

Entitätenspezifische Qualitätskonferenz des KKRBB zum Lungenkarzinom

Einführung von GKV-finanziertem Lungenkrebs- Screening in Deutschland

– Rundherdmanagement, Qualitätssicherung: Chancen und
Herausforderungen für Krebsregister

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Conflict of interest disclosure

I have no real or perceived conflicts of interest that relate to this presentation.

I have the following real or perceived conflicts of interest that relate to this presentation:

Affiliation / Financial interest	Commercial Company
Grants/research support:	EU4Health, EU IMI, EU IHI
Honoraria or consultation fees:	Astra, Boehringer Ingelheim, Lilly, MSD, Pfizer, Roche
Participation in a company sponsored bureau:	-
Stock shareholder:	-
Spouse / partner:	-
Other support / potential conflict of interest:	-

Definition Lungenrundherd

—

Management von Screening-detektierten
Lungenrundherden

Solitary Pulmonary Nodules

The management of an asymptomatic patient in whom a solitary, well-circumscribed pulmonary opacity (coin lesion) has been discovered on routine x-ray examination is a perennial problem. The differential diagnosis in these cases includes bronchial carcinoma, a single pulmonary metastatic deposit, a benign tumour or cyst, and a tuberculous focus. With few exceptions the nature of the lesion can be established only if it is resected and submitted to pathological examination. In some cases there may indeed be no logical alternative to this policy, as for example when the patient is middle-aged or elderly, is a heavy cigarette smoker, and is known to have had a normal chest radiograph within the previous two years. To withhold or delay thoracotomy in these circumstances may be to deny the patient effective treatment for what may prove to be an early bronchial carcinoma.

- common problem

- different diagnoses!

- confirmation needed (?)

- assess risk factors!

- chance to cure lung cancer!

Glossary of Terms for Thoracic Radiology: Recommendations of the Nomenclature Committee of the Fleischner Society¹

nodule, *n.*, -s. 1. *Morphol/Gen'l med.* Any small, nearly spherical collections of differentiated tissue. 2. *Radiol.* Any pulmonary or pleural lesion represented in a radiograph by a sharply defined, discrete, nearly circular opacity 2–30 mm in diameter. — *Qualifiers:* Should always be qualified with respect to size, location, border characteristics, number, and opacity. — *Synonym:* coin lesion (q.v.); cf. *mass*. — *Evaluation:* A useful and recommended descriptor to be used in preference to *coin lesion*.

nodule

Radiographs and CT scans.—The chest radiographic appearance of a nodule is a rounded opacity, well or poorly defined, measuring up to 3 cm in diameter. (a) Acinar nodules are round or ovoid poorly defined pulmonary opacities approximately 5–8 mm in diameter, presumed to represent an anatomic acinus rendered opaque by consolidation. This classification is used only in the presence of numerous such opacities. (b) A pseudonodule mimics a pulmonary nodule; it represents, for example, a rib fracture, a skin lesion, a device on the surface of the patient, anatomic variants, or composite areas of increased opacity (94).

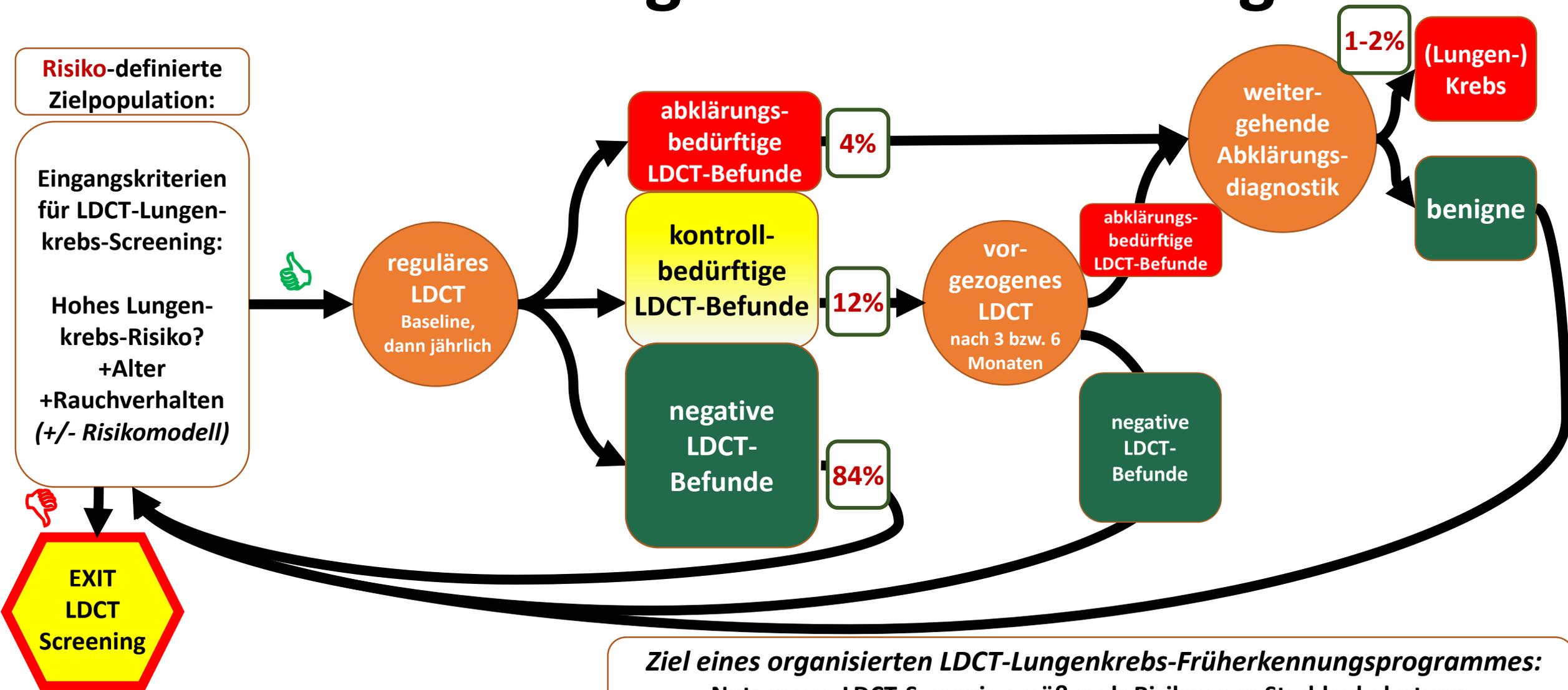
Solitary pulmonary nodule (SPN) is defined as a single lung opacity of size less than 3 cm. It is usually discrete and does not attach to the lung border or pleura. Associated lymphadenopathy is characteristically absent.

