

FAQs

Catalogue of Requirements for the Lung Cancer 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: 31. August 2022

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

Catalogue of Requirements Lungs	Version I3	31.08.2022
Indicator Sheet Lungs	Version I1.1	31.08.2022

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Indicator sheet

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9	Interventional bronchoscopy (thermal procedures and stenting)	14.07.2016
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31	CTCAE stage V on systemic therapy	13.05.2022
33	PD-L1 testing for NSCLC in stage III with radio-chemotherapy	22.10.2020

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1.1 Structure of the network

Section	Requirements	Explanatory remarks of the Lung Cancer Centre	
1.1.1	<p>Precondition for multi-location cooperation models:</p> <ul style="list-style-type: none"> • At least 1x/month a joint tumour board (TB). In the other weeks, site-specific TB, in which all requirements for the TB must be fulfilled (= among other things, all main treatment partners present according to CoR 1.2). • The technical requirements and performance indicators must be fulfilled and demonstrated individually for each site. • Common tumour documentation system • -Patients must be fully documented at the site or assigned to the site responsible for presentation at the tumour board. • Prior structural evaluation OnkoZert is required before the certificate is issued. • Number of cooperating thoracic surgeons/pneumologists: max. 3 pneumologists and 3 thoracic surgeons 	<p><u>FAQ (13.05 2022):</u> How should the following case be counted? Site A has a thoracic surgery and a pneumology department, site B only a pneumology department. The case is diagnosed at site B and brought to the joint tumour board, then operated on at site A. Follow-up care/chemotherapy takes place at site B again. Follow-up care/chemotherapy is again provided at site B. Is the case assigned to site A or site B?</p> <p>Answer: It is assigned to site B, but the surgery can be counted for site A's surgical expertise.</p>	

