgical expertise</b></p> <ul style="list-style-type: none"> <li>• 40 surgical interventions in malignant tumours of the liver (resections/transplantations)/Centre/year</li> <li>• Definition resection/transplantation: 5-502*, 5-504*</li> <li>• Up to 15 atypical liver resections (OPS 5-501.0; 5-501.2) can be counted towards these 40 surgeries.</li> </ul>   | <p><a href="#">FAQ (22.04.2021)</a><br/>What is the counting date for the survey of surgical expertise?</p> <p>Answer: The date of surgery is decisive.</p>  |  |
| - Esophagus -                          | <p><b>Surgical expertise esophagus</b></p> <ul style="list-style-type: none"> <li>• At least 20 complex surgical procedures on the esophagus/year (not restricted to C15/C16.0<sup>2</sup>, incl. benign diagnoses)</li> <li>• Definition complex surgical procedures: OPS: 5-423*, 5-424*, 5-425*, 5-426*, 5-438.0 and 1 and x</li> </ul> <p><sup>2</sup> Tumours that affect the esophagogastric junction and whose centre is within the prox. 2 cm of the esophagogastric junction (proportion Siewert type I/Siewert type II), are counted as esophageal carcinomas.</p>   | <p><a href="#">FAQ (22.04.2021)</a><br/>What is the counting date for the survey of surgical expertise?</p> <p>Answer: The date of surgery is decisive.</p>  |  |
| 5.2.10<br>- Stomach -<br>- Esophagus - | <p><b>Expertise for each endoscopic surgeon:</b></p> <ul style="list-style-type: none"> <li>• Endoscopic en-bloc resections stomach or endoscopic resection esophagus ≥ 30 resections cumulative total and</li> <li>• 3 endoscopic en bloc resections or endoscopic resections of esophagus/stomach/year (Proof of competence based on surgical /endoscopy reports as first surgeon or assistant, as trainer; no parallel recognition of cases with 2 surgeons/endoscopic surgeons)</li> <li>• Inpatient follow-up surveillance after endoscopic en bloc resection</li> <li>• Aftercare after endoscopic en bloc resection for Pt1a, N0, M0 in line with LL</li> </ul> | <p><a href="#">FAQ (22.04.2021)</a><br/>Can both en bloc resections of the stomach and endoscopic resections of the esophagus be recognised for the 30 required endoscopic resections if, for example, the scope of the Visceral Oncology Centre only includes a gastric cancer centre?</p> <p>Answer:<br/>For the expertise of the endoscopist, both en bloc resections of the stomach and endoscopic resections of the esophagus are recognised.</p> |  |

## 10. Tumour documentation/Outcome quality

| Section             | Requirements   |  |  |
|---------------------|--|--|--|
| 10.3<br><br>- All - | <p>Cooperation with cancer register</p> <ul style="list-style-type: none"> <li>• Cooperation with the competent 65c cancer registry is to be documented on the basis of the cooperation agreement. <a href="#">Link Tumorzentren.de</a></li> <li>• 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.</li> <li>• The presentation of the Catalogue of Requirements and outcome quality should be ensured via the cancer registry to the extent that this information is of relevance for the cancer registry.</li> <li>• 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.</li> </ul> | <p><a href="#">FAQ (05.10.2017)</a><br/>What is a 65c cancer registry?</p> <p>Answer:<br/>A 65c cancer registry is designated by the federal state in accordance with the requirements of §65c of the SGB V (Cancer Early Detection Registry Act).</p> |  |

### FAQs - Indicator Sheet Colorectal (=Excel-Template)

Interpretations regarding the indicators colorectal are not shown in this document, as the FAQs for this organ are stored in the specification document.