Wyker A, Henderson WW. Solitary Pulmonary Nodule. [Updated 2022 Dec 19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK556143/>

Pulmonary nodules

- **Morphologic subtyping according to Fleischner-Society:**
 - Solid
 - Subsolid
 - Part solid
 - Pure ground glass
 - **Discrimination between Incidental and Screening-detected pulmonary nodules:**
 - ***Incidental pulmonary nodules:*** Prevalence in general population approx. 13% (2-24%)
 - ***Screening-detected pulmonary nodules:*** Prevalence in LDCT-Screening-populations 33% (17-53%)
- Also:
- ***Pulmonary nodules after previous cancer disease:*** Incidence depending on primary cancer

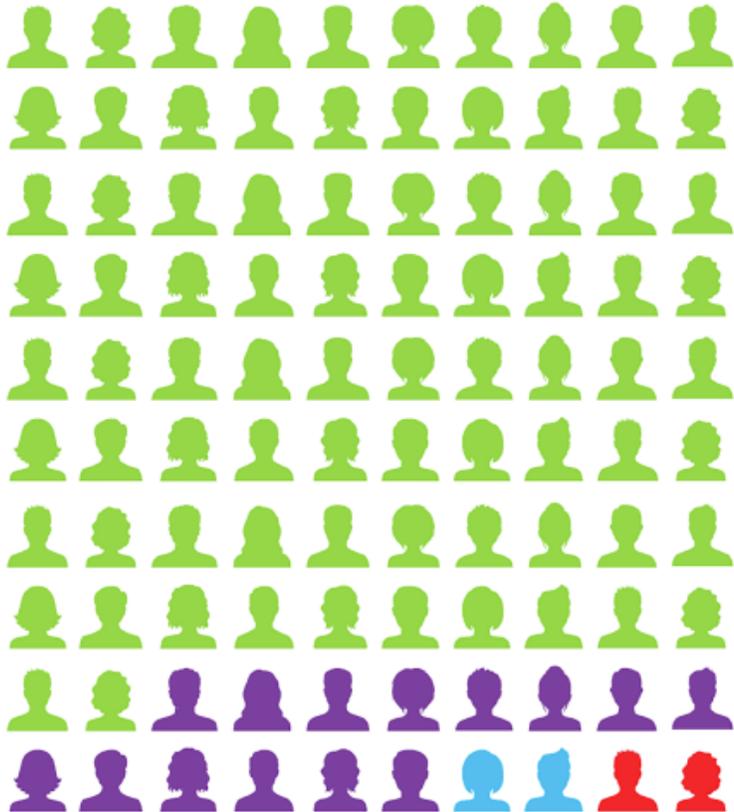
aktuelles LDCT Lungenkrebs-Screening-Modell



Ziel eines organisierten LDCT-Lungenkrebs-Früherkennungsprogrammes:
Nutzen von LDCT-Screening größer als Risiken von Strahlenbelastung,
(unnötiger) invasiver Diagnostik/Therapie und Überdiagnosen

UK: Analysis of the baseline performance of five UK lung cancer screening programs

**LDCT LCS:
effective & safe**



82 People
Are likely to have a negative scan, which means there is no sign of lung cancer

14 People
Are likely to have a small lung nodule or other minor finding that needs another scan in 3 months. Almost all of these people will NOT have lung cancer on their repeat scans

2 People
Are likely to be asked to attend the hospital for further tests but will NOT be found to have lung cancer

2 People
Are likely to be diagnosed with lung cancer

- Similar efficacy & safety:
- national Croatian LDCT LCS program; Samaržija M et al. unpublished data
 - HANSE LDCT LCS pilot study (Germany); Vogel-Claussen J et al. Lancet Oncology in press

invasive diagnostics/therapy: no serious morbidity or mortality

apply robust clinical algorithms for *LDCT reading!*

Guidelines for incidental nodules

Guidelines for screening-detected nodules

Fleischner Society 2017 Guidelines for Management of Incidentally Detected Pulmonary Nodules in Adults

A: Solid Nodules*

Nodule Type	Size			Comments
	<6 mm (<100 mm ³)	6–8 mm (100–250 mm ³)	>8 mm (>250 mm ³)	
Single				
Low risk [†]	No routine follow-up	CT at 6–12 months, then consider CT at 18–24 months	Consider CT at 3 months, PET/CT, or biopsy	Nodules <6 mm do not require routine follow-up in low-risk patients (recommendation 1A). Certain patients at high risk with suspicious nodule morphology, upper lobe location, or both may warrant 12-month follow-up (recommendation 1A).
High risk [†]	Optional CT at 12 months	CT at 3–6 months, then at 18–24 months	CT at 3–6 months, then at 18–24 months	Use most suspicious nodule as guide to management. Follow-up intervals may vary according to size and risk (recommendation 2A).