1.2 Interdisciplinary cooperation

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1.2.1	<p>The Lung Cancer Centre must treat at least 200 patients a year with a primary diagnosis of "lung cancer" in their own Centre.</p> <p>Definition primary case of the Centre:</p> <ul style="list-style-type: none"> • All patients with newly diagnosed or not yet pre-treated/treated lung cancer, who are presented to the Centre or the tumour board, and receive large parts of their treatment there. • Patient can only be counted as a primary case for 1 Centre; pretreated patients or patients seeking a second opinion are not counted • Patients (not stays, not surgery) • Complete recording in the tumour documentation system • Pathology report must be available (ICD, C34.0-34.9) • The time of counting is the time of the pathological confirmation of diagnosis • Patients with no pathological confirmation of diagnosis may be counted if (all of the following apply): <ul style="list-style-type: none"> ○ Solitary pulmonary nodule, suspected malignoma ○ FDG-PET positive ○ Documented size progression over course of time (at least 8 weeks) ○ High risk for patients through pathological confirmation ○ Presentation tumour board and indication radiotherapy without pathological confirmation ○ Time of counting is date of presentation tumour board • A primary case with synchronous treatment of bronchial carcinomas • Two primary cases with metachronous treatment of bronchial carcinomas if these occur on different sides (not counted as a second primary case is the occurrence in different lobes on the same side) • Synchronous tumour in another tumour entity can be counted as a primary case for each tumour entity 	<p>Details in the Indicator Sheet: Basic data / Indicator 1 (Excel template)</p> <p><u>FAQ (14.07.2016):</u> In the explanatory remarks it is stated that here all primary cases of the Centre diagnosed for the first time and operated on during the data year can be counted. But what about the overlaps, i.e. the patients who are diagnosed at the end of December of one year and are operated on in January or later?</p> <p>Answer: The time of counting is the date of the first diagnosis even if the surgery is carried out the following calendar year.</p> <p><u>FAQ (14.07.2016):</u> Do patients who die early with a confirmed pathological diagnosis but before the commencement of specific treatment count as primary cases?</p> <p>Answer: Best supportive care also counts as treatment.</p> <p><u>FAQ (13.07.2021)</u> Is the following case 1 primary case or 2 primary cases? At the initial diagnosis, 2 tumour foci are present in the right and left lung. First, a tumour resection is carried out on the left and at a later date the resection of the right tumour focus.</p> <p>Answer: Both tumour sites are discovered at the same time when lung carcinoma is diagnosed, so the therapy is also planned and carried out taking both tumour sites into account. This is more a two-stage intervention than a metachronous treatment. In this respect, only 1 primary case would have to be counted here.</p> <p><u>FAQ (13.07.2021)</u> If one lung focus is discovered on the opposite side, e.g. 3 months after resection of the first lung focus, and this is then treated, can both focuses be counted as independent primary cases?</p>	
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		<p>Answer:</p> <p>In this case, only 1 pulmonary focus was initially discovered and treated under this premise, then at a later time another round focus is discovered in the other lung and then treated again. Thus, 2 primary cases can be counted. In the case of metachronous treatment of 2 bronchial carcinomas on the same side, only 1 primary case can be counted.</p>	
	<p>Therapy discontinuations:</p> <p>Can be counted in the case of first treatment as a primary case. Are to be entered in the tumour documentation system. Number of patients is to be indicated.</p> <p>Not included when the patient has switched to another Centre after diagnosis or before the commencement of treatment</p>	<p><u>FAQ (14.07.2016):</u></p> <p>What is the definition of "discontinuation of therapy"?</p> <p>Answer:</p> <p>When the originally planned treatment is not carried¹⁾ out in full. See spreadsheet of the Working Group of German Cancer Centres (<i>Arbeitsgemeinschaft Deutscher Tumorzentren e.V. - ADT</i>): field discontinuation</p> <p>¹⁾ Must be defined by service provider.</p>	
1.2.3	<p>Participants tumour board</p> <p>b) The main treatment partners (Section 1.1.1.) attend each tumour board. Participation must be proven, for instance in a list of participants. Palliative physicians should regularly attend the tumour board.</p> <p>In line with needs, associated specialty units (e.g. psycho-oncology, nursing care) and other specialties (neurology, neurosurgery, surgery, pain therapy, orthopaedics, etc.) are to be included in the tumour board.</p>	<p><u>FAQ (21.03.2018)</u></p> <p>Is it mandatory for nuclear medicine specialists to attend the weekly tumour board?</p> <p>Answer:</p> <p>No. The presence of a nuclear medicine physician is to be made possible if necessary (e.g. need to discuss lung scintigraphy).</p>	
1.2.5	<p>Pretreatment tumour board</p> <ul style="list-style-type: none"> - Primary cases - Local recurrence/distant metastases 		
	<p>Indication conference</p> <ul style="list-style-type: none"> • In centres with >500 primary cases, the pre-therapeutic tumour board can be conducted as an indication conference. • Participants: Pneumology/haemato-oncology; thoracic surgery, radiology. Optional: radiotherapist 	<p><u>FAQ (14.07.2016):</u></p> <ul style="list-style-type: none"> - Patients with stage IV must be presented at the pre-therapeutic tumour board - Patients with stage I can be prepared as a working document for the tumour board 	

1.4 Psycho-oncology

Section	Requirements	Explanatory remarks of the Lung Cancer Centre	
1.4.2	<p>Psycho-oncology - Offer and access Each patient must be promptly offered a psycho-oncological consultation in the vicinity (proof required). The offer must be made in a low-threshold manner.</p> <p>Documentation and evaluation Psycho-oncological treatment is to be documented and evaluated in an ongoing manner using suitable instruments (e.g. Basic Documentation for Psycho-Oncology - PO-BaDo). To identify treatment needs, screening of mental strain must be undertaken (instrument e.g. see S3 Guidelines Psycho-Oncology, and the result is to be documented.</p> <p>Scope of treatment Patients who have received psycho-oncological support are to be documented. The frequency and duration of the sessions is to be recorded.</p>	<p>FAQ (21.07.2016): Can the establishment of contact <i>in situ</i> replace screening?</p> <p>Answer: No. To identify treatment needs it is necessary to conduct standardised screening for mental strain (see S3 Guidelines Psycho-Oncology: e.g. distress thermometer (DT) or the Hospital Anxiety and Depression Scale - HADS), and to document the result.</p>	

1.5 Social work and rehabilitation

Section	Requirements	Explanatory remarks of the Lung Cancer Centre	
1.5.1	<p>Qualifications social work</p> <ul style="list-style-type: none"> • 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 <p>Resources: For patient counselling in the Centre at least 1 full-time staff member is available for 400 counselled patients (not cases) of the Centre (primary cases, secondary metastasis, recurrence). The personnel resources can be grouped centrally, an organisation plan must be available.</p> <p>Premises: A suitable room is to be provided for social counselling work.</p> <p>Organisation plan: 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.</p>	<p>FAQ (13.07.2018) How are the required personnel resources to be calculated/proved?</p> <p>Answer: The personnel resources are to be calculated based on the patients actually consulted at the centre. The basis for calculation is the numerator of the key figure no. 5, counselling social service (patients who were counseled by the social service on an inpatient or outpatient basis - related to the patient collective defined in the denominator of the key figure). One Patient who received counselling more than once is counted only once.</p>	

1.6 Patient involvement

Section	Requirements	Explanatory remarks of the Lung Cancer Centre	
1.6.6	<p>Event for patients</p> <p>The Centre is to stage an information event for patients and/or interested persons at least once a year. If possible, in cooperation with self-help groups</p> <p>If patient events are (co-)financed by industry, this fact, including potential conflicts of interest of the lecturers, must be disclosed. The centre must exclude any direct influence on patients by industry representatives.</p>	<p><u>FAQ (21.07.2022)</u></p> <p>How can the Lung Cancer Centre prove the exclusion of direct influence by industry representatives?</p> <p>Answer:</p> <p>Evidence can be provided, for example, via internal compliance rules or, alternatively, via a self-disclosure by the Lung Cancer Centre. In this, the Lung Cancer Centre should provide information on free access to the event, excluding the industry exhibition/information stands, and information on contact between industry representatives and patients</p>	

1.7 Study management

Section	Requirements	Explanatory remarks of the Lung Cancer Centre	
1.7.5	<p>Proportion study patients</p> <ul style="list-style-type: none"> Initial certification: <p>At the time of initial certification ≥ 1 patients must have been included in the studies.</p> <ul style="list-style-type: none"> after 1 year: <p>at least 5% of the primary case number</p>	<p>Specification in data sheet (Excel template) Indicator 6</p>	
	<p>All patients with lung cancer included in studies can be taken into account when calculating the study rate (share study patients based on the Centre's primary case number).</p> <p>Only the inclusion of patients in studies for which a valid ethical vote is available counts as study participation.</p> <p>Inclusion in studies whose sole objective is to collect material (biobanking) does not count.</p> <p>General preconditions for the definition of the study quota:</p> <ul style="list-style-type: none"> Patients can be counted once per study, time: date of patient consent. Patients in the palliative and adjuvant situation can be counted, no limitations regarding stage of disease. Patients who are taking part in several studies can be counted several times. 	<p><u>FAQ (24.06.2020)</u></p> <p>Which studies may be counted?</p> <p>Answer:</p> <p>Studies with an ethical vote in which centre patients were introduced in the audit-relevant calendar year are counted. Studies whose sole aim is the <u>collection</u> of material (biobanking) are excluded. However, interventional and observational studies with a concrete research question, such as the CRISP study, are eligible.</p> <p><u>FAQ (10.02.2022)</u></p> <p>Can negatively screened study patients be counted?</p> <p>Answer:</p> <p>Patients who have signed a informed consent form for screening for study participation can be counted for the numerator of the respective study indicator, even if the results of screening examinations carried out with special diagnostics (no routine diagnostics) do not allow the patients to participate in the study.</p>	

2.2 Diagnostic

Section	Requirements	Explanatory remarks of the Lung Cancer Centre	
2.2.3	<ul style="list-style-type: none"> (...) 		
	<ul style="list-style-type: none"> Transbronchial lung biopsies (1430.2) 	<p><u>FAQ (05.08.2019)</u> Can the transoesophageal lung biopsies also be counted here?</p> <p>Answer: Yes, the transoesophageal lung biopsies may be counted.</p>	

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----	Basic data	Columns B - J	UICC / TNM (pre-/post-therapeutic tumour status)	<p><u>FAQ (12.09.2017)</u> Is it correct that patients with ypT0 cannot be included in the basic data or should these patients be mapped with the pre-therapeutic tumour status?</p> <p>Answer: after neoadjuvant and surgical therapy: always indicate cT.</p> <p><u>FAQ (12.09.2017)</u> What should be done if the stage changes? E.g. initial stage III, postoperative stage IA, adjuvant therapy, final stage 0?</p> <p>Answer: After neoadjuvant therapy +/- surgery: c-stage After surgery alone: p-stage</p> <p><u>FAQ (13.05.2022)</u> Do neuroendocrine tumours of the lung count as primary cases?</p> <p>Answer: Yes.</p>
1b	Patients with recent recurrence and/or distant metastases	Numerator	Patients with recent recurrence and/or distant metastases	<p><u>FAQ (02.08.2021)</u> Are only first-time distant metastases counted in the denominator, i.e. no distant metastases were present at the time of initial diagnosis, or is every new distant metastasis occurring for the first time in the indicator year counted, i.e. also in the case of pre-existing distant metastases at other locations in previous case years?</p> <p>Answer: There is no restriction to first-time distant metastases. General rules for counting distant metastases are described in the document "Counting cases in the certification system" (Link).</p>
		Target value	No details right now.	
2b	Presentation of new recurrences and/or distant metastases after prior curative treatment in the tumour board	Numerator	Patients of the denominator who were presented in the tumour board	<p><u>FAQ (14 July 2016):</u> Do patients who were treated curatively in the ED but then receive palliative treatment during the course of the disease and develop a metastasis/recurrence in the</p>
		Denominator	Patients with new recurrence and/or remote metastases after prior curative treatment	

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		Target value	≥ 90%	<p>indicator year have to be counted for this indicator?</p> <p>Answer: Yes. These patients must be presented (for the indicator) at the transition from curative to palliative, i.e. at the first palliative therapy.</p> <p><u>FAQ (13.07.2018)</u> What is the key figure target?</p> <p>Answer: Patients with a new recurrence or distant metastasis are only to be discussed pre-therapeutically in the tumour board if they present for treatment at the centre. Patients who are treated close to home outside the centre structure are not covered by this regulation.</p>
8	Flexible bronchoscopy	Numerator	Flexible bronchoscopies for each service provider	<p><u>FAQ (13.05.2022)</u> Are all patients counted who had a flexible bronchoscopy? That is, regardless of whether a C34 diagnosis is given or not?</p> <p>Answer: Yes.</p>
9	Interventional bronchoscopy (thermal procedures and stenting)	Numerator	Interventional surgery (thermal procedures and stenting) for each service provider	<p><u>FAQ (14 July 2016):</u> May cryo-therapies (tumour removal with a cryoprobe) also be included in interventional bronchoscopy?</p> <p>Answer: Yes, but not cryo-biopsies as they are not interventional procedures.</p>
		Denominator	---	
		Target value	≥ 10	
11b	Lung resections	Numerator	<p>Surgical expertise Number anatomical resections (OPS: 5-323 to 5-328, for each ICD-10 C diagnosis, including ICD-10 C34)</p>	<p><u>FAQ (12.09.2017)</u> What exactly is the new counting method for anatomical resections?</p>