Download: <http://www.xml-oncobox.de/de/Zentren/DarmZentren>

### FAQs - Indicator Sheet Pancreas (=Excel-Vorlage)

|    |                              |              |   |  |
|----|------------------------------|--------------|---|--|
| 6  | Patients enrolled in a study | Numerator    | Patients who were included in a study with an ethical vote  | <p><b>FAQ (29.09.2022):</b><br/>Does the quality objective "inclusion of as many patients as possible in studies" mean that patients should be included in several studies if possible?</p> <p><b>Answer:</b><br/>No. The aim is to give as many patients as possible access to suitable studies. Inclusion in several studies is possible and can in this case also be counted several times in the numerator. Thus, study enrolments are counted here.</p> |
|    |                              | Denominator  | Primary cases (= Indicator 1)   |  |
|    |                              | Target value | ≥ 5%  |  |
|    |                              | Denominator  | ERCPs for each endoscopy unit   |  |
|    |                              | Target value | ≤ 10%   |  |
| 7a | Endoscopy complications      | Numerator    | ERCPs of the denominator with specific complications after ERCP (CR 2.1)  | <p><b>FAQ (14.07.2016):</b><br/>What is the counting method for this metric: the number of actual exams or the number of pat. or the number of cases?</p> <p><b>Answer:</b><br/>The counting method is based on the number of exams.</p> <p><b>FAQ (14.07.2016):</b><br/>Are patients counted in both numerator 7a and 7b if they had both types of complications?</p> <p><b>Answer: Yes.</b></p>  |
|    |                              | Denominator  | ERCPs for each endoscopy unit   |  |
|    |                              | Target value | ≤ 10%   |  |
| 7b |                              | Numerator    | ERCPs of the denominator with specific complications Bleeding and perforation after ERCP (CR 2.1)                     |  |
|    |                              | Denominator  | ERCPs for each endoscopy unit   |  |
| 15 | Pathology reports            | Target value | ≤ 5%  |  |
|    |                              | Numerator    | Pathology reports of denominator with details of: pT, pN, M; tumour grading: ratio of affected to removed lymph nodes |  |
|    |                              | Denominator  | Pathology reports of surgical primary cases (OPS: 5-524*, 5-525* ausschließlich mit ICD-10 C25) ohne NET und NEC      | <p><b>FAQ (14.07.2016):</b><br/>What is the counting method for this indicator: the (total) number of diagnostic reports or the number of patients with at least one diagnostic report or the number of cases with at least one diagnostic report?</p> <p><b>Answer:</b></p>   |

|  |  |              |       |   |
|--|--|--------------|-------|---|
|  |  | Target value | ≥ 80% | Surgical primary cases with the final findings report, which should include the listed information. |
|--|--|--------------|-------|---|

### FAQs - Indicator Sheet Stomac (=Excel-Template)

|   |                              |              |   |  |
|---|------------------------------|--------------|---|--|
| 7 | Patients enrolled in a study | Numerator    | Patients included in a study with an ethical vote | <p>FAQ (29.09.2022):<br/>Does the quality objective "inclusion of as many patients as possible in studies" mean that patients should be included in several studies if possible?</p> <p>Answer:<br/>No. The aim is to give as many patients as possible access to suitable studies. Inclusion in several studies is possible and can in this case also be counted several times in the numerator. Thus, study enrolments are counted here.</p> |
|   |                              | Denominator  | Primary cases (= Indicator 1)                     |  |
|   |                              | Target value | ≥ 5%  |  |

### FAQs - Indicator Sheet Liver (=Excel-Template)

|    |  |              |  |   |
|----|--|--------------|--|---|
| 3a | Post-surgical presentation in tumour board     | Numerator    | Primary cases of the denominator presented in the tumour board                                   | <p>FAQ (03.04.2019):<br/>Does the postoperative presentation of transplanted patients in the transplant outpatient clinic replace the presentation in the tumour board?</p> <p>Answer:<br/>No. Even transplanted patients must also be presented postoperatively at the tumour board.</p> |
|    |  | Denominator  | Surgical expertise – Number of surgical interventions for primary cases                          |   |
|    |  | Target value | ≥ 95%  |   |
| 3b | Post-intervention presentation in tumour board | Numerator    | Interventions of the denominator presented 4-12 weeks after the intervention in the tumour board | <p>FAQ (03.04.2019):<br/>When should the post-interventional presentation of patients with TACE take place?</p> <p>Answer:<br/>The presentation should take place once at the end of the entire cycle.</p>  |
|    |  | Denominator  | Intervention expertise – Interventions for primary cases   |   |
|    |  | Target value | ≥ 95%  |   |
| 7  | Patients enrolled in a study                   | Numerator    | Patients included in a study with an ethical vote  | <p>FAQ (29.09.2022):<br/>Does the quality objective "inclusion of as many patients as possible in studies" mean that patients should be included in several studies if possible?</p>  |
|    |  | Denominator  | Primary cases (= Indicator 1)  |   |
|    |  | Target value | ≥ 5%   |   |

|     |  |              |   |  |
|-----|--|--------------|---|--|
|     |  |              |   | <p>Answer:<br/>No. The aim is to give as many patients as possible access to suitable studies. Inclusion in several studies is possible and can in this case also be counted several times in the numerator. Thus, study enrolments are counted here.</p>  |
| 10  | mRECIST-/EASL-Klassifikation nach TACE/TAE   | Numerator    | Primary cases of the denominator for which treatment response was evaluated using RECIST or modified RECIST and/or EASL classification  | <p><a href="#">FAQ (03.04.2019):</a><br/>Can be used for the evaluation of response after TACE/TAE TACE/TAE another classification, other than RECIST or modified RECIST or/ and EASL classification, be used?</p> <p>Answer:<br/>No. At the meeting on 03.04.2019, the Certification Commission again advocates the use of the RECIST/mRECIST or/and EASL classification.</p> |
|     |  | Denominator  | Primary cases with TACE/TAE   |  |
|     |  | Target value | ≥ 95%   |  |
| 11b | Complications after percutaneous radiofrequency ablations (RFA) + microwave ablation (MWA) | Numerator    | Primary cases of the denominator with complications necessitating intervention Bleeding (T81.0), vessel damage (T81.2), non-target embolisations (T81.7) intrahepatic abscess (T81.4), damage to other organs (T81.2), liver failure (K91.9) after percutaneous RFA + MWA | <p><a href="#">FAQ (05.10.2017):</a><br/>Can "high intensity focused ultrasound" be considered additionally?</p> <p>Answer:<br/>No consideration of "high intensity focused ultrasound".</p>   |
|     |  | Denominator  | Primary cases with percutaneous RFA + MWA (OPS: 5-501.53)   |  |
|     |  | Target value | ≤ 5%  |  |
| 12  | Number of surgical interventions   | Numerator    | Surgical interventions (resection, transplantation) for malignant liver tumours (OPS: 5-502* or 5-504*)   | <p><a href="#">FAQ (05.10.2017):</a><br/>Can "high intensity focused ultrasound" be additionally considered?</p> <p>Answer:</p>  |
|     |  | Denominator  | -----   |  |



|  |  |              |           |   |
|--|--|--------------|-----------|---|
|  |  | Target value | $\geq 25$ | <p>"High intensity focused ultrasound" cannot be taken into account for the calculation of the indicator.</p> <p><u>FAQ (03.04.2019):</u><br/>Which diseases are meant by "malignant tumour diseases in the liver"?</p> <p>Answer:<br/>Resections/transplantations (OPS: 5-502* or 5-504*) performed for primary or secondary (= e.g. metastases) malignant tumour diseases of the liver can be counted here as evidence of surgical expertise. Adenomas, haemangiomas, FNH or the suspicion of e.g. gallbladder carcinoma that was not confirmed in the histology are not counted.</p> |
|--|--|--------------|-----------|---|

### FAQ's - Data Sheet Esophageal (=Excel-Teampate)

|   |                              |              |  |   |
|---|------------------------------|--------------|--|---|
| 8 | Patients enrolled in a study | Numerator    | Patients that were included in a study | <p><u>FAQ (29.09.2022):</u><br/>Does the quality objective "inclusion of as many patients as possible in studies" mean that patients should be included in several studies if possible?</p> <p>Answer:<br/>No. The aim is to give as many patients as possible access to suitable studies. Inclusion in several studies is possible and can in this case also be counted several times in the numerator. Thus, study enrolments are counted here.</p> |
|   |                              | Denominator  | Primary cases (= indicator 1a)         |   |
|   |                              | Target value | $\geq 5\%$                             |   |

### FAQ's - Data Sheet Anal Cancer (=Excel-Teampate)

|   |                                       |              |  |   |
|---|---------------------------------------|--------------|--|---|
| 3 | Psycho-oncological distress screening | Numerator    | Pat. of the denominator who were screened psycho-oncologically               | <p>FAQ (16.08.2022)<br/>Can on-site contact replace screening?</p> <p>Answer:<br/>No. In order to identify the need for treatment, it is necessary to conduct a standardised screening on psychological distress (see BestPractice (Stengel A et al. Best Practice: psychooncological screening at Comprehensive Cancer Centers. Forum 2021;36:278-283) or S3 Guideline Psychooncological Diagnosis, Counselling and Treatment of Adult Cancer Patients) and document the result.</p> |
|   |                                       | Denominator  | Total primary cases + patients with new recurrence and/or distant metastases |   |
|   |                                       | Target value | ≥ 65%  |   |
| 5 | Patients enrolled in a study          | Numerator    | Patients that were included in a study                                       | <p>FAQ (29.09.2022):<br/>Does the quality objective "inclusion of as many patients as possible in studies" mean that patients should be included in several studies if possible?</p> <p>Answer:<br/>No. The aim is to give as many patients as possible access to suitable studies. Inclusion in several studies is possible and can in this case also be counted several times in the numerator. Thus, study enrolments are counted here.</p>  |
|   |                                       | Denominator  | Primary cases (= indicator 1a)   |   |
|   |                                       | Target value | ≥ 5%   |   |