B: Subsolid Nodules*

Nodule Type	Size		Comments
	<6 mm (<100 mm ³)	≥6 mm (>100 mm ³)	
Single			
Ground glass	No routine follow-up	CT at 6–12 months to confirm persistence, then CT every 2 years until 5 years	In certain suspicious nodules < 6 mm, consider follow-up at 2 and 4 years. If solid component(s) or growth develops, consider resection. (Recommendations 3A and 4A).
Part solid	No routine follow-up	CT at 3–6 months to confirm persistence. If unchanged and solid component remains <6 mm, annual CT should be performed for 5 years.	In practice, part-solid nodules cannot be defined as such until ≥6 mm, and nodules <6 mm do not usually require follow-up. Persistent part-solid nodules with solid components ≥6 mm should be considered highly suspicious (recommendations 4A–4C).

MacMahon H et al. Radiology 2017



Lung-RADS® v2022

Release Date: November 2022

Lung-RADS	Category Descriptor	Findings	Management
0	Incomplete Estimated Population Prevalence: ~ 1%	Prior chest CT examination being located for comparison (see note 9)	Comparison to prior chest CT;
		Part or all of lungs cannot be evaluated	Additional lung cancer screening CT imaging needed;
		Findings suggestive of an inflammatory or infectious process (see note 10)	1-3 month LDCT
1	Negative Estimated Population Prevalence: 39%	No lung nodules OR	12-month screening LDCT
		Nodule with benign features: • Complete, central, popcorn, or concentric ring calcifications OR • Fat-containing	
2	Benign - Based on imaging features or indolent behavior Estimated Population Prevalence: ~ 97%	Juxtapleural nodule: • < 10 mm (524 mm ³) mean diameter at baseline or new AND • Solid; smooth margins; and oval, lentiform, or triangular shape	12-month screening LDCT
		Solid nodule: • < 6 mm (< 113 mm ³) at baseline OR • New < 4 mm (< 34 mm ³)	
		Part solid nodule: • < 6 mm total mean diameter (< 113 mm ³) at baseline	

www.acr.org

Snoeckx A et al. Eur Radiol 2025

- **European Society of Thoracic Imaging 2025**
- **International Early Lung Cancer Action Program (I-ELCAP)**
- **NCCN LCS** www.nccn.org
- **European Position Statement on LCS**

www.ielcap.org

Oudkerk M et al. Lancet Oncol 2017



British Thoracic Society guidelines for the investigation and management of pulmonary



negative or insignificant LDCT result

Screening-detektierte Lungenrundherde: Negative Befunde



Lung-RADS® v2022

Release Date: November 2022

Lung-RADS	Category Descriptor	Findings	Management
0	Incomplete Estimated Population Prevalence: ~ 1%	Prior chest CT examination being located for comparison (see note 9)	Comparison to prior chest CT;
		Part or all of lungs cannot be evaluated	Additional lung cancer screening CT imaging needed;
		Findings suggestive of an inflammatory or infectious process (see note 10)	1-3 month LDCT
1	Negative Estimated Population Prevalence: 39%	No lung nodules OR	12-month screening LDCT
		Nodule with benign features: <ul style="list-style-type: none"> • Complete, central, popcorn, or concentric ring calcifications OR • Fat-containing 	
2	Benign - Based on imaging features or indolent behavior Estimated Population Prevalence: 45%	Juxtapleural nodule: <ul style="list-style-type: none"> • < 10 mm (524 mm³) mean diameter at baseline or new AND • Solid; smooth margins; and oval, lentiform, or triangular shape 	
		Solid nodule: <ul style="list-style-type: none"> • < 6 mm (< 113 mm³) at baseline OR • New < 4 mm (< 34 mm³) 	
		Part solid nodule: <ul style="list-style-type: none"> • < 6 mm total mean diameter (< 113 mm³) at baseline 	
		Non solid nodule (GGN): <ul style="list-style-type: none"> • < 30 mm (< 14,137 mm³) at baseline, new, or growing OR • ≥ 30 mm (≥ 14,137 mm³) stable or slowly growing (see note 7) 	
		Airway nodule, subsegmental - at baseline, new, or stable (see note 11)	
Category 3 lesion that is stable or decreased in size at 6-month follow-up CT OR Category 4B lesion proven to be benign in etiology following appropriate diagnostic workup			

~ 84%

indeterminate
LDCT
result

Screening-detektierte Lungenrundherde: Kontrollbedürftige Befunde

~ 13%

3	Probably Benign - Based on imaging features or behavior Estimated Population Prevalence: 9%	Solid nodule: • ≥ 6 to < 8 mm (≥ 113 to < 268 mm ³) at baseline OR • New 4 mm to < 6 mm (34 to < 113 mm ³)	6-month LDCT
		Part solid nodule: • ≥ 6 mm total mean diameter (≥ 113 mm ³) with solid component < 6 mm (< 113 mm ³) at baseline OR • New < 6 mm total mean diameter (< 113 mm ³)	
		Non solid nodule (GGN): • ≥ 30 mm ($\geq 14,137$ mm ³) at baseline or new	
		Atypical pulmonary cyst: (see note 12) • Growing cystic component (mean diameter) of a thick-walled cyst	
		Category 4A lesion that is stable or decreased in size at 3-month follow-up CT (excluding airway nodules)	
4A	Suspicious Estimated Population Prevalence: 4%	Solid nodule: • ≥ 8 to < 15 mm (≥ 268 to $< 1,767$ mm ³) at baseline OR • Growing < 8 mm (< 268 mm ³) OR • New 6 to < 8 mm (113 to < 268 mm ³)	3-month LDCT; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm ³) solid nodule or solid component
		Part solid nodule: • ≥ 6 mm total mean diameter (≥ 113 mm ³) with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm ³) at baseline OR • New or growing < 4 mm (< 34 mm ³) solid component	
		Airway nodule, segmental or more proximal - at baseline (see note 11)	
		Atypical pulmonary cyst: (see note 12) • Thick-walled cyst OR • Multilocular cyst at baseline OR • Thin- or thick-walled cyst that becomes multilocular	

