AOS | Academy of Surgeons

HERZLICH **WILLKOMMEN**

PETER ERRHALT UK KREMS PNEUMOLOGIE

SALZBURGER SYMPOSIUM **THORAXCHIRURGIE**

20. – 21.02.2025

Oxford Debate: Neoadjuvante Chemo-Immuntherapie beim funktionell resektablen Stadium IIIA NSCLC: Pro

- Was sagen die Guidelines?
  - ESMO: 2021
  - Onkopedia: 1/2025
  - NCCN: 1/ 2025

Table 2. Staging and stage grouping UICC TNM 8 [30]

Occult carcinoma	TX	N0	M0
Stage 0	Tis	N0	M0
Stage IA1	T1a(mi)	N0	M0
	T1a	N0	M0
Stage IA2	T1b	N0	M0
Stage IA3	T1c	N0	M0
Stage IB	T2a	N0	M0
Stage IIA	T2b	N0	M0
Stage IIB	T1a–c	N1	M0
	T2a–b	N1	M0
	T3	N0	M0
Stage IIIA	T1a–c	N2	M0
	T2a–b	N2	M0
	T3	N1	M0
	T4	N0	M0
	T4	N1	M0
Stage IIIB	T1a–c	N3	M0
	T2a–b	N3	M0
	T3	N2	M0
	T4	N2	M0
Stage IIIC	T3	N3	M0
	T4	N3	M0

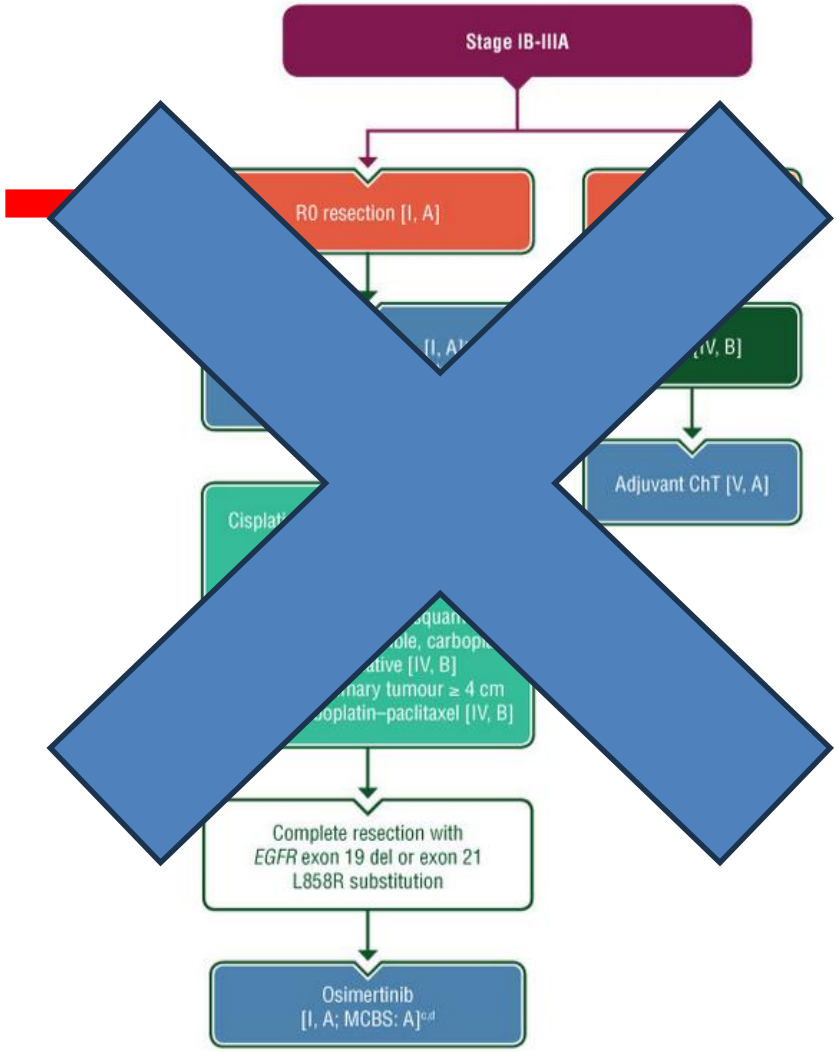
UICC, Union for International Cancer Control; TNM, tumour, node and metastasis.
Reprinted from [30] with permission from John Wiley & Sons, Inc.

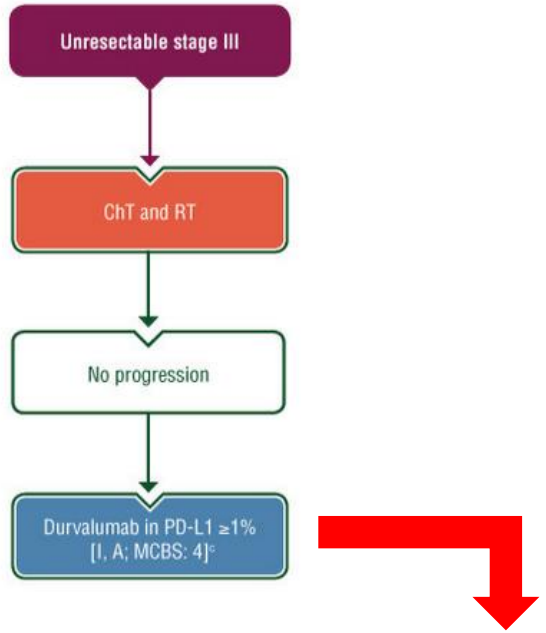
COI

- Für diesen Vortrag bestehen keine Interessenskonflikte

ESMO 2021

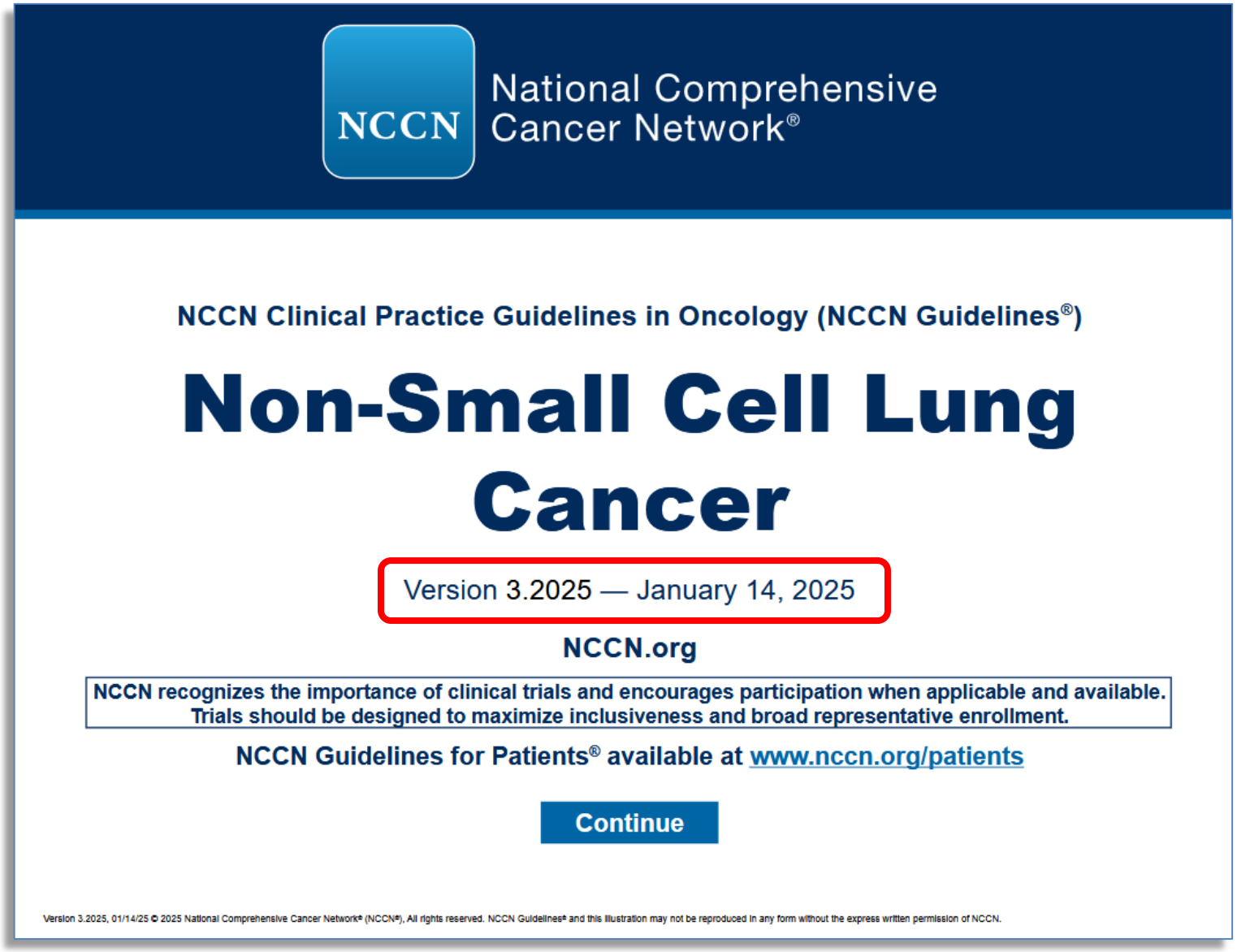
OP sofort
Keine neoadjuvante IO-CHT
Keine perioperative IO-CHT





Radiochemotherapie gefolgt von Durvalumab bei PD-L1 > 1%) und zumindest SD: „Pacific“

NCCN 2025:

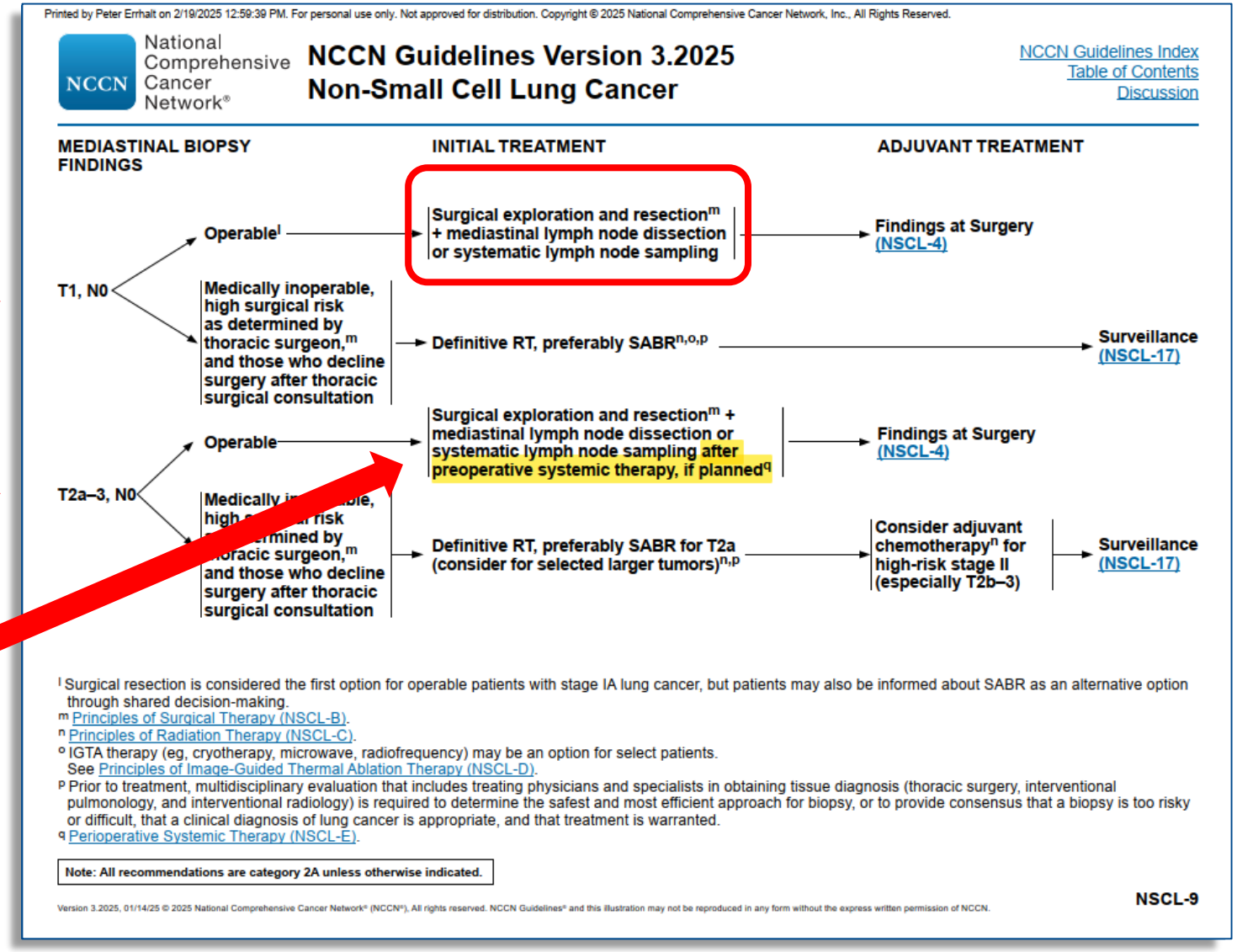

NCCN
National Comprehensive Cancer Network®
NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)
Non-Small Cell Lung Cancer
Version 3.2025 — January 14, 2025
NCCN.org
NCCN recognizes the importance of clinical trials and encourages participation when applicable and available. Trials should be designed to maximize inclusiveness and broad representative enrollment.
NCCN Guidelines for Patients® available at www.nccn.org/patients
Continue
Version 3.2025, 01/14/25 © 2025 National Comprehensive Cancer Network® (NCCN®), All rights reserved. NCCN Guidelines® and this illustration may not be reproduced in any form without the express written permission of NCCN.

NCCN 2025

Stadium IA1-3

Stadium IB-IIB

(neoadjuvante CHT)
CM 816 neoadjuvant
KN 671 perioperativ



National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2025
Non-Small Cell Lung Cancer

NCCN Guidelines Index
Table of Contents
Discussion

MEDIASTINAL BIOPSY FINDINGS		INITIAL TREATMENT	ADJUVANT TREATMENT
T1, N0	Operable[l]	Surgical exploration and resection[m] + mediastinal lymph node dissection or systematic lymph node sampling	Findings at Surgery (NSCL-4)
	Medically inoperable, high surgical risk as determined by thoracic surgeon,[m] and those who decline surgery after thoracic surgical consultation	Definitive RT, preferably SABR[n,o,p]	Surveillance (NSCL-17)
T2a–3, N0	Operable	Surgical exploration and resection[m] + mediastinal lymph node dissection or systematic lymph node sampling after preoperative systemic therapy, if planned[q]	Findings at Surgery (NSCL-4)
	Medically inoperable, high surgical risk as determined by thoracic surgeon,[m] and those who decline surgery after thoracic surgical consultation	Definitive RT, preferably SABR for T2a (consider for selected larger tumors)[n,p]	Consider adjuvant chemotherapy[n] for high-risk stage II (especially T2b–3) → Surveillance (NSCL-17)

[l] Surgical resection is considered the first option for operable patients with stage IA lung cancer, but patients may also be informed about SABR as an alternative option through shared decision-making.
[m] Principles of Surgical Therapy (NSCL-B).
[n] Principles of Radiation Therapy (NSCL-C).
[o] IGTA therapy (eg, cryotherapy, microwave, radiofrequency) may be an option for select patients. See Principles of Image-Guided Thermal Ablation Therapy (NSCL-D).
[p] Prior to treatment, multidisciplinary evaluation that includes treating physicians and specialists in obtaining tissue diagnosis (thoracic surgery, interventional pulmonology, and interventional radiology) is required to determine the safest and most efficient approach for biopsy, or to provide consensus that a biopsy is too risky or difficult, that a clinical diagnosis of lung cancer is appropriate, and that treatment is warranted.
[q] Perioperative Systemic Therapy (NSCL-E).

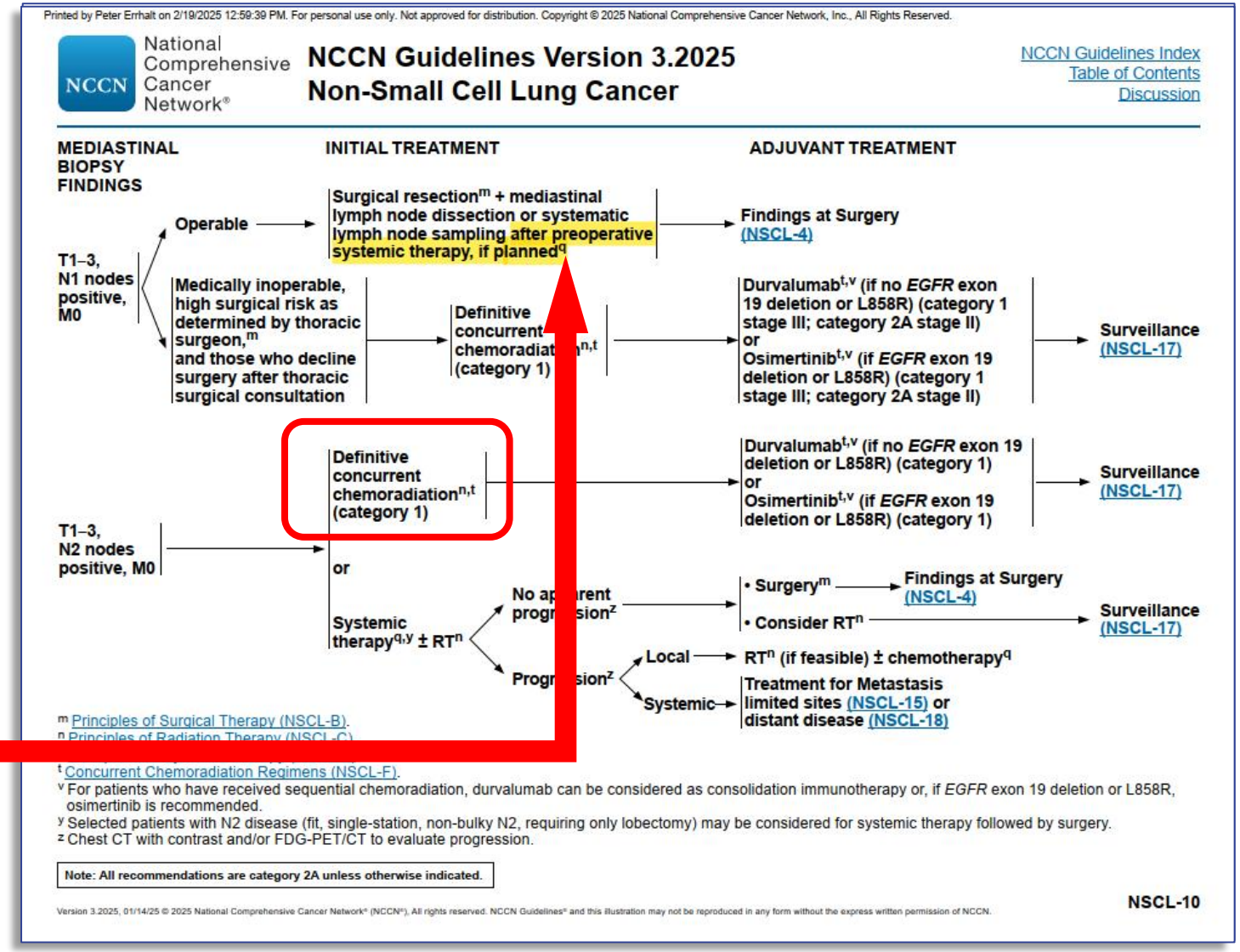
Note: All recommendations are category 2A unless otherwise indicated.

NCCN 2025

Stadium IIB-IIIA

Stadium IIIA-IIIB

(neoadjuvante CHT)
CM 816 neoadjuvant
KN 671 perioperativ



Onkopedia: 2025

onkopedia

onkopedia leitlinien

Inhaltsverzeichnis

- Änderungen gegenüber Vorversion
- Zusammenfassung
- Grundlagen
  - Definition und Basisinformationen
  - Epidemiologie
  - Pathogenese
  - Risikofaktoren
- Vorbeugung und Früherkennung
  - Vorbeugung
  - Früherkennung
- Klinisches Bild
- Diagnose

Lungenkarzinom, nicht-kleinzellig (NSCLC)

ICD-10: C34.-

Stand: Januar 2025

Dies ist die aktuell gültige Version des Dokuments

Erstellung der Leitlinie: Regelwerk Interessenkonflikte Leitlinien-Report

Autoren: Frank Griesinger, Gudrun Absenger, Annalen Bleckmann, Wilfried Eberhardt, Martin Eichhorn, Nikolaj Frost, Martin Früh, Oliver Gautschi, Sylvia Gütz, Wolfgang Hilbe, Hans Hoffmann, Rudolf Maria Huber, Klaus Kraywinkel, Sonja Loges, Christoph Pöttgen, Martin Reck, Niels Reinmuth, Martin Sebastian, Jan Michael Siehl, Cornelius Waller, Jürgen Wolf, Bernhard Wörmann
In Kooperation mit der AIO

Vorherige Autoren: Robert Pirker, Ron Pritzkuleit, Jan Stöhlmacher, Michael Thomas, Dieter Ukena, Martin Wolf
In Kooperation mit der AIO

Beteiligte Fachgesellschaften: DGHO, ÖGHO, SGH+SSH, SSMO SSOM SGMO, AIO

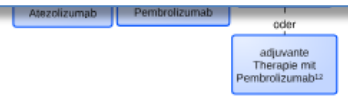
Onkopedia: 2025

Stage IIIB ????	T1a–c	N3	M0
	T2a–b	N3	M0
	T3	N2	M0
	T4	N2	M0

Tabelle 8: Subklassifikation der Stadien T3 / T4 N2 nach Robins

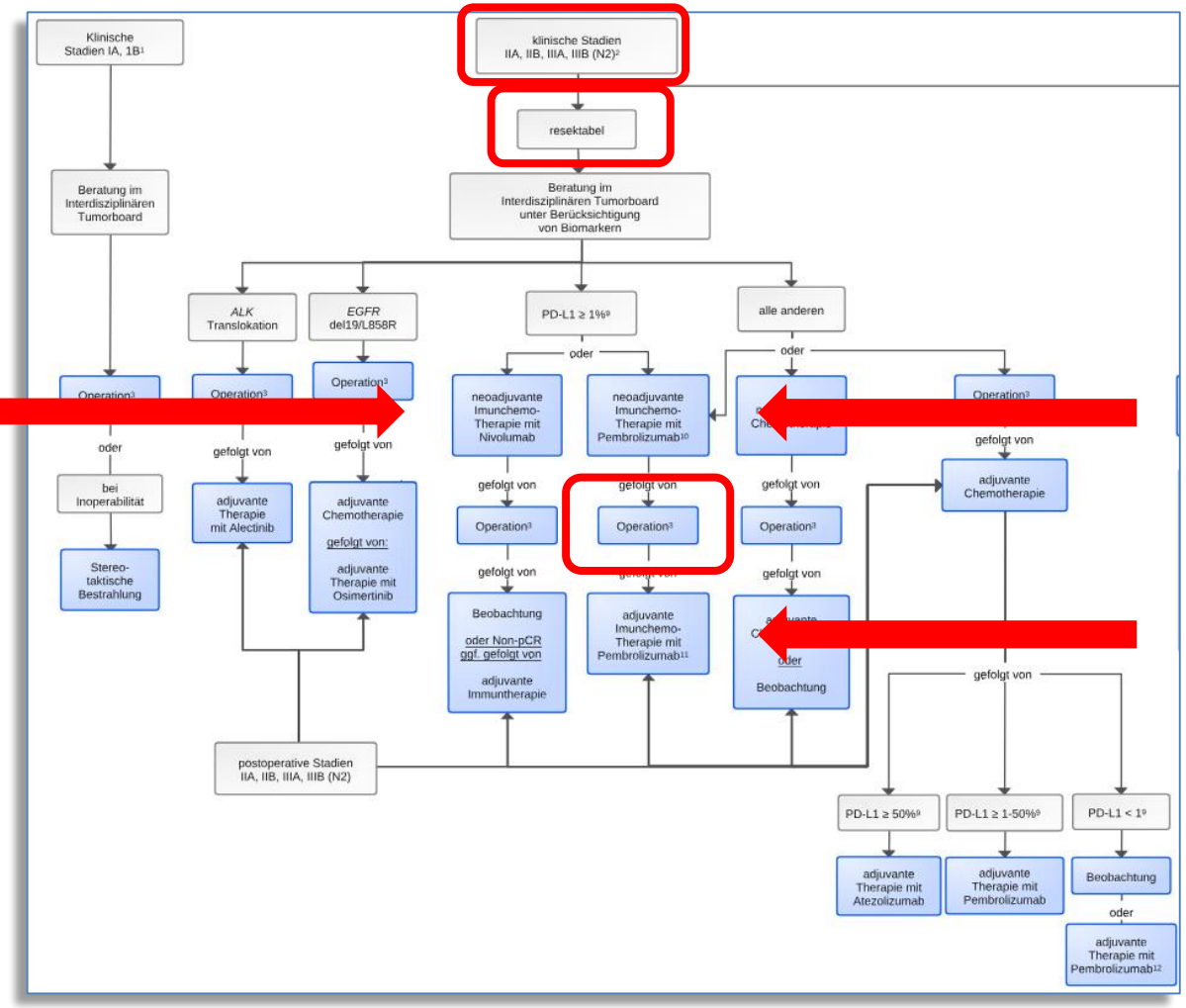
Stadium	Beschreibung
$IIIA_1$	inzidentelle Lymphknotenmetastasen in einer oder mehreren Lymphknotenstationen nach postoperativer Aufarbeitung im Präparat
$IIIA_2$	intraoperativer Nachweis von Lymphknotenmetastasen in einer mediastinalen Lymphknotenstation (intraoperativer Schnellschnitt) und ggf. Abbruch des Eingriffs ohne Resektion
$IIIA_3$*	präoperativer Nachweis von Lymphknotenmetastasen in einer oder mehreren Lymphknotenstationen (PET, Mediastinoskopie, Biopsie), potentiell resektabel
$IIIA_4$	ausgedehnte (‚bulky') oder fixierte N2-Metastasen oder Metastasen in mehreren Lymphknotenstationen (mediastinale Lymphknoten > 2 – 3 cm) mit extrakapsulärer Infiltration; nicht resektabel

Legende:
** klinisch ist in diesem Stadium eine weitere Unterteilung in unilevel (U) und multilevel (M) sinnvoll*



Onkopedia: 2025

CM 816 neoadjuvant



KN 671 perioperativ

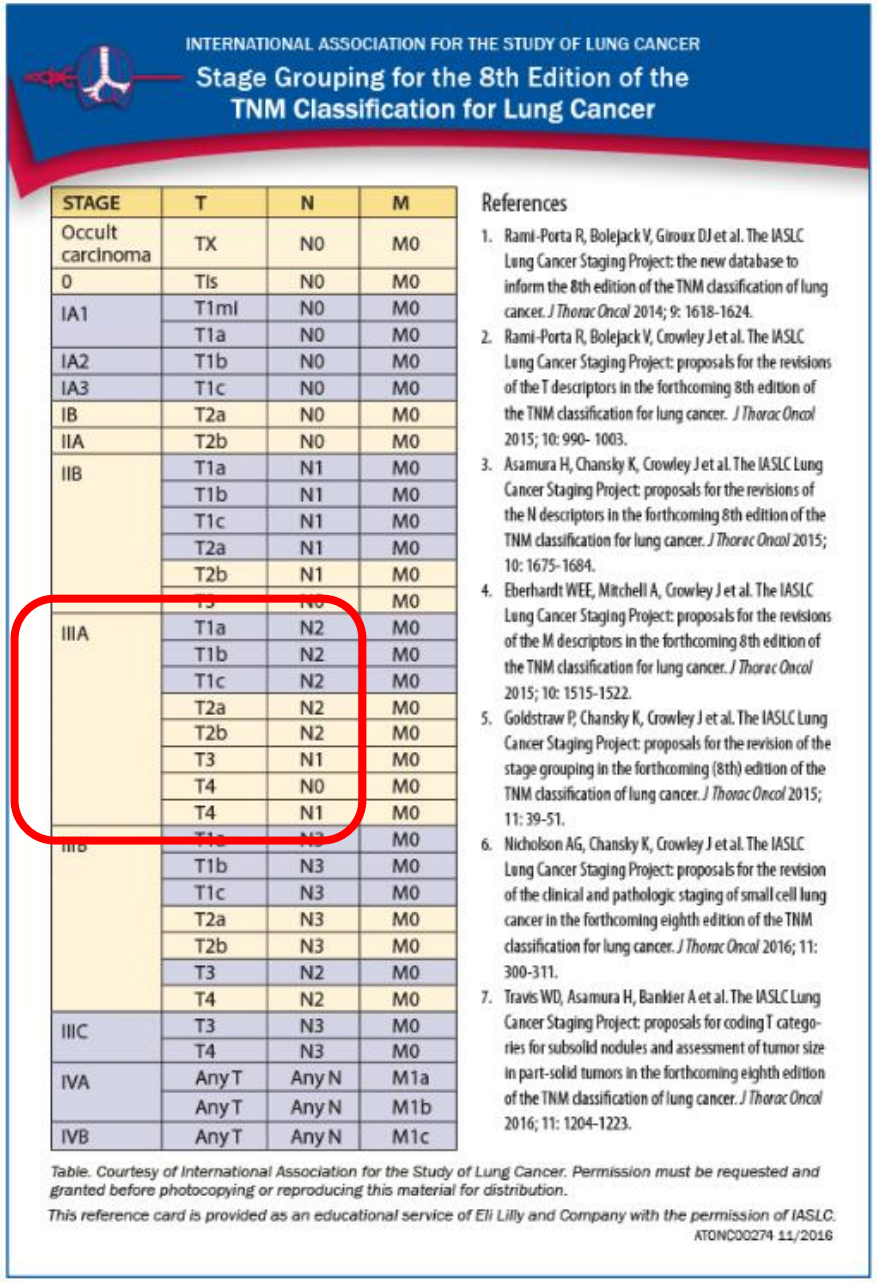
KN 671 perioperativ

Welches Stadium III ist also gemeint??

- IIIA ausgesprochen heterogen!
- T1aN2 bis T4N1

- In den meisten Studien auch N2 inkludiert
- zumindest > T2a (= > 4cm).....

- Plus Robinson Klassifikation!



INTERNATIONAL ASSOCIATION FOR THE STUDY OF LUNG CANCER

Stage Grouping for the 8th Edition of the TNM Classification for Lung Cancer

STAGE	T	N	M
Occult carcinoma	TX	N0	M0
0	Tis	N0	M0
IA1	T1mi	N0	M0
	T1a	N0	M0
IA2	T1b	N0	M0
IA3	T1c	N0	M0
IB	T2a	N0	M0
IIA	T2b	N0	M0
IIB	T1a	N1	M0
	T1b	N1	M0
	T1c	N1	M0
	T2a	N1	M0
	T2b	N1	M0
	T3	N0	M0
IIIA	T1a	N2	M0
	T1b	N2	M0
	T1c	N2	M0
	T2a	N2	M0
	T2b	N2	M0
	T3	N1	M0
	T4	N0	M0
	T4	N1	M0
IIIB	T1a	N3	M0
	T1b	N3	M0
	T1c	N3	M0
	T2a	N3	M0
	T2b	N3	M0
	T3	N2	M0
	T4	N2	M0
IIIC	T3	N3	M0
	T4	N3	M0
IVA	Any T	Any N	M1a
	Any T	Any N	M1b
IVB	Any T	Any N	M1c

References

1. Rami-Porta R, Bolejack V, Giroux DJ et al. The IASLC Lung Cancer Staging Project: the new database to inform the 8th edition of the TNM classification of lung cancer. *J Thorac Oncol* 2014; 9: 1618-1624.
2. Rami-Porta R, Bolejack V, Crowley J et al. The IASLC Lung Cancer Staging Project: proposals for the revisions of the T descriptors in the forthcoming 8th edition of the TNM classification for lung cancer. *J Thorac Oncol* 2015; 10: 990- 1003.
3. Asamura H, Chansky K, Crowley J et al. The IASLC Lung Cancer Staging Project: proposals for the revisions of the N descriptors in the forthcoming 8th edition of the TNM classification for lung cancer. *J Thorac Oncol* 2015; 10: 1675-1684.
4. Eberhardt WEE, Mitchell A, Crowley J et al. The IASLC Lung Cancer Staging Project: proposals for the revisions of the M descriptors in the forthcoming 8th edition of the TNM classification for lung cancer. *J Thorac Oncol* 2015; 10: 1515-1522.
5. Goldstraw P, Chansky K, Crowley J et al. The IASLC Lung Cancer Staging Project: proposals for the revision of the stage grouping in the forthcoming (8th) edition of the TNM classification of lung cancer. *J Thorac Oncol* 2015; 11: 39-51.
6. Nicholson AG, Chansky K, Crowley J et al. The IASLC Lung Cancer Staging Project: proposals for the revision of the clinical and pathologic staging of small cell lung cancer in the forthcoming eighth edition of the TNM classification for lung cancer. *J Thorac Oncol* 2016; 11: 300-311.
7. Travis WD, Asamura H, Bankier A et al. The IASLC Lung Cancer Staging Project: proposals for coding T categories for subsolid nodules and assessment of tumor size in part-solid tumors in the forthcoming eighth edition of the TNM classification of lung cancer. *J Thorac Oncol* 2016; 11: 1204-1223.

Welches N2???

Tabelle 8: Subklassifikation der Stadien T3 / T4 N2 nach Robinson [114]

Stadium	Beschreibung
$IIIA_1$	inzidentelle Lymphknotenmetastasen in einer oder mehreren Lymphknotenstationen nach postoperativer Aufarbeitung im Präparat
$IIIA_2$	intraoperativer Nachweis von Lymphknotenmetastasen in einer mediastinalen Lymphknotenstation (intraoperativer Schnellschnitt) und ggf. Abbruch des Eingriffs ohne Resektion
$IIIA_3$*	präoperativer Nachweis von Lymphknotenmetastasen in einer oder mehreren Lymphknotenstationen (PET, Mediastinoskopie, Biopsie), potentiell resektabel
$IIIA_4$	ausgedehnte (‚bulky') oder fixierte N2-Metastasen oder Metastasen in mehreren Lymphknotenstationen (mