EUROPEAN CANCER CENTRES

Deutsche Gesellschaft für Pneumologie und Beatmungsmedizin e.V. **(German Respiratory Society - DGP)**

Deutsche Gesellschaft für Thoraxchirurgie **(German Society for Thoracic Surgery)**

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)

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

Catalogue of Requirements Lungs	Version I2	15.09.2023
Indicator Sheet Lungs	Version I2.1	15.09.2023

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FAQs - Catalogue of Requirements - Lungs

1.1 Structure of the network

Section	Requirements	Explanatory remarks of the Lung Cancer Centre	
1.1.1i	Precondition for multi-location cooperation models: • At least 1x/month a joint tumour board (TB). In the other weeks, site-specific TB, in which all requirements for theTB 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 is required by the Certificate award Committee before the certificate is issued. • Number of cooperating thoracic surgeons/pneumologists: max. 3 pneumologists and 3 thoracic surgeons	FAQ (13.05 2022): 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? Answer: It is assigned to site B, but the surgery can be counted for site A's surgical expertise.	

1.2 Interdisciplinary cooperation

Section	Requirements		
1.2.1 a	The Lung Cancer Centre must treat at least 200 patients a year with a primary diagnosis of "lung cancer" in their own Centre. Definition primary case of the Centre: • 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): o Solitary pulmonary nodule, suspected malignoma o FDG-PET positive o Documented size progression over course of time (at least 8 weeks) o High risk for patients through pathological confirmation o Presentation tumour board and indication radiotherapy without pathological confirmation o 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 • Synchronous tumour in another tumour entity can be counted as a primary case for each tumour entity	Details in the Indicator Sheet: Basic data / Indicator 1 (Excel template) <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? Answer: The time of counting is the date of the first diagnosis even if the surgery is carried out the following calendar year. <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? Answer: Best supportive care also counts as treatment. <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. 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. <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?	
Section	Requirements		

		Answer: 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.	
	Therapy discontinuations: 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. Not included when the patient has switched to another Centre after diagnosis or before the commencement of treatment	FAQ (14.07.2016): What is the definition of "discontinuation of therapy"? Answer: When the originally planned treatment is not carried[1)] out in full. See spreadsheet of the Working Group of German Cancer Centres (*Arbeitsgemeinschaft Deutscher Tumorzentren e.V.* - ADT): field discontinuation [1)] Must be defined by service provider.	
1.2.3 b	Participants tumour board 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. 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.	FAQ (21.03.2018) Is it mandatory for nuclear medicine specialists to attend the weekly tumour board? Answer: No. The presence of a nuclear medicine physician is to be made possible if necessary (e.g. need to discuss lung scintigraphy).	
1.2.6 b	Indication conference • 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	FAQ (14.07.2016): - 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	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. Documentation and evaluation To identify treatment needs, screening of mental strain must be undertaken (see indicator “psycho-oncological distress-screening”), and the result is to be documented. The proportion of patients with excessive stress in the distress screening should be presented. Scope of treatment Psycho-oncological care, in particular for patients with excessive stress in the distress screening, must be presented.	FAQ (21.07.2016): Can the establishment of contact *in situ* replace screening? 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. FAQ (28.08.2023) How should the proportion of patients with excessive distress in distress screening and further psycho-oncological care be presented? Answer: The number of screened patients who have shown an excessive test should be described. The processes of psycho-oncological care should be described; the number of counselling sessions carried out should be recorded. A separate FAQ document on psycho-oncology (Catalogue of Requirement and Indicators) is expected to be published in early 2024.	

1.5 Social work and rehabilitation

Section	Requirements	Explanatory remarks of the Lung Cancer Centre	
1.5.1	Qualifications social work • 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 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. Premises: A suitable room is to be provided for social counselling work. 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.	FAQ (13.07.2018) How are the required personnel resources to be calculated/proved? 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.	

1.6 Patient involvement

Section	Requirements	Explanatory remarks of the Lung Cancer Centre	
1.6.6	Event for patients 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 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.	FAQ (21.07.2022) How can the Lung Cancer Centre prove the exclusion of direct influence by industry representatives? Answer: 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 patents	

1.7 Study management

Section	Requirements	Explanatory remarks of the Lung Cancer Centre	
1.7.5 b	Proportion study patients • Initial certification: At the time of initial certification >= 1 patients must have been included in the studies. • after 1 year: at least 5% of the primary case number	Specification in data sheet (Excel template) Indicator 6	
	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). Only the inclusion of patients in studies for which a valid ethical vote is available counts as study participation. Inclusion in studies whose sole objective is to collect material (biobanking) does not count. General preconditions for the definition of the study quota: • 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.	FAQ (24.06.2020) Which studies may be counted? Answer: Studies with an ethical vote in which centre patents were introduced in the audit-relevant calendar year are counted. Studies whose sole aim is the collection of material (biobanking) are excluded. However, interventional and observational studies with a concrete research question, such as the CRISP study, are eligible. FAQ (10.02.2022) Can negatively screened study patients be counted? Answer: 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. FAQ (28.08.2023) Can patients referred to a Centre for Personal-ised Medicine (CPM) for the purpose of com-plex diagnostics, interdisciplinary consultation and individual therapy recommendations who participate in a study there be counted towards the study quota of the sending centre? Answer: Yes, in this case the study inclusion can be counted by both the sending centre and the CPM. The other requirements for study inclu-sion according to the survey form will apply.	

2.2 Diagnostic

Section	Requirements	Explanatory remarks of the Lung Cancer Centre	
2.2.3 f	• (…)		
	• Transbronchial lung biopsies (1430.2)	FAQ (05.08.2019) Can the transoesophageal lung biopsies also be counted here? Answer: Yes, the transoesophageal lung biopsies may be counted.	

FAQs - Indicator Sheet - Lungs

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1b	Patients with recent recurrence and/or distant metastases	Numerator	Patients with recent recurrence and/or distant metastases	FAQ (02.08.2021) 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? 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**).
		Target value	No target value	
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	FAQ (14.07.2016): 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 indicator year have to be counted for this indicator? Answer: Yes. These patients must be presented (for the indicator) at the transition from curative to palliative, i.e. at the first palliative therapy. FAQ (13.07.2018) What is the key figure target? 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.
		Denominator	Patients with new recurrence and/or remote metastases after prior curative treatment	
		Target value	≥ 90%	

8	Flexible bronchoscopy	Numerator	Flexible bronchoscopies for each service provider	FAQ (13.05.2022) Are all patients counted who had a flexible bronchoscopy? That is, regardless of whether a C34 diagnosis is given or not? Answer: Yes.
9	Interventional bronchoscopy (thermal procedures and stenting)	Numerator	Interventional surgery (thermal procedures and stenting) for each service provider (OPS: 5-319.14, 5319.15, 5-320.0)	FAQ (14 July 2016): May cryo-therapies (tumour removal with a cryoprobe) also be included in interventional bronchoscopy? Answer: Yes, but not cryo-biopsies as they are not interventional procedures.
		Denominator	---	
		Target value	≥ 10	
11b	Lung resections	Numerator	Surgical expertise Number anatomical resections (OPS: 5-323 to 5-328, for each ICD-10 C diagnosis, including ICD-10 C34)	FAQ (12.09.2017) What exactly is the new counting method for anatomical resections? Answer: 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.
		Target value	≥ 75	
12	Ratio of broncho-/angioplasty surgeries to pneumonectomie	Numerator	Primary cases of denominator with broncho-/angioplasty surgeries	FAQ (13.05.2022) Can primary cases that had broncho-angioplasty followed by pneumonectomy be counted in the denominator? Answer 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.
		Denominator	Primary cases with pneumonectomies and primary cases with broncho-/angioplasty surgeries.	
		Target value	No target value	
19	Stereotactic radiotherapy for inoperability	Numerator	Primary cases of the denominator with stereotactic radiotherapy	FAQ (21.07.2022) What are the requirements for stereotaxy?

		Denominator	Primary cases NSCLC stage IA, IB, IIA with tumour board recommendation against	Answer: Based on the consultation version of the GL Lung Cancer (version 2.01, May 2022) and the DEGRO/DGMP position paper (Guckenberger et al., 2020), body stereotactic radiotherapy (SBRT) for the treatment of NSCLC is defined as follows: • Percutaneous application of a high radiation dose with high precision • Definition of the target volume by means of imaging control of the tumour's respiratory excursion using breath-triggered 4D CT series in the irradiation position • Application of dose concepts with few (max. 12) fractions with individual doses of at least 5 Gy <u>FAQ (06.07.2023)</u> Can stereotactic therapies in functionally inoperable patients without histological confirmation (nevertheless primary case according to definition) be included in the indicators? Answer: No, stereotactic therapies in functionally inoperable patients without histological confirmation are not recorded. The denominator of this indicator also explicitly states in accordance with quality indicator 11 of the NSCLC guideline, which implies histological confirmation.
		Target value	No target value	

20	Pathology reports	Numerator	Examined malignant lung cases ≥ 200 malignant lung cases (for each specialist 100 L.)	FAQ (13.07.2018) May biopsies and second assessments also be counted for the proof of pathological assessments? Answer: Yes, biopsies may be counted. Second assessments may only be counted if they are reference pathologies and not duplicate findings. FAQ (13.05.2022) Do molecular pathology assessments also count towards the ratio? Answer: No.
21	Adjuvant cisplatin-based chemotherapy stages II-IIIA1/2	Numerator	Primary cases of the denominator with cisplatin-based chemotherapy	FAQ (14.07.2016) Are neoadjuvant pre-treated R0 and LN resected primary NSCLC cases stad. II-IIIA 1/2 included in the denominator? Answer: No, neoadjuvantly pre-treated patients cannot be counted for the denominator. FAQ (24.06.2020) Can carcinoids also be counted in the denominator? Answer: No.
		Denominator	R0 and lymph node-resected NSCLC primary cases with anatomical lung resection stages II-IIIA1/2 with ECOG 0/1	
		Target value	No target value	
26	First-line therapy with EGFRTKI 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	FAQ (13.05.2022) 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? Answer: Yes, this is possible.
		Denominator	Primary cases with stage IV NSCLC, typical activating EGFR mutation (del 19, L858R) and ECOG 0-2.	
		Target value	No target value	

31	CTCAE stage V on systemic therapy	Numerator	Primary cases of the denominator with CTCAE stage V on systemic therapy	FAQ (13.05.2022) Does the denominator refer to non-operated primary cases only? 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).
		Denominator	Primary cases stages III or IV on systemic therapy	
		Target value	No target value	
33	PD-L1 testing for NSCLC in stage III with radiochemotherapy	Numerator	Primary cases of the denominator with PD-L1 testing before starting radio-chemotherapy	FAQ (22.10.2020) Is it necessary to wait for the PD-L1 test result before starting radiochemotherapy? Answer: The start of radiochemotherapy should not be delayed just because the test result is not yet available.
		Denominator	Primary cases with NSCLC stage III with radio-chemotherapy	
		Target value	≥ 75%	