

FAQs

Catalogue of Requirements for the Visceral Oncology Centres

of the German Cancer Society (Deutsche Krebsgesellschaft - DKG)

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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: 06 September 2021

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

Catalogue of Requirements Viszeral	Version L1	06.09.2021
Catalogue of Requirements Colorectal	Version L1	06.09.2021
Indicator Sheet Colorectal	Version L1.1	06.09.2021
Indicator Sheet Pancreas	Version L1.1	06.09.2021

Indicator Sheet Stomach	Version L1.1	06.09.2021
Indicator Sheet Liver	Version L1.1	06.09.2021
Indicator Sheet Esophagus	Version L1.1	06.09.2021

Overview of FAQs

Catalogue of Requirements

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10 Tumour documentation / Outcome quality	10.3	Cooperation with cancer register	05.10.2017

Indicator Sheet (=Excel-Vorlage)

	Indicator	Last update
7a	Pancreas: Endoskopie Komplikationen	14.07.2016
7a / b	Pancreas: Endoskopie Komplikationen	14.07.2016
15	Pancreas: Inhalt Pathologieberichte	14.07.2016
3a	Liver: Post-surgical presentation in tumour bord	03.04.2019
3b	Liver: Post-intervention presentation in tumour board	03.04.2019
12	Liver: RECIST/EASL classification according to TACE/TAE	03.04.2019
13a	Liver: Complications after TACE/TAE	05.10.2017
14	Liver: Number of surgical interventions	03.04.2019



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 or "Pancreas"
Only relevant for "Stomach"
Only relevant for "Liver"
Only relevant for "Esophagus"

FAQs - Catalogue of Requirements Visceral

1.2 Interdisciplinary cooperation

Section	Requirements	
1.2.0	Number of primary cases	
- Stomach -	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, 16.0¹, 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	FAQ (06.07.2020) Does squamous cell carcinoma in the lower third (C15.5) or abdominal portion (C15.2) of the esophagus count towards the Gastric Cancer Centre?
	 16.02² can be included in the scope of the stomach cancer centre. Definition: Patients and not stays or surgical procedures Histology / cytology report must be available (biopsy or resection). Patient with initial disease The time of counting is the time of the histological confirmation of diagnosis Patients, who are only presented for the purposes of seeking a second opinion or for 	Answer: 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. FAQ (14.07.2016)
	the purposes of consultation, are not included. 1 Tumours, whose centre is > 2 cm from the esophagogastric junction, are classified as gastric carcinomas even if the esophagogastric junction is affected. 2 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.	Are patients with a GIST also recognised as primary cases? Answer: 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 guideline on gastric cancer does not cover the tumour entity GIST.
		FAQ (05.10.2017) The findings usually report cm from the dentition. Does the abdominal portion of the esophagus begin below the diaphragm? Answer: 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. FAQ (05.10.2017) Do distal oesophageal carcinomas that do not extend into the oesophagogastric junction count as primary cases or are only AEG tumours and

1.2 Interdisciplinary cooperation

Section	Requirements	
		Answer: Tumours whose centre is > 2 cm from the oesophagogastric junction are classified as gastric carcinomas, even if the oesophagogastric junction is included
		FAQ (10.07.2018) Which carcinomas of the gastro-esophageal junction (= AEG tumours) are assigned to the stomach and which to the esophagus? Answer: 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).
		FAQ (22.04.2021) 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.
		Answer: Yes, provided that a proportion of adenocarcinoma can be detected, counting as a primary case is possible.
-Pan-creas -	 The Centre must treat 25 patients annually with a primary diagnosis of pancreatic cancer (ICD-10 C 25). Definition: Patients and not stays or surgical procedures Adenocarcinomas, neuroendocrine carcinomas are counted. IPMNs (intraductal papillary mucinous neoplasms) are not counted. Histological/cytological findings must be available (biopsy or resection) from primary tumour or metastasis with concomitant presence of a pancreatic tumour in medical imaging. Patient with initial disease The time of counting is the time of the histological confirmation of diagnosis Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not 	FAQ (05.10.2017) Does carcinosarcoma of the pancreas count as a primary case? Answer: Yes.

1.2 Interdisciplinary cooperation

Section	Requirement		
Esophagu s-	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). of which at least 20 patients with a primary diagnosis	FAQ (10.07.2018) Which carcinomas of the gastro-oesophageal junction (= AEG tumours) are assigned to the stomach and which to the esophagus?	
	 (ICD-10 C15, 16.0², D00.1 (HGD, HGIEN)) Definition primary diagnosis: Patients and not stays or surgical procedures Patient with initial disease (incl. primary M1) The time of counting is the time of the histological/imaging confirmation of diagnosis Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not included. ² 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. 	Answer: 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).	
1.2.9 - All -	 The therapeutic procedure should be oriented towards the treatment plans or recommendations of the tumour conference. 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. 	FAQ (09.04.2021) Is TNT (Total Neoadjuvant Therapy) according to the AIO statement (https://aio-portal.de/tl_files/aio/stellungnahmen/Stellungnahme%20AIO_ACO_ARO%20Rektumkarzinom%2 0_%2007_2020.pdf) a therapy concept that conforms to requirements? Answer: After consultation with the coordinators of the S3-LL CRC, no amendment of the LL is currently being sought because the three studies cited in the AIO statement are not yet available as a complete paper. The LL will be updated next year and the TNT will then be discussed. Until then, it is possible to deviate from the LL, but this must be justified.	

1.4 Psycho-oncology

Section	Requirements	
1.4.1	Psycho-oncology – qualifications	FAQ (24.10.2018)
	Qualified psychologists / Master in	Can the further training "Systemic Therapist" be
- All -	Psychology, which qualifies for a scientifically	recognised as psychotherapeutic further
	recognised psychotherapy procedure or	training?
	physicians	
	Diploma/master's degree in social pedagogy	Answer:
	qualifying for a scientifically recognised	The further training "Systemic Therapy" can be
	psychotherapy	recognised.
	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 (psychologicalor 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 psychooncological qualifications. For this, a case-bycase examination is required. The assumption of psycho-oncological tasks by the social services, self-help groups or pastoral care is not sufficient. They supplement psychooncological care. The process of patient care in the centre (screening, evaluation of screening results, care) must be demonstrated in the audit based on examples. Psycho-oncology - Offer and access 1.4.2 FAQ (21.07.2016) Each patient must be offered the option of Can an on-site contact replace the screening? psycho-oncological counselling in a timely - All manner in the vicinity. The offer must be made in Answer: a low-threshold manner. No. To identify the need for treatment, it is Documentation and evaluation necessary to carry out a standardised screening To identify treatment needs, screening of mental on psychological stress (see page 3 guideline strain must be undertaken (for instance see S3 Psycho-oncology: e.g. Distress Thermometer or Guidelines Psycho-Oncology) and the outcome is HADS) and to document the result. to be documented. Psycho-oncological care is to be documented and evaluated in an ongoing manner using suitable instruments (e.g. Basic Documentation for Psycho-Oncology - PO-BaDo).

1.7 Study management

Section	Requirements	

1.7.6	Proportion study patients	FAQ (05.10.2017)	l
		Does the requirement of "1 patient at initial	l
- All -	Initial certification: At the time of initial	certification" also apply to the modules of the	l
	certification ≥ 1 patients must have been included in stud-ies (guidance value: ≤ 6	Visceral Oncology Centre?	
	months prior to certification)	Answer:	l
	2. after 1 year: at least 5% of the primary case	If no patient is included in studies at the initial	l
	number	certification of the pancreas, stomach, liver and	1
		esophagus modules, the centre must prove its	l
	The requirement applies to each tumour entity.	activity for study inclusion and at the same time	l
		fulfil the study quota for the colorectal cancer	l
		centre. A certificate can only be granted under	1
		certain conditions (reduced validity). By the 1st	1
		surveillance audit, 1 patient per module must be	1
		included in studies.	l

1.8 Nursing care

Section	Requirements	
1.8.5 - Colorectal -	Stomatherapy – Staff Qualification head of stomatherapy Qualified representative is to be ensured. Name of staff member is to be given. If stomatherapy is administered externally, a cooperation agreement is to be entered into. 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	FAQ (30.11.2018): 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? Answer: 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.
	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).	
1.8.6 - Colorectal -	 Stomatherapy – Definition of tasks Pre-inpatient or pre-operative and post-inpatient instructions, counselling and training of patients and their relatives. Participation in pre-operative marking (or regulated exchange of experience) Where appropriate, holding of stoma consulting hours 	FAQ (28.08.2019): Does the preoperative marking of the stoma always have to be done by stoma therapy? Answer: 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.

2.1 Consulting hours

Section	Requirements	
2.1.5 - Colorectal -	Qualification rectum diagnosis Details expertise per treatment unit for: Rectal endosonography Rigid rectoscopy Chromoendoscopy Proctology	
	 Height localisation rectum Rigid rectoscopy or MRI examination can be used for height localisation. The height localisation must be specified in the report. 	FAQ (26.11.2020): How is the height localisation of a rectal cancer by MRI examination? Answer: 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.

5.2 Organ-specific surgical therapy

Section	Requirements	
5.2.4	Surgical expertise Centre	
- Pan- creas-	Operative Expertise Pankreas At least 20 pancreatic resections/year At least 12 surgical primary cases pancreatic cancer/year Definitions Primary cases counted: adenocarcinomas, neuroendocrine carcinomas; not counted IPMNs (intraductal	FAQ (05.10.2017) Do all 3 of the following criteria have to be fulfilled or only one of them for a certificate to be granted/renewed? • 25 patients with a primary diagnosis of pancreatic carcinoma (ICD-10 C 25) (CR1.2.0) • 20 pancreatic resections / year (CR5.2.4) • 12 primary surgical pancreas cases (CR5.2.4)
	 papillary mucinous neoplasms); for full definition see CR 1.2.0 Surgical primary cases Only ICD-10 C25 in combination with OPS: 5-524*, 5-525* = adenocarcinoma, neuroendocrine carcinoma, NO IPMNs Pancreatic resections Benign + malignant ICDs, also IPMNs; only 	Answer: 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.
	type of surgical procedure is relevant (=left resection of the pancreas, pancreatic head resection, total pancreatectomy; OPS: 5-524*, 5-525*)	FAQ (22.04.2021) What is the counting date for the survey of surgical expertise? Answer: The date of surgery is decisive.

5.2 Organ-specific surgical therapy

Section	Requirements	
	Surgical expertise stomach (primary cases)	FAQ (14.07.2016)
	 At least ≥ 20 surgical resections stomach/AEJ (abdominal gastrectomies, sub-total stomach resections and/or transhiatal/abdominothoracic extended gastrectomies in patients with gastric cancer or AEJ) 	Can ESD and laparoscopic resections (sleeve-resection 5.434.51) be counted as surgical primary cases? Answer: No.
	Definition surgical resection stomach/AEJ: ICD-10 C16.0¹, 16.1-16.9, OPS: 5-425*, 5-426*, 5-435* to 5-438* 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 16.02² can be included (see also Chapter 1.2.0).	FAQ (22.04.2021) What is the counting date for the survey of surgical expertise? Answer: The date of surgery is decisive.
	¹ Tumours, whose centre is > 2 cm from the esophagogastric junction, are classified as gastric carcinomas even if the esophagogastric junction is affected. ² 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.	
- Liver -	 Surgical expertise 25 surgical interventions in malignant tumours of the liver (resections/transplantations)/Centre/year Definition resection/transplantation: 5-502*, 5-504* 	FAQ (22.04.2021) What is the counting date for the survey of surgical expertise? Answer: The date of surgery is decisive.
- Esophagus -	 Surgical expertise esophagus At least 20 complex surgical procedures on the esophagus/year (not restricted to C15/C16.0², incl. benign diagnoses) Definition complex surgical procedures: OPS: 5-423*, 5-424*, 5-425*, 5-426*, 5-438.0 and 1 and x ² 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 	FAQ (22.04.2021) What is the counting date for the survey of surgical expertise? Answer: The date of surgery is decisive.
	carcinomas.	
5.2.10 - Stomach – - Esophagus	 Expertise for each endoscopic surgeon: Endoscopic en-bloc resections stomach or endoscopic resection esophagus ≥ 30 resections cumulative total and 3 endoscopic en bloc resections or endoscopic resections of esophagus/stomach/year (Proof of competence based on surgical /endoscopy reports as first surgeon or 	FAQ (22.04.2021) 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?
	 assistant, as trainer; no parallel recognition of cases with 2 surgeons/endoscopic surgeons) Inpatient follow-up surveillance after endoscopic en bloc resection 	Answer:

·	For the expertise of the endoscopist, both en bloc resections of the stomach and endoscopic	
	resections of the esophagus are recognised.	

10. Tumour documentation/Outcome quality

Section Requirements	
10.3 Cooperation with cancer register Cooperation with the competent 65c cancer registry is to be documented on the basis of the cooperation agreement. Link Tumorzentren.de 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 Requirements 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.	s of



FAQs - Indicator Sheet Cororectal (=Excel-Vorlage)

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)

7a	Endoscopy complications	Numerator	ERCPs of the denominator with specific complications after ERCP (CR 2.1)	FAQ (14.07.2016): What is the counting method for this metric: the number of actual exams or the number of
		Denominator	ERCPs for each endoscopy unit	pat. or the number of cases?
		Target value	≤ 10%	Answer: The counting method is based on the number of exams.
7a	- Endoscopy complications	Numerator	ERCPs of the denominator with specific complications after ERCP (CR 2.1)	FAQ (14.07.2016): Are patients counted in both
		Denominator	ERCPs for each endoscopy unit	
		Target value	≤ 10%	numerator 7a and 7b if they had both types of
7b		Numerator	ERCPs of the denominator with specific complications Bleeding and perforation after ERCP (CR 2.1)	complications? Answer: Yes.
		Denominator	ERCPs for each endoscopy unit	
		Target value	≤ 5%	
15	Pathology reports	Numerator	Pathology reports of denominator with details of: pT, pN, M; tumour grading: ratio of affected to removed lymph nodes	FAQ (14.07.2016): 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? Answer:
		Denominator	Pathology reports of surgical primary cases (OPS: 5-524*, 5-525* ausschließlich mit ICD-10 C25) ohne NET und NEC	
		Target value	No target value	Surgical primary cases with the final findings report, which should include the listed information.



FAQs - Indicator Sheet Liver (=Excel-Vorlage)

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3a	Post-surgical presentation in tumour bord	Numerator	Primary cases of the denominator presented in the tumour board	FAQ (03.04.2019): Does the postoperative presentation of transplanted
		Denominator	Surgical expertise – Number of surgical interventions for primary cases	patients in the transplant outpatient clinic replace the presentation in the tumour board?
		Target value	≥ 95%	Answer: No. Even transplanted patients must also be presented postoperatively at the tumour board.
3b	Post-intervention presentation in tumour board	Numerator	Interventions of the denominator presented 4-12 weeks after the intervention in the tumour board	FAQ (03.04.2019): When should the post- interventional presentation of patients with TACE take place?
		Denominator	Intervention expertise – Interventions for primary cases	Answer: The presentation should take
		Target value	≥ 95%	place once at the end of the entire cycle.
12	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	FAQ (03.04.2019): Can be used for the evaluation of response after TACE/TAE TACE/TAE another classification, other than RECIST or modified RECIST
		Denominator	Primary cases with TACE/TAE	or/ and EASL classification, be used?
		Target value	≥ 95%	Answer: No. At the meeting on 03.04.2019, the Certification Commission again advocates the use of the RECIST/mRECIST or/and EASL classification.
13b	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 Primary cases with percutaneous RFA + MWA	FAQ (05.10.2017): Can "high intensity focused ultrasound" be considered additionally? Answer: No consideration of "high intensity focused ultrasound".
		Target value	(OPS: 5-501.53) ≤ 5%	

14	Number of surgical interventions	Numerator	Surgical interventions (resection, transplantation) for malignant liver tumours (OPS: 5-502* or 5-504*)	FAQ (05.10.2017): Can "high intensity focused ultrasound" be additionally considered?
		Denominator Target value	 ≥ 25	Answer: "High intensity focused ultrasound" cannot be taken into account for the calculation of the indicator.
				FAQ (03.04.2019): Which diseases are meant by "malignant tumour diseases in the liver"?
				Answer: 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.