Lungenkrebs-Screening – wie kann es aussehen?

21.11.2023

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

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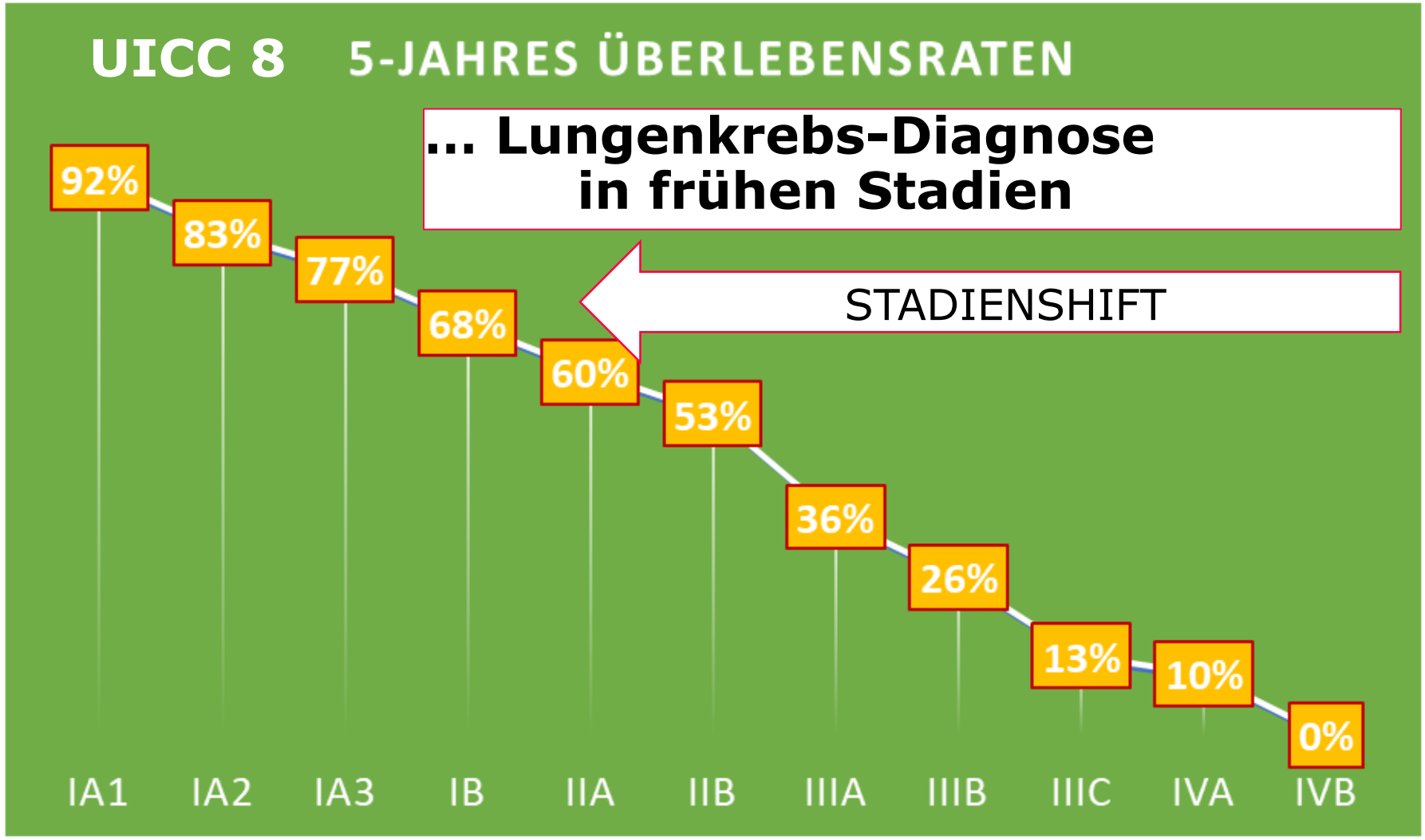
Rationale

Low-dose CT Lungenkrebs-Screening

das Ziel von Low-dose CT Screening …



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Goldstraw P et. J Thor Oncol 2015; 11:39-51

Evidenz

Low-dose CT Lungenkrebs-Screening

Übersicht RCTs LDCT Screening 1/2 – Studiendesign

		Personen	LDCT vs.	Intervall Screening	Runden Screening	Follow-up
DANTE	I	2450	--	1 J.	5	8 Jahre
DEPISCAN	F	765	Röntgen	1 J.	3	--
DLCST	DK	4104	--	1 J.	5	10 Jahre
ITALUNG	I	3206	--	1 J.	4	9 Jahre
LSS	USA	3318	--	1 J.	2	1 Jahr
LUSI	D	4052	--	1 J.	5	6,5 Jahre
MILD	I	4099	--	1 J., 2 J.	7, 4	10 Jahre
NELSON	NL/B	15822	--	1 J./2 J./2,5 J.	4	16 Jahre
NLST	USA	53452	Röntgen	1	3	6,5 Jahre
UKLS	UK	4055	--	--	1	--

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Übersicht RCTs LDCT Screening 2/2 – Einschlusskriterien

		Einschlusskriterien		
		Alter	**Nikotinkonsum**	**Nikotinstopp**
DANTE	I	60-74	≥20 Packungsj.	max. 10 J.
DEPISCAN	F	50-75	≥15 Zig./Tag für 20 J.	max. 15 J.
DLCST	DK	50-70	≥20 Packungsj.	max. 10 J.
ITALUNG	I	55-69	≥20 Packungsj.	--
LSS	USA	55-74	≥30 Packungsj.	max. 10 J.
LUSI	D	50-69	≥15 Zig./Tag für 25 J. bzw. ≥10 Zig./Tag für 30 J.	max. 10 J.
MILD	I	49-75	≥20 Packungsj.	max. 10 J.
NELSON	NL/B	50-75	≥15 Zig./Tag für 25 J. bzw. ≥10 Zig./Tag für 30 J.	max. 10 J.
NLST	USA	55-75	≥30 Packungsj.	max. 15 J.
UKLS	UK	50-75	LLP-Risikoscore ≥5%	--