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		Target value	≥ 75	<p>Answer:</p> <p>A minimum of 75 anatomical lung resections must still be demonstrated, but no longer exclusively for primary cases with bronchial carcinoma (ICD-10 C.34), but for all patients with C diagnoses. The aim of the modified requirement is that clinics which have just not reached the previous target of 75 primary cases operated on with anatomical lung resection can also undergo certification/quality assurance in future.</p>
12	Ratio of broncho-/angioplasty surgeries to pneumonectomy	Numerator	Primary cases of denominator with broncho-/angioplasty surgeries	<p><u>FAQ (13.05.2022)</u></p> <p>Can primary cases that had broncho-angioplasty followed by pneumonectomy be counted in the denominator?</p> <p>Answer</p> <p>No, these cannot be counted. If a broncho-angioplasty operation is followed by a salvage pneumonectomy due to residual tumour or a complication, the primary cases are not counted in the denominator. Primary cases are not counted for the indicator.</p>
		Denominator	Primary cases with pneumonectomies and primary cases with broncho-/angioplasty surgeries.	
		Target value	No details right now.	
20	Pathology reports	Numerator	Examined malignant lung cases	<p><u>FAQ (13.07.2018)</u></p> <p>May biopsies and second assessments also be counted for the proof of pathological assessments?</p> <p>Answer:</p> <p>Yes, biopsies may be counted. Second assessments may only be counted if they are reference pathologies and not duplicate findings.</p> <p><u>FAQ (13.05.2022)</u></p> <p>Do molecular pathology assessments also count towards the ratio?</p> <p>Answer:</p> <p>No.</p>
			≥ 200 malignant lung cases (for each specialist 100 L.)	

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21	Adjuvant cisplatin-based chemotherapy stages II-III A1/2	Numerator	Primary cases of the denominator with cisplatin-based chemotherapy	<p><u>FAQ (14.07.2016)</u> Are neoadjuvant pre-treated R0 and LN resected primary NSCLC cases stad. II-III A 1/2 included in the denominator?</p> <p>Answer: No, neoadjuvantly pre-treated patients cannot be counted for the denominator.</p> <p><u>FAQ (24.06.2020)</u> Can carcinoids also be counted in the denominator?</p> <p>Answer: No.</p>
		Denominator	R0 and lymph node-resected NSCLC primary cases with anatomical lung resection stages II-III A1/2 with ECOG 0/1	
		Target value	No details right now.	
26	First-line therapy with EGFR TKI in pat. stage IV NSCLC with common activating EGFR mutation (del 19, L858R) and ECOG 0-2.	Numerator	Primary cases of the denominator with commencement of first-line therapy with EGFR-TKI	<p><u>FAQ (13.05.2022)</u> Can a therapy be counted as first-line therapy if a systemic/chemotherapy was initially given due to high treatment pressure to bridge the gap until the molecular pathological findings were available, and then immediately switched to a specific TKI therapy after the molecular pathological findings were received?</p> <p>Answer: Yes, this is possible.</p>
		Denominator	Primary cases with stage IV NSCLC, typical activating EGFR mutation (del 19, L858R) and ECOG 0-2.	
		Target value	No details right now.	
31	CTCAE stage V on systemic therapy	Numerator	Primary cases of the denominator with CTCAE stage V on systemic therapy	<p><u>FAQ (13.05.2022)</u> Does the denominator refer to non-operated primary cases only?</p> <p>Answer: No. The recording of side effects under system therapy is independent of the therapy position (definitive system therapy, neo-/adjuvant (postoperative) system therapy, palliative).</p>
		Denominator	Primary cases stages III or IV on systemic therapy	
		Target value	No details right now.	
33	PD-L1 testing for NSCLC in stage III with radiochemotherapy	Numerator	Primary cases of the denominator with PD-L1 testing before starting radiochemotherapy	<p><u>FAQ (22.10.2020)</u> Is it necessary to wait for the PD-L1 test result before starting radiochemotherapy?</p> <p>Answer: The start of radiochemotherapy should not be delayed just because the test result is not yet available.</p>
		Denominator	Primary cases with NSCLC stage III with radiochemotherapy	
		Target value	≥ 75%	