Lung RADS v2022

positive
LDCT
result

Screening-detektierte Lungenrundherde: Abklärungsbedürftige Befunde

~ 3%

4B	Very Suspicious Estimated Population Prevalence: 2%	Airway nodule, segmental or more proximal - stable or growing (see note 11)	Referral for further clinical evaluation
		Solid nodule: • ≥ 15 mm (≥ 1767 mm ³) at baseline OR • New or growing ≥ 8 mm (≥ 268 mm ³)	Diagnostic chest CT with or without contrast; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm ³) solid nodule or solid component; tissue sampling; and/or referral for further clinical evaluation Management depends on clinical evaluation, patient preference, and the probability of malignancy (see note 13)
		Part solid nodule: • Solid component ≥ 8 mm (≥ 268 mm ³) at baseline OR • New or growing ≥ 4 mm (≥ 34 mm ³) solid component	
		Atypical pulmonary cyst: (see note 12) • Thick-walled cyst with growing wall thickness/nodularity OR • Growing multilocular cyst (mean diameter) OR • Multilocular cyst with increased loculation or new/increased opacity (nodular, ground glass, or consolidation)	
Slow growing solid or part solid nodule that demonstrates growth over multiple screening exams (see note 8)			
4X	Estimated Population Prevalence: < 1%	Category 3 or 4 nodules with additional features or imaging findings that increase suspicion for lung cancer (see note 14)	
S	Significant or Potentially Significant Estimated Population Prevalence: 10%	Modifier: May add to category 0-4 for clinically significant or potentially clinically significant findings unrelated to lung cancer (see note 15)	As appropriate to the specific finding

Lung RADS v2022

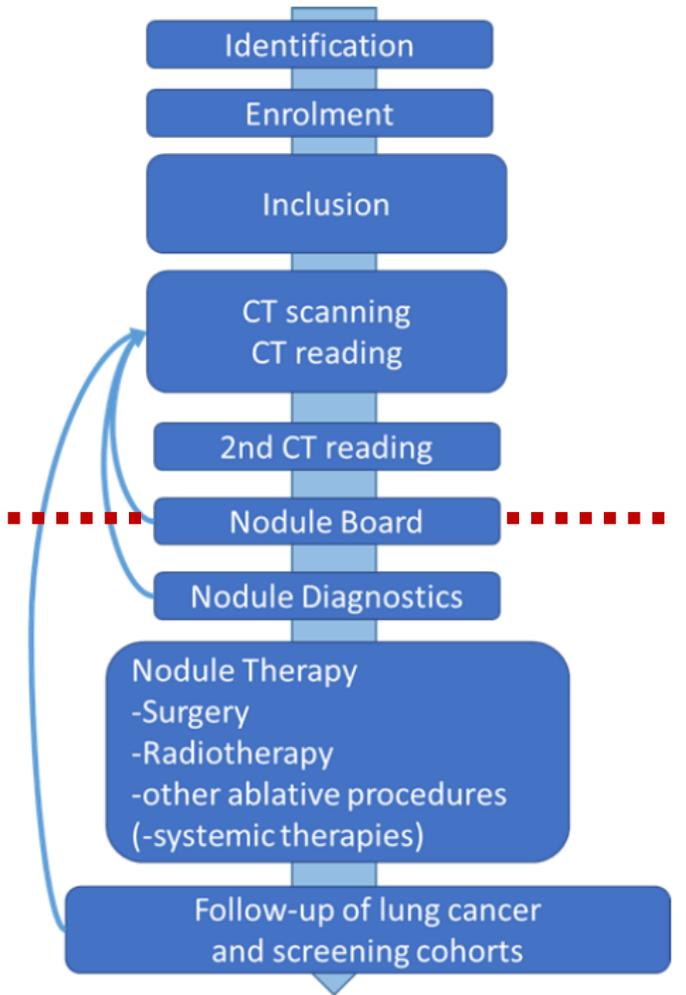
Weitere klinische Abklärung

Management von Screening-detektierten
Lungenrundherden

Leitlinien zum Lungenrundherd-Management:

- 1) Inzidentelle vs. screening-detektierte Lungenrundherde
- 2) Radiologisches vs. weiteres klinisches Management

	Incidental nodules	Screening-detected nodules
Radiological management	Fleischner	I-ELCAP
		Lung RADS 2022
		ESTI 2025
Further clinical management of positive nodules	BTS 2015	BTS 2015
		NCCN 2025
		ERS/ESR 2026



Rundherd-Management aktuell in Deutschland gemäß S3-Leitlinie

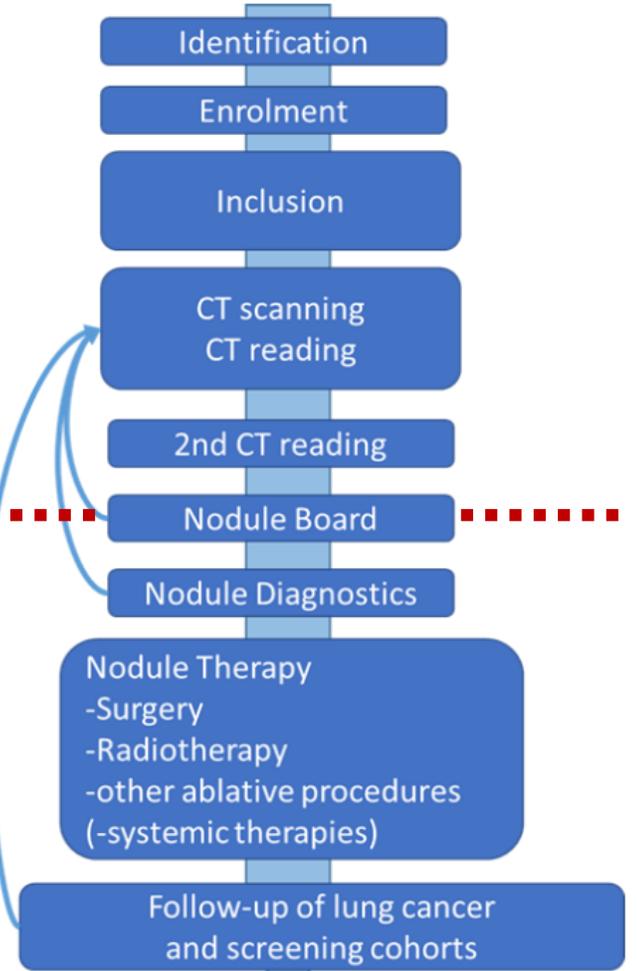
– radiologisch und im Rahmen der weiteren klinischen Abklärung

• LungRADS 2022 mit Volumetrie

<https://www.acr.org/-/media/ACR/Files/RADS/Lung-RADS/Lung-RADS-2022.pdf>

Beschreibung	Kategorie	Geschätzte Häufigkeit*	Weiteres Vorgehen
Unvollständig	0	~1%	Vergleich mit früherem LDCT oder erneutes LDCT
Negativ	1	~30%	Weiter mit jährlichem LDCT-Screening
Gutartig	2	~60%	
Kontrollbedürftig	3	~5%	LDCT-Kontrolle nach 6 Monaten
	4A	~2%	LDCT-Kontrolle nach 3 Monaten
Abklärungsbedürftig	4A (PET)	~0,5%	Abklärung mittels PET/CT
	4B	~1%	Vorstellung zur klin. Abklärung mit initialer Fallkonferenz
	4X	~1%	

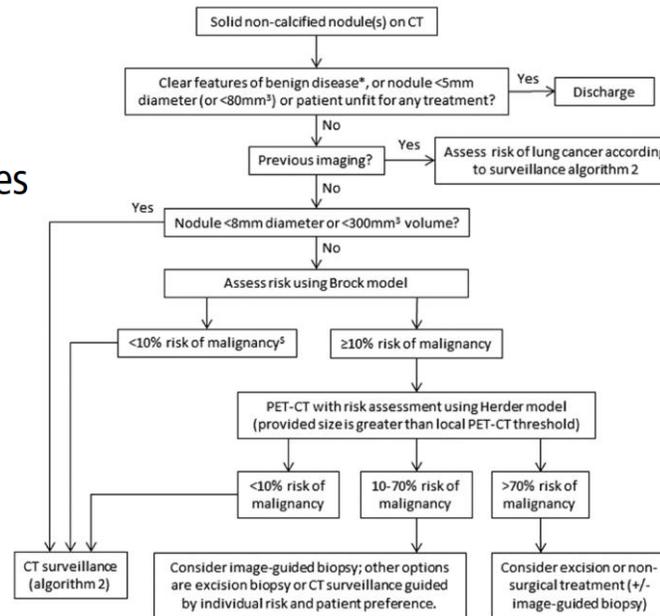
*basierend auf den Daten der HANSE-Studie [21].



• BTS 2015

British Thoracic Society guidelines for the investigation and management of pulmonary nodules

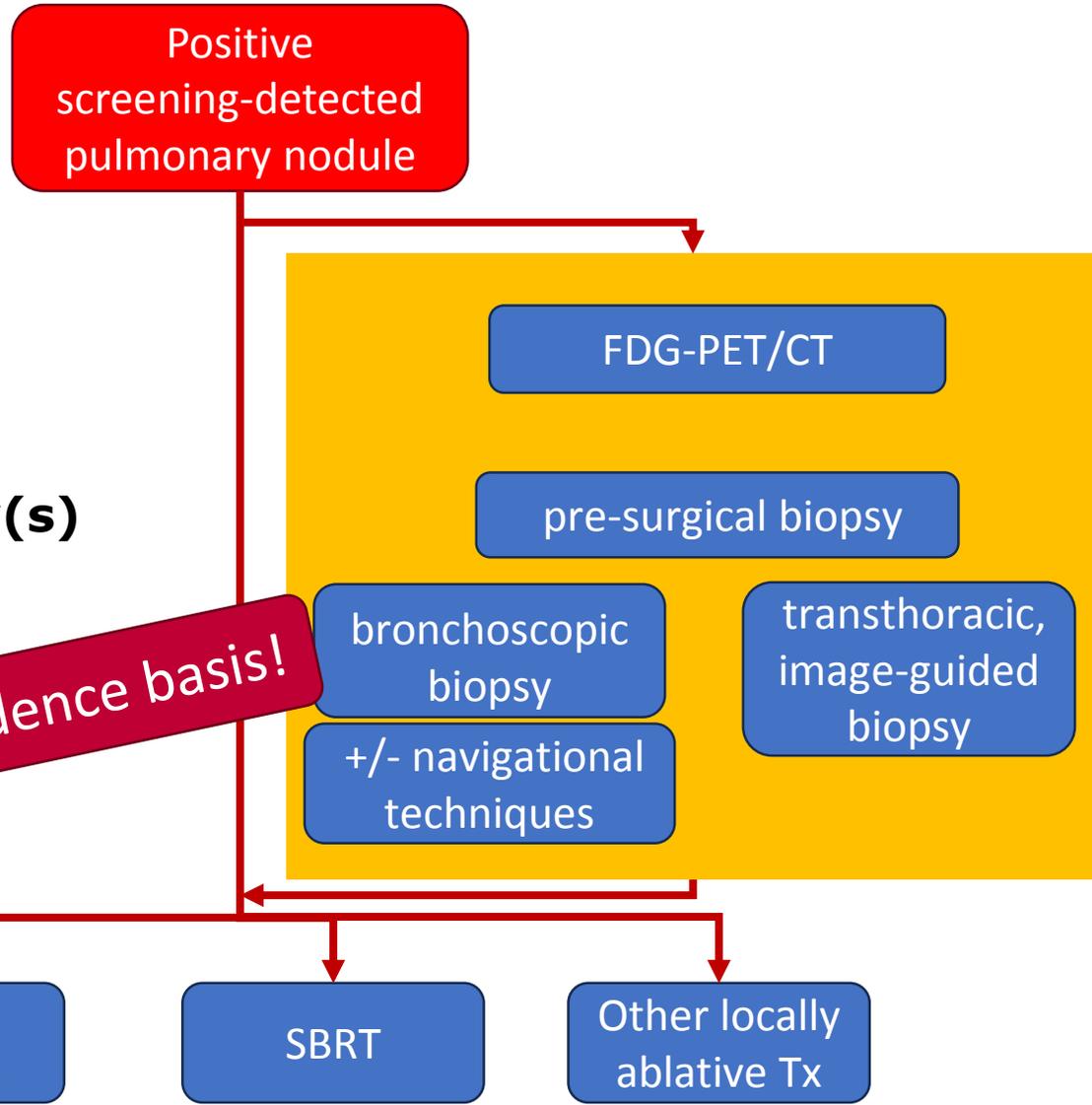
Callister ME et al.
Thorax 2015; 70 Suppl 2:ii1-ii54



Übersicht klinische Abklärung

Management von Screening-detektierten
Lungenrundherden

overview clinical work-up



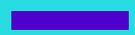
? What are the best pathway(s) in different Subgroups?

Very limited evidence basis!

Factors to consider:

- **Localisation of nodule**
- **Morphology of nodule**
 - Solid vs. part solid/non-solid
- **Size of nodule**
- **Number of nodules**
- **Fitness of patient**

FDG-PET/CT



Management von Screening-detektierten
Lungenrundherden

FDG-PET/CT

9 studies in LDCT LCS cohorts:

- 1,188 participants
- used either PET or PET+CT classification scheme

Test characteristics:

	Sensitivity	Specificity	PPV	NPV	Accuracy
Minimum	63,73%	63,16%	78,91%	31,58%	65,26%
Maximum	93,10%	95,24%	91,18%	95,12%	91,00%

Curative resection rates:

	OR	lower 95% CI	upper 95% CI
Minimum	3,30	1,16	9,39
Maximum	105,30	24,19	583,19

Prä-operative Biopsie vs. primäre Resektion



Management von Screening-detektierten
Lungenrundherden

Präoperative Biopsie vs. primäre Resektion

3 studies in LDCT LCS cohorts:

- 400 patients with positive pulmonary nodules

Surgical resection of unconfirmed nodules

- malignant confirmation rates 72.5%-88.9%
- benign confirmation rates 11.1%-27.5%

Bronchoscopy:

- malignant confirmation rates 48.1%-100%
- benign confirmation rates 0-3.7%
- non-diagnostic rates 0%-48.1%

CT-guided biopsy

- malignant confirmation rates 51.6%-73.1%
- benign confirmation rates 3.2%-4.6%
- non-diagnostic rates 22.2%-45.2%

Nicht-solide Lungenrundherde (Milchglas-Lungenrundherde)

Management von Screening-detektierten
Lungenrundherden

Nicht-solide Lungenrundherde (Milchglas-Lungenrundherde)

3 studies in LDCT LCS cohorts

- 575 patients with non-solid nodules (pure ground glass)

1 study (89 pts.):

- 77 pts. with no change/decrease of non-solid nodule size
- 12 pts. with increased non-solid nodule size; median watchful waiting period: 59 months
- 12 pts: resection due to growing non-solid nodules; median post-operative follow-up period: 51 months, overall survival rate: 100%.

1 study (97 pts.):

- mean watchful waiting period of 15.1 months before surgery
- mean post operative follow-up period in all pts.: 86.9 months
- overall survival rate: 95.9% (93/97 pts,), all deaths due to other causes than lung cancer

1 study (389 pts.):

- mean follow-up period of 9.2 yrs.; watchful waiting in 381 pts.
- 8 pts. with surgical resection of subsolid nodules
- overall survival rates 93.6% (364/389 pts.), all deaths not related to subsolid nodules.

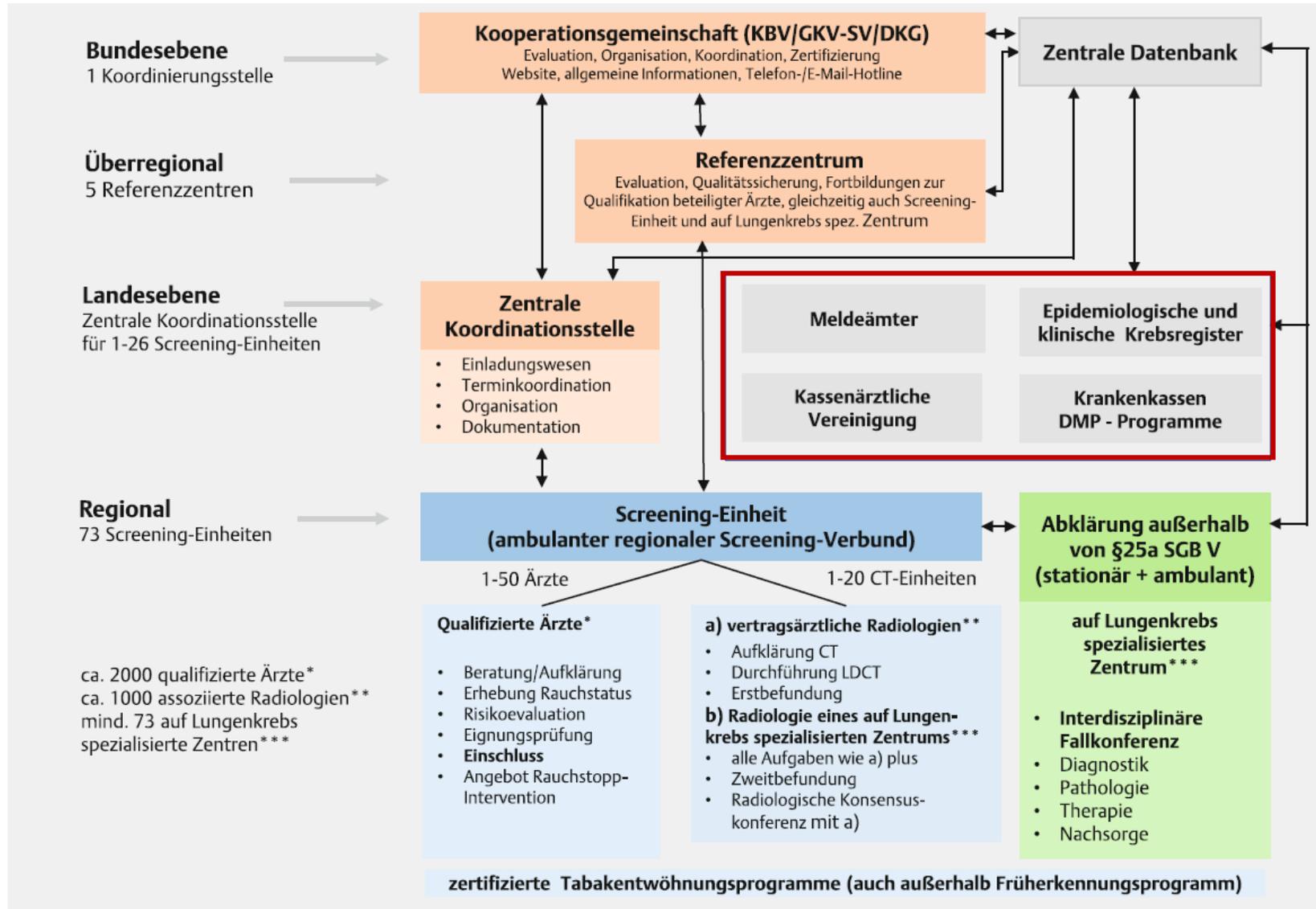
Qualitätssicherung



Lungenkrebs-Screening in Deutschland

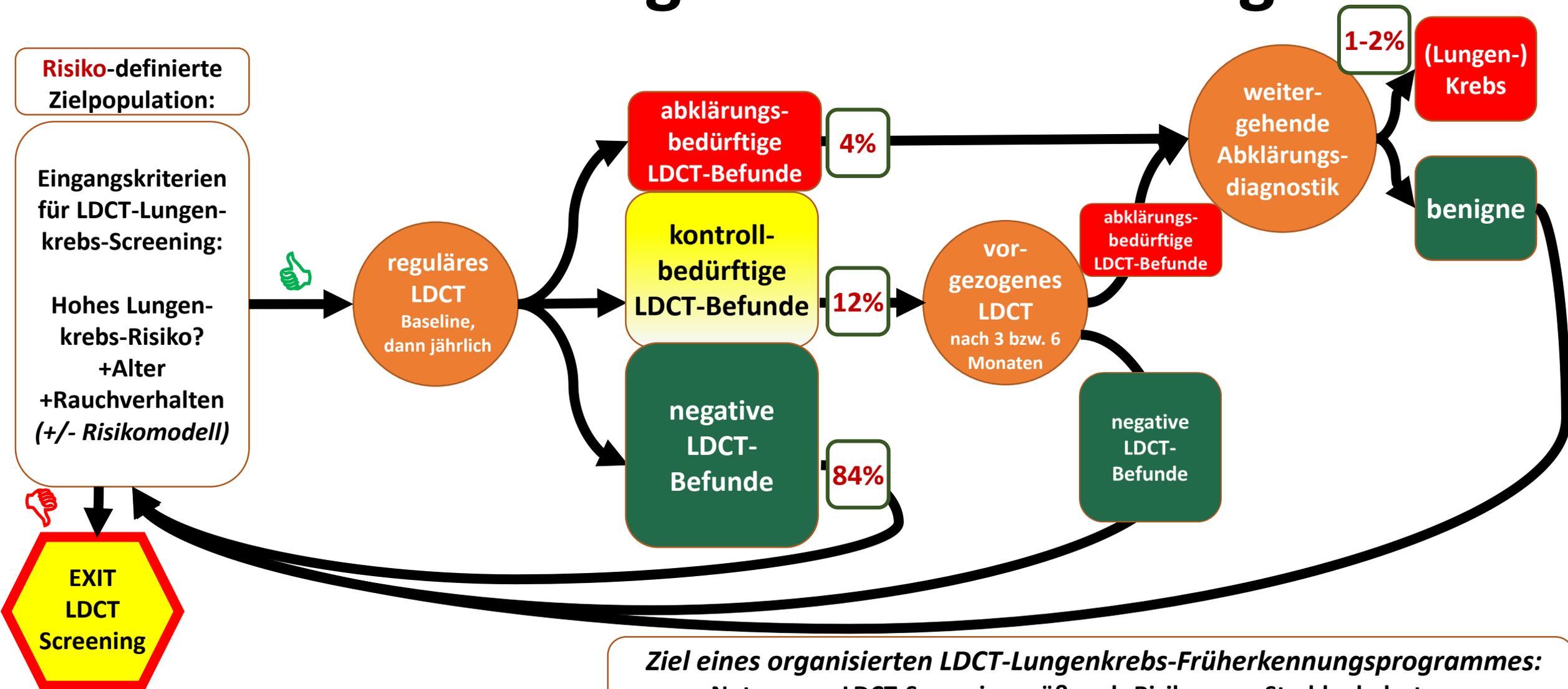
Einbindung der Krebsregister!