Risiko-adaptiertes Screening: Alter plus Nikotinkonsum

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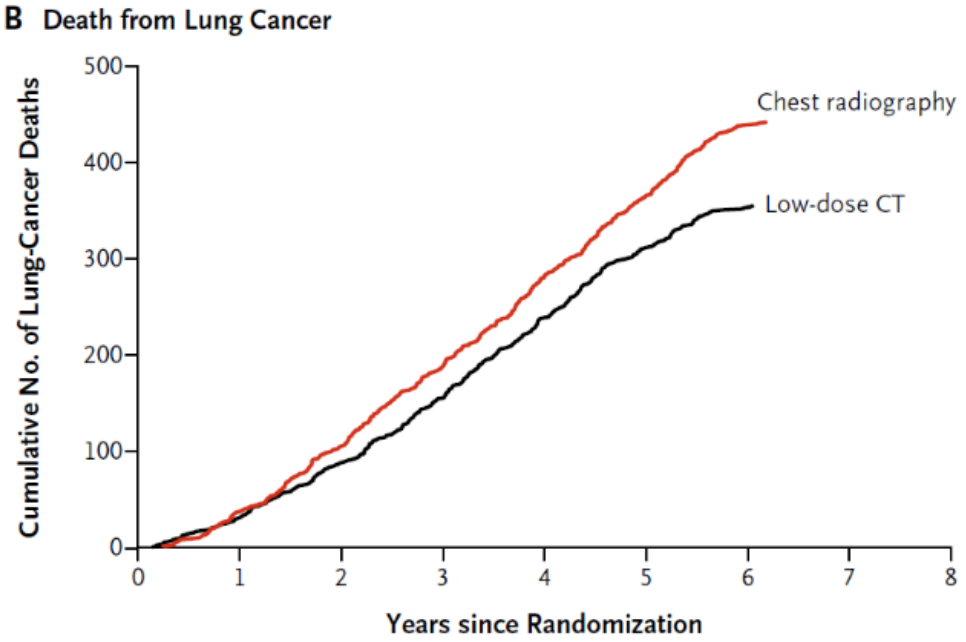
National Lung Screening Trial (USA)

	Low dose CT Group	Radiography Group
total Participants screened	26,309 (98.5%)	26,035 (97.4%)
Part. with positive screening	7,191 (27.3%)	2,387 (9.2%)
Part. with any follow-up diagnostic procedure	6,369 (90.4%)	2,176 (92.7%)
-Clinical evaluation	5,083 (72.2%)	1,414 (60.2%)
-Imaging studies	5,717 (81.1%)	201 (85.6%)
-Percutaneous biopsy	155 (2.2%)	83 (3.5%)
-Bronchoscopy	306 (4.3%)	107 (4.6%)
-Surgical procedure	297 (4.2%)	121 (5.2%)
Part. with Dx. of lung cancer	292 (1.1%)	190 (0.7%)
-Stage I	158 (54.8%)	70 (37.9%)
-Stage II	22 (7.7%)	13 (7.0%)
-Stage III-IV	108 (37.5%)	101 (55.2%)
Sensitivity	93.8%	73.5%
Specificity	73.4%	91.3%

Auch übertragbar auf Europa?

	Low dose CT Group	Radiography Group
Deaths from lung cancer per 100,000 person years	247	309
Relative Risk Reduction in mortality		
-from lung cancer	20.0% (95% CI, 6.8 to 26.7; p = 0.004)	
-from any cause	6.7% (95% CI, 1.2 to 13.6; P = 0.02)	

The National Lung Screening Trial Research Team
N Engl J Med
2011; 365: 395-409
2013; 368: 1980-1891



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NELSON – Studiendesign

- Bevölkerungsbasierte randomisierte klinische Studie in den NL
- Low dose CT Screening vs. kein Screening
- Einschlusskriterien:
  - Alter: 50-75 Jahre
  - ≥15 Zig/d über ≥25 Jahre oder ≥ 10 Zig/d über ≥ 30 Jahre; aktiv oder beendet innerhalb der letzten 10 Jahre
- CT zu den Zeitpunkten 0, 1, 3 und 5,5 Jahre
- 15.792 Personen 1:1 randomisiert, 7.900 gescreent
- Follow-up mind. 10 Jahre (wenn nicht gestorben) bei 93,7% der Studienteilnehmer

De Koning H et al.
NEJM 2020

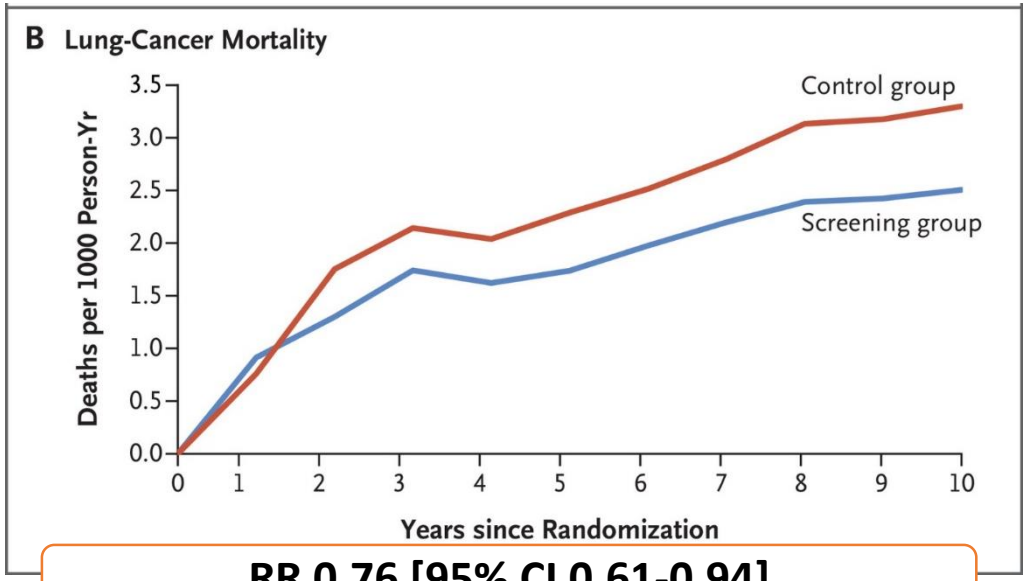
NELSON – Ergebnisse 1/2

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 FEBRUARY 6, 2020 VOL. 382 NO. 6

Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial

H.J. de Koning, C.M. van der Aalst, P.A. de Jong, E.T. Scholten, K. Nackaerts, M.A. Heuvelmans, J.-W.J. Lammers, C. Weenink, U. Yousaf-Khan, N. Horeweg, S. van 't Westeinde, M. Prokop, W.P. Mali, F.A.A. Mohamed Hoesein, P.M.A. van Ooijen, J.G.J.V. Aerts, M.A. den Bakker, E. Thunnissen, J. Verschakelen, R. Vliegenthart, J.E. Walter, K. ten Haaf, H.J.M. Groen, and M. Oudkerk



RR 0,76 [95% CI 0,61-0,94]

Variable	Screening Group			Control Group
	Screening-Detected Lung Cancer (N=203)†	Non–Screening-Detected Lung Cancer (N=141)	Any Lung Cancer (N=344)	Any Lung Cancer (N=304)
Stage				
IA	95 (46.8)	10 (7.1)	105 (30.5)	21 (6.9)
IB	24 (11.8)	10 (7.1)	34 (9.9)	20 (6.6)
IIA	8 (3.9)	4 (2.8)	12 (3.5)	13 (4.3)
IIB	11 (5.4)	6 (4.3)	17 (4.9)	17 (5.6)
IIIA	20 (9.9)	14 (9.9)	34 (9.9)	43 (14.1)
IIIB	13 (6.4)	14 (9.9)	27 (7.8)	34 (11.2)
IV	19 (9.4)	73 (51.8)	92 (26.7)	139 (45.7)

Stadienshift = mehr kurative Therapien

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NELSON – Ergebnisse 2/2

- Resektionsraten:
  - CT-Screeningarm: 67,7 %
  - Kontrollarm: 24,5 %

- Risikoreduktion der Lungenkrebsmortalität
  - Männer: 26 %, p=0,0003
  - Frauen: 39 %, p=0,0054

De Koning H et al.
NEJM 2020

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Cochrane Review/Meta-Analyse: RCTs LDCT Screening

SUMMARY OF FINDINGS

Summary of findings 1. Low-dose computed tomography (LDCT) screening compared to no LDCT screening for lung cancer-related mortality

Low-dose computed tomography (LDCT) screening compared to no LDCT screening for lung cancer-related mortality

Patient or population: healthy adults
Setting: hospitals or screening centres
Intervention: LDCT screening
Comparison: no LDCT screening

Outcomes	№ of participants (trials) follow-up	Certainty of the evidence	Relative effect	Anticipated absolute effects	
Lung cancer-related mortality - planned time points Follow-up: 6 years to 10 years from randomisation			(0.72 to 0.87)	Trial population **21 per 1000**	**4 fewer per 1000 people screened** (3 fewer to 6 fewer)
All-cause mortality - planned time points Follow-up: 6 years to 10 years from randomisation	91,107 (8 RCTs)	⊕⊕⊕⊖ **Moderate**[a]	**RR 0.95** (0.91 to 0.99)	Trial population **89 per 1000**	**4 fewer per 1000 people screened** (1 fewer to 8 fewer)

Cave: RCTs nutzten unterschiedliche Protokolle
a) Bewertung von Screeningbefunden
b) Rundherd-Management

Cochrane Library
Trusted evidence.
Informed decisions.
Better health.

Bonney A et al. 2022

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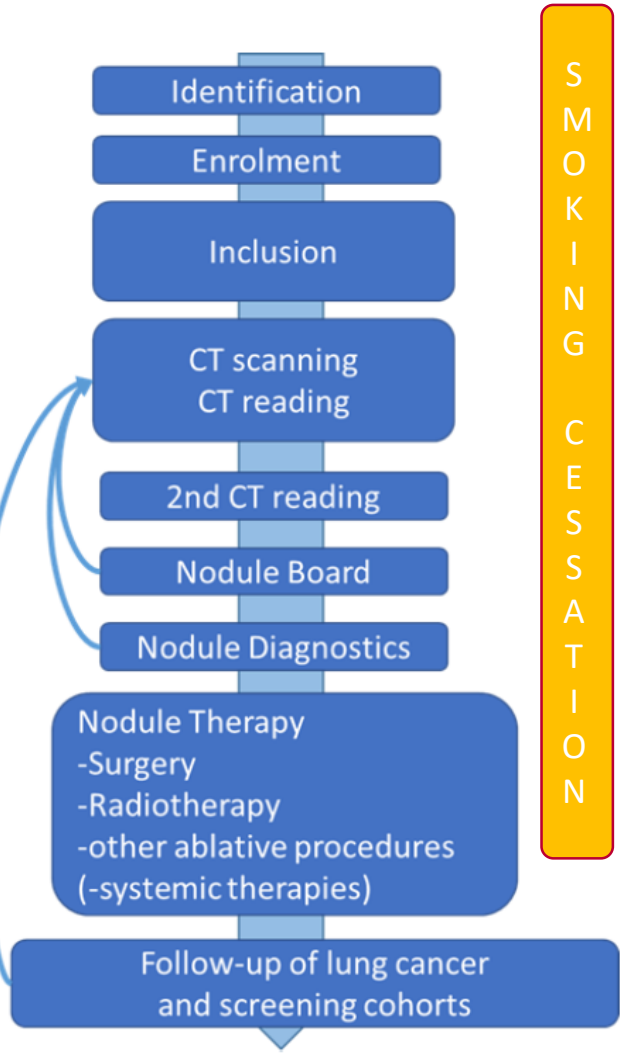
Probleme und Lösungen

Low-dose CT Lungenkrebs-Screening in Risikopopulationen

Let‘s improve LDCT lung cancer screening by implementation!



- **Definition der Risikopopulationen:**

➔ aktuelle Definitionen beinhalten nicht alle erwarteten Lungenkarzinome, Nieraucher derzeit ausgeschlossen

Tammemagy MC et al. NEJM 2013; Hüsing A et al. Eur J Epidemiol 2020

- **falsch-positive CT-Befunde/unnötige invasive Eingriffe**

➔ RCTs: unklare/positive CT-Befunde 3,6-24,2%➔falsch-positive CT-Befunde 84-96%

➔ NELSON: invasive Abklärung von falsch-positiven CT-Befunden in 24,5%

Hunger T et al. Diagnostics 2021; Horeweg N et al. ERJ 2013

- **Überdiagnosen**
- **optimale/individualisierte reguläre Screeningintervalle bzw. kurzfristigere Verlaufskontrollen (RCTs: 5,8-52,7%)**

Robbins HA et al. J Natl Cancer Inst 2019; Hunger T et al. Diagnostics 2021

- **inzidentelle CT-Befunde**
- **Folgerisiken durch Strahlenbelastung**

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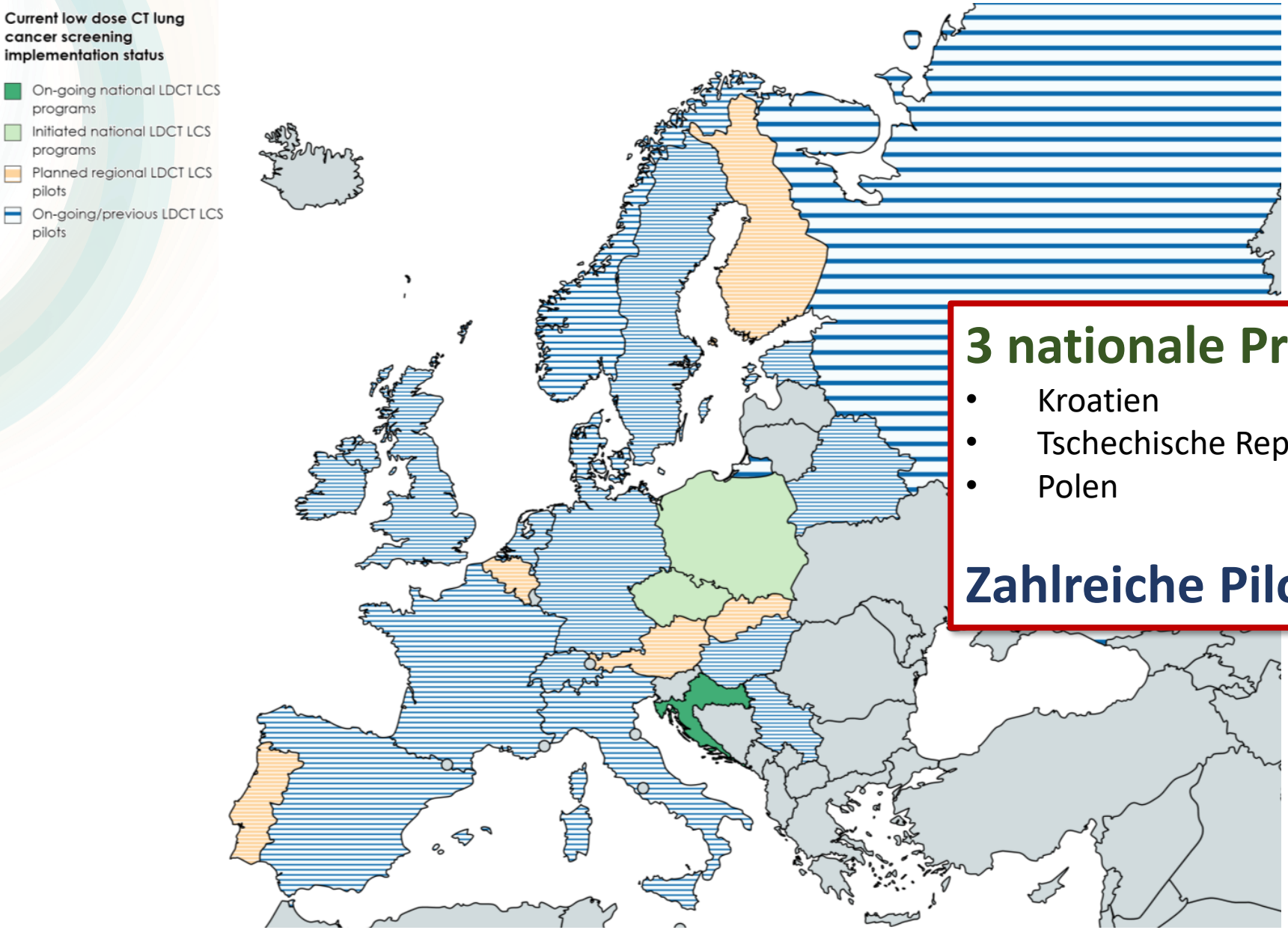
Implementierung

populationsbezoges Low-dose CT Lungenkrebs-Screening



3 nationale Programme in EU

- Kroatien
- Tschechische Republik
- Polen

Zahlreiche Pilot-Programme

Co-funded by the European Union

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

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

Balata H et al.
Lung Cancer 2021

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

Table 2
Details of cumulative reported harms.

Reported screening related harm	Total % (n)	Per 1,000 screening scans
False positive rate	2% (219)	19.6
Invasive investigation* for benign disease (excluding surgery)	0.6% (61)	5.5
Surgical resection for benign disease	0.07% (8)	0.7
Major complication+ from invasive investigation/treatment for benign disease	0% (0)	0
Deaths from invasive investigation/treatment for benign disease	0% (0)	0

*image guide biopsies or bronchoscopic procedures; +as defined by NLST.

Balata H et al.
Lung Cancer 2021

Essentiell: EIN klarer klinischer Algorithmus zur Befundung der LDCT

Guidelines for Management of Incidental Pulmonary Nodules Detected on CT Images: From the Fleischner Society 2017[1]

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

A: Solid Nodules*

Nodule Type	Size <6 mm (<100 mm³)	Size 6–8 mm (100–250 mm³)	Size >8 mm (>250 mm³)	Comments
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 tissue sampling	Nodules <6 mm do not require routine follow-up in low-risk patients (recommendation 1A).
High risk†	Optional CT at 12 months	CT at 6–12 months, then CT at 18–24 months	Consider CT at 3 months, PET/CT, or tissue sampling	Certain patients at high risk with suspicious nodule morphology, upper lobe location, or both may warrant 12-month follow-up (recommendation 1A).
Multiple				
Low risk†	No routine follow-up	CT at 3–6 months, then consider CT at 18–24 months	CT at 3–6 months, then consider CT at 18–24 months	Use most suspicious nodule as guide to management. Follow-up intervals may vary according to size and risk (recommendation 2A).
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 <6 mm (<100 mm³)	Size ≥6 mm (>100 mm³)	Comments
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)
Multiple	CT at 3–6 months. If stable, consider CT at 2 and 4 years.	CT at 3–6 months. Subsequent management based on the most suspicious nodule(s).	Multiple <6 mm pure ground-glass nodules are usually benign, but consider follow-up in selected patients at high risk at 2 and 4 years

MacMahon H et al. *Radiology 2017*

Lung-RADS® v2022

Release Date: November 2022

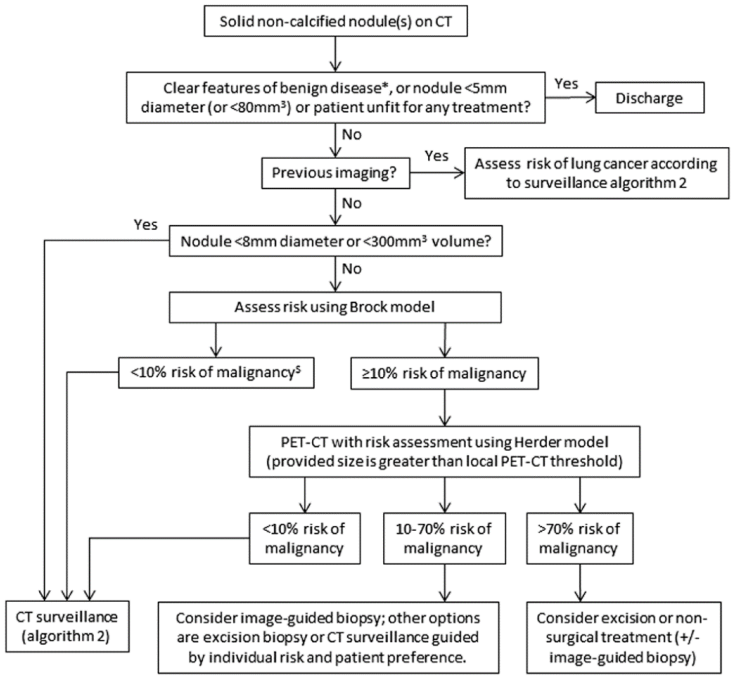
Lung-RADS	Category Descriptor	Findings	Management
0	**Incomplete** Estimated Population Prevalence: ~ 1%	Prior chest CT examination being located for comparison (see note 9)	Comparison to prior chest CT;
		Part or all oflungs cannot be evaluated	Additional lung cancer screening CT imaging needed;
		Findings 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	**Juxtapleural nodule:** • < 10 mm (524 mm³) mean diameter at baseline or new **AND** • Solid; smooth margins; and oval, lentiform, or triangular shape	
		Solid nodule: • < 6 mm (< 113 mm³) at baseline **OR** • New < 4 mm (< 34 mm³)	
		Part solid nodule: • < 6 mm total mean diameter (< 113 mm³) at baseline	
		Non solid nodule (GGN):	

www.acr.org

Essentiell: EIN klarer klinischer Algorithmus zum Management von positiven Screening-Befunden

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

als Basis in der S3-LL Lungenkarzinom zum Management von inzidentellen Befunden



Recently started Clinical Practice Guideline:

Taskforce on the management of positive findings in low-dose CT screening for lung cancer

– a joint ERS and ESR/ESTI Clinical Practice Guideline in collaboration with ESTRO, ESTS and ELF

EU4Health SOLACE: Implementierung von LDCT-Lungenkrebs-Screening in der EU - gemeinsam Ressourcen sparen & voneinander lernen!

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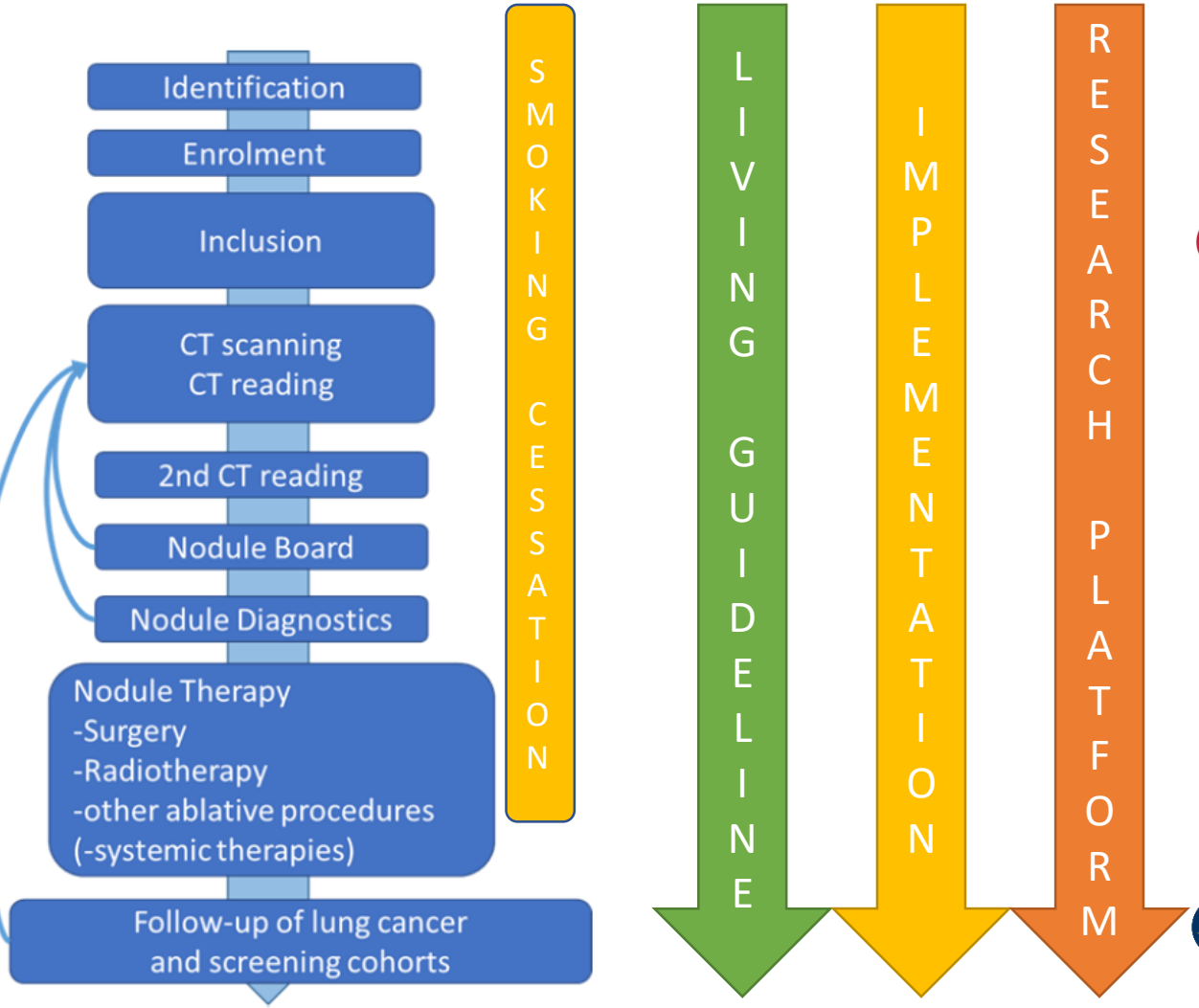

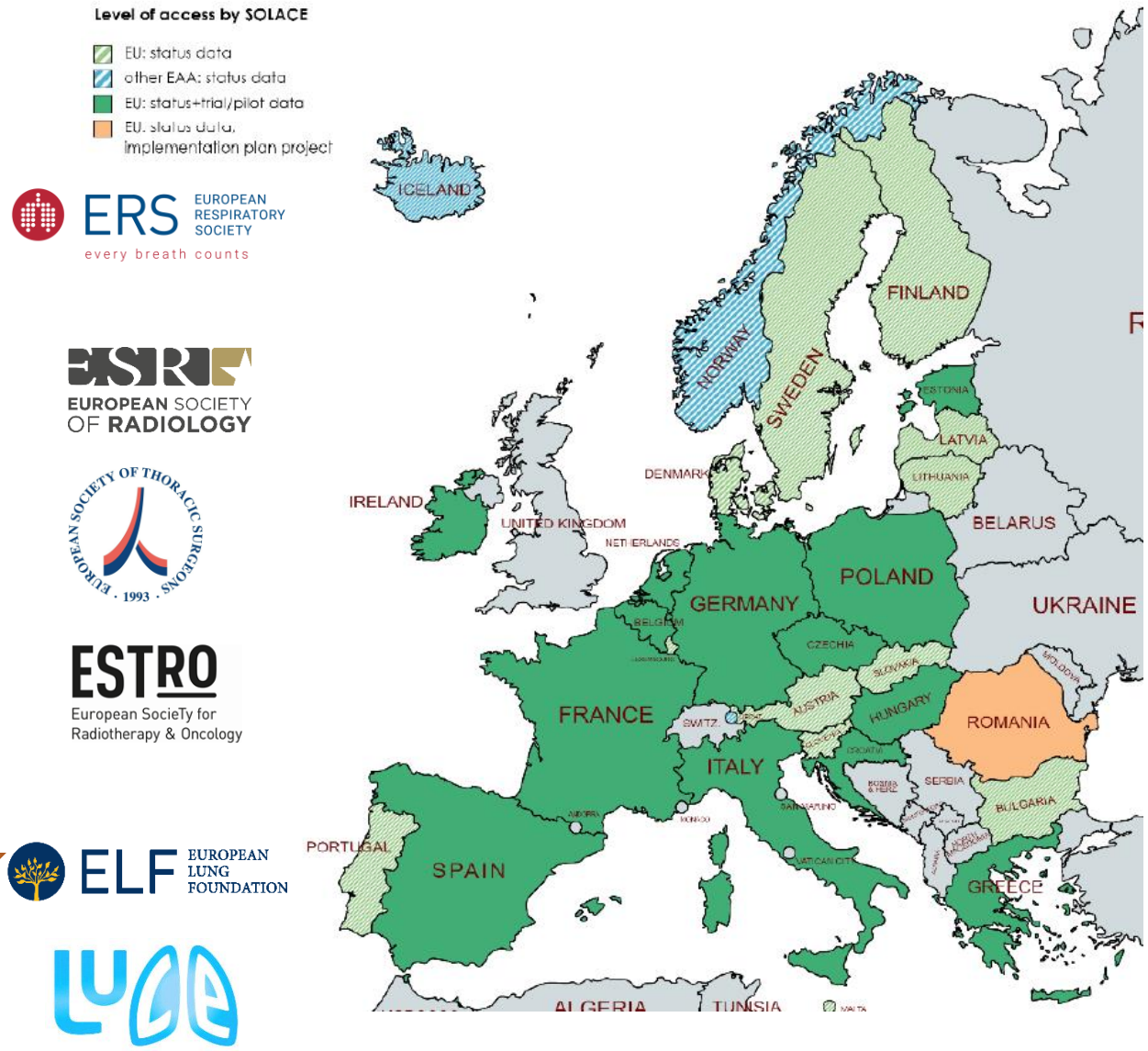

Unser gemeinsamer Vorschlag für Deutschland

Positionspapier

Thieme

Positionspapier zur Implementierung eines nationalen organisierten Programms in Deutschland zur Früherkennung von Lungenkrebs in Risikopopulationen mittels Low-dose-CT-Screening inklusive Management von abklärungsbedürftigen Screeningbefunden

Statement paper on the implementation of a national organized program in Germany for the early detection of lung cancer in risk populations using low-dose CT screening including management of screening findings

Autorinnen/Autoren

Torsten Gerriet Blum[1,2*], Jens Vogel-Claussen[3,4*], Stefan Andreas[5,6,7], Torsten T. Bauer[1], Jörg Barkhausen[8], Volker Harth[9], Hans-Ulrich Kauczor[10,11], Wulf Pankow[12], Katrin Welcker[13], Rudolf Kaaks[11,14**], Hans Hoffmann[15**]

Deutsche Röntgengesellschaft
Deutsche Gesellschaft für Pneumologie und Beatmungsmedizin
Deutsche Gesellschaft für Thoraxchirurgie

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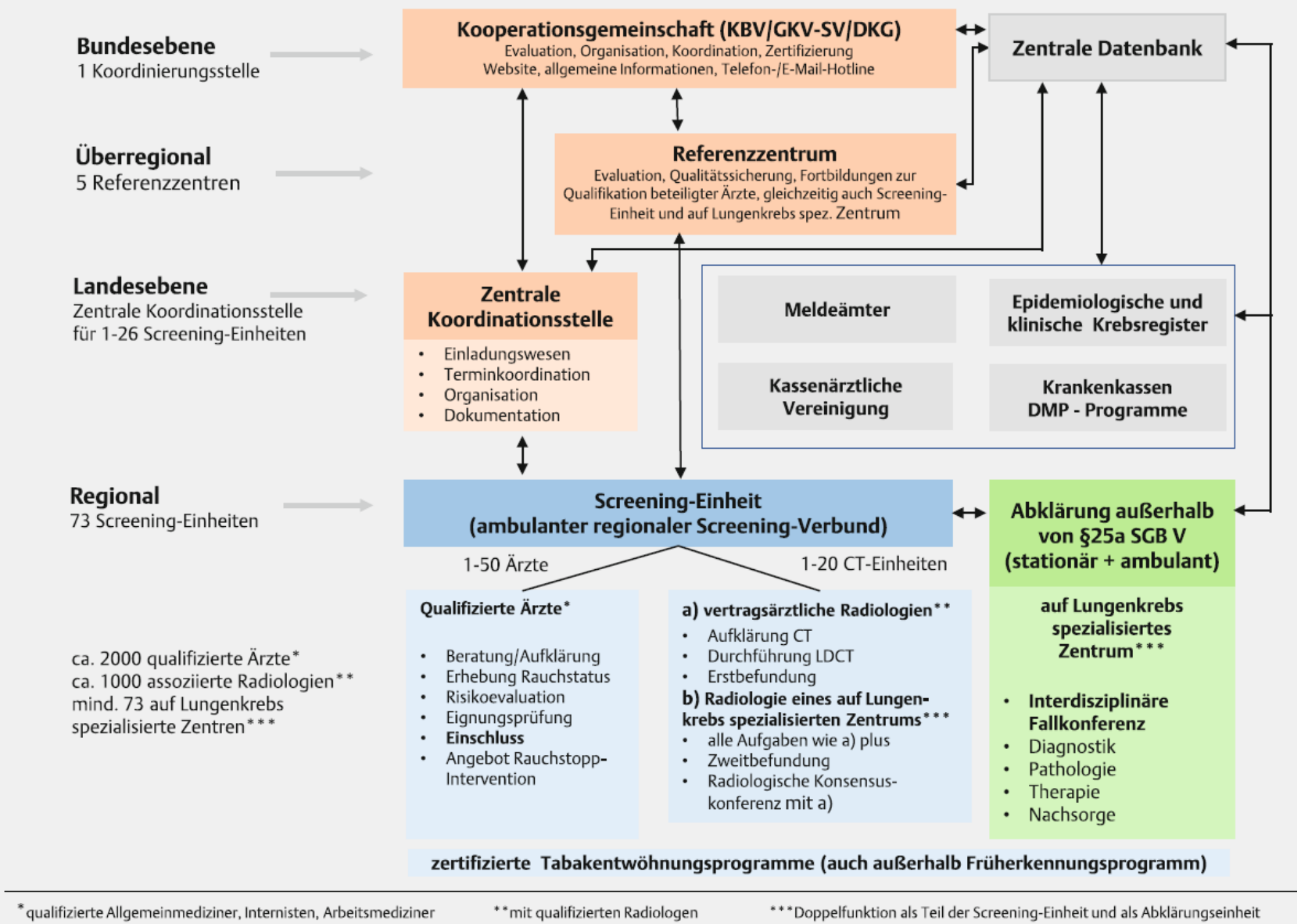
Pneumologie 2023
RöFo 2023
Zentral für Chirurgie 2023

LDCT LCS in Deutschland:
Ziel: §25a SGB V (organisierte Früherkennung)



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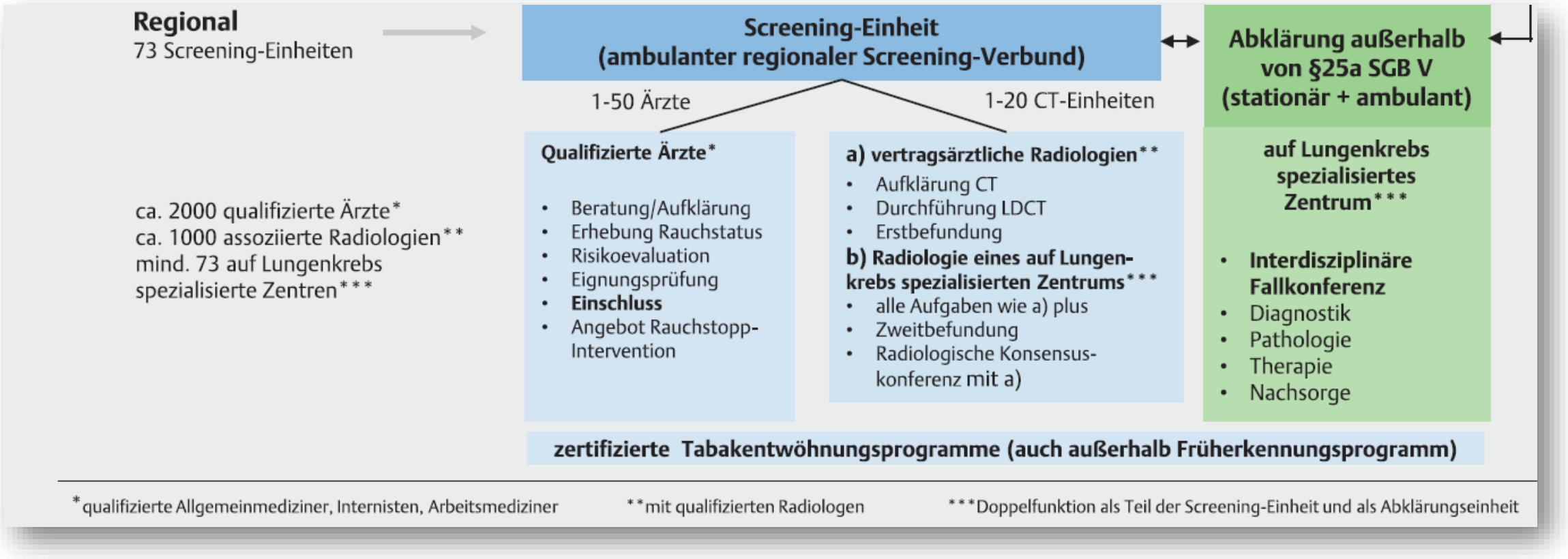
Pneumologie 2023
DOI 10.1055/a-2175-4580

LDCT LCS in Deutschland:
Kopplung von Screening-Einheit und Lungenkrebszentrum



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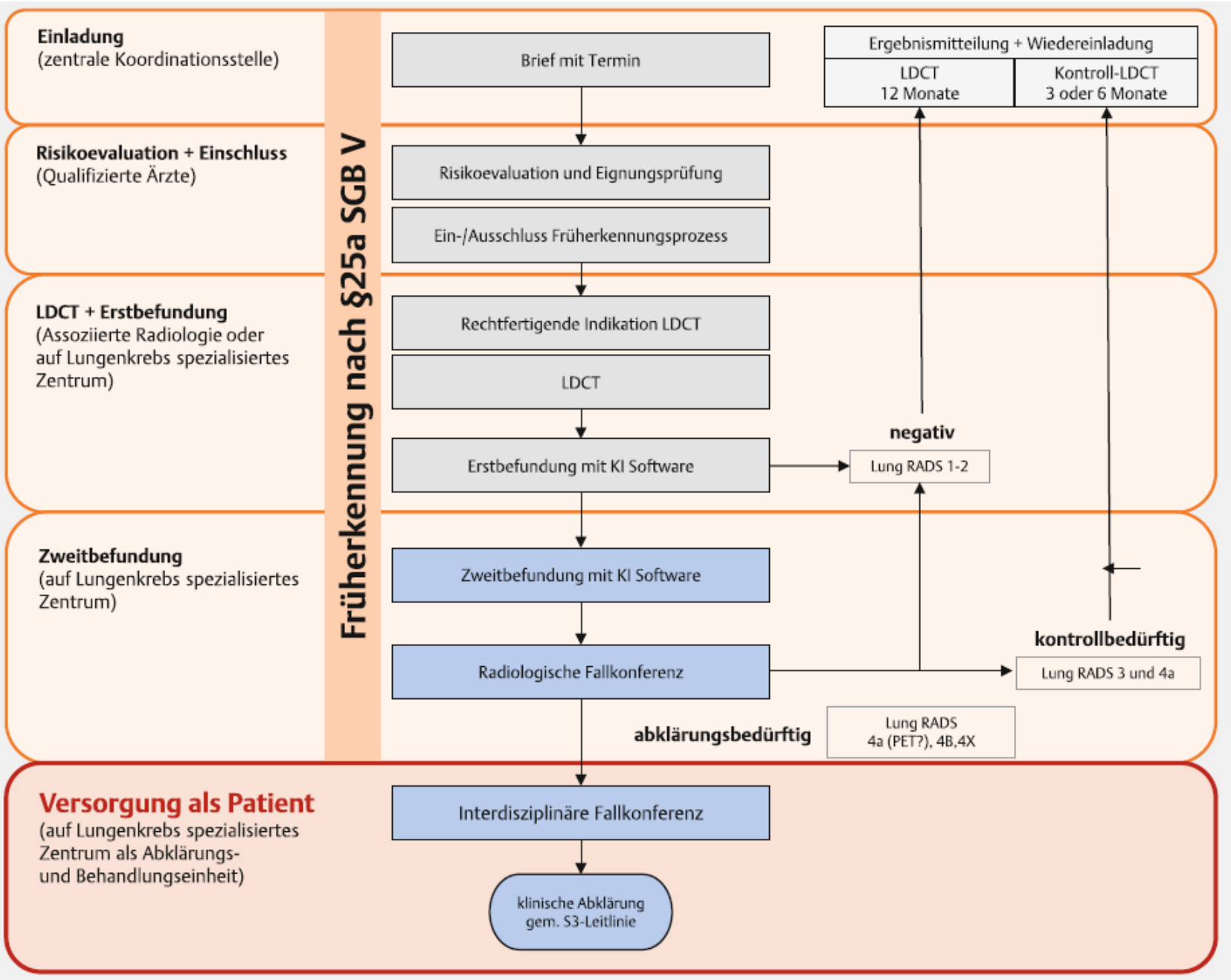
Pneumologie 2023
DOI 10.1055/a-2175-4580

➔ **Steigerung der Einschlussraten**

➔ **Reduktion von Überdiagnosen und Übertherapien**

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



▸ **Abb. 2** Vorschlag zu einem Algorithmus in einem organisierten Früherkennungsprogramm des Lungenkarzinoms nach §25a SGB V.

Helios Pneumologie 2023
DOI 10.1055/a-2175-4580

LDCT LCS-Algorithmus: negative Befunde (ca. 84%)

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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 oflungs 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: 45%	**Juxtapleural nodule:** • < 10 mm (524 mm^3) mean diameter at baseline or new **AND** • Solid; smooth margins; and oval, lentiform, or triangular shape	
		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	
		Non solid nodule (GGN): • < 30 mm (< 14,137 mm^3) at baseline, new, or growing **OR** • ≥ 30 mm (≥ 14,137 mm^3) 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	

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

LDCT LCS-Algorithmus: kontrollbedürftige Befunde (ca. 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 (≥ 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**

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

LDCT LCS-Algorithmus: kontrollbedürftige Befunde (ca. 3-4%)

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

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

Zusammenfassung

Low-dose CT Lungenkrebs-Screening

Low-dose CT Lungenkrebs-Screening – Zusammenfassung

- RCT-basierte Evidenz zeigt klaren Nutzen von LDCT Lungenkrebs-Screening in Risikopopulationen, die Implementierungsstudien Effizienz und Sicherheit

- Implementierung von populations-/risikobezogenen, **strukturierten** LDCT Lungenkrebs-Screeningprogrammen im Rahmen von §25a SGB V der entscheidende nächste Schritt

- gute LDCT Lungenkrebs-Screeningprogramme bieten mehr als nur das CT:
  - multiprofessionelle, sektorübergreifende Strukturen
  - Rekrutierung von „hard-to-reach"-Population
  - Integration von Raucherentwöhnungsprogrammen
  - stringentes Rundherdmanagement als essenzieller Bestandteil
  - fortlaufende Evaluation und Optimierung
  - Integration von Biomarkern im Rahmen klinischer/translationaler Forschung

- Chance zur Früherkennung und damit Prognoseverbesserung von Patienten mit Lungenkarzinomen

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Low-dose CT Lungenkrebs-Screening ist ein bisschen wie der BER
- sehr vielversprechend,
aber es braucht Zeit und gemeinsame Anstrengungen bis zur Implementierung

Herzlichen Dank!

Helios - Lungenklinik Heckeshorn

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