LDCT LCS in Deutschland – Qualitätssicherung: Vision: §25a SGB V (organisierte Früherkennung)



Blum TG et al.
Pneumologie 2023
DOI 10.1055/a-2175-4580

aktuelles LDCT Lungenkrebs-Screening-Modell



Ziel eines organisierten LDCT-Lungenkrebs-Früherkennungsprogrammes:
Nutzen von LDCT-Screening größer als Risiken von Strahlenbelastung,
(unnötiger) invasiver Diagnostik/Therapie und Überdiagnosen

Einschluss durch:

- Allgemeinmediziner
- Internisten
- Arbeitsmediziner

→ Steigerung der Einschussraten

→ Reduktion von Überdiagnosen und Übertherapien

Radiologisches Management

- Erst-/Zweitbefunder
- KI-Befundung

• Kopplung an zertifizierte Lungenkrebszentren

→ Reduktion von falsch-positiven Befunden mit unnötiger invasiver Diagnostik und Therapie

Tabakrauchentwöhnung Tabakrauchentwöhnung

Einladung
(zentrale Koordinationsstelle)

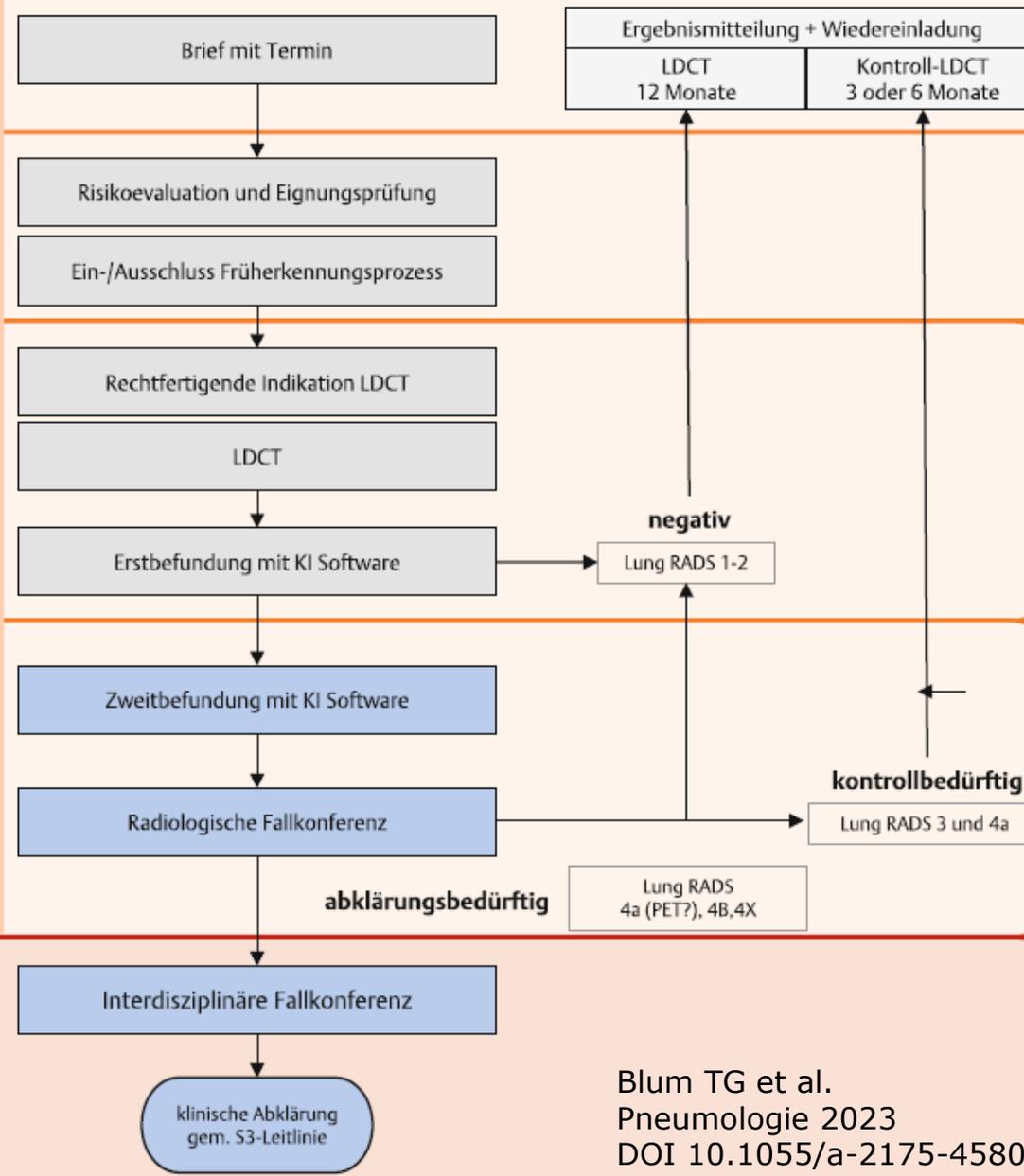
Risikoevaluation + Einschluss
(Qualifizierte Ärzte)

LDCT + Erstbefundung
(Assoziierte Radiologie oder auf Lungenkrebs spezialisiertes Zentrum)

Zweitbefundung
(auf Lungenkrebs spezialisiertes Zentrum)

Versorgung als Patient
(auf Lungenkrebs spezialisiertes Zentrum als Abklärungs- und Behandlungseinheit)

Früherkennung nach §25a SGB V



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Vielen Dank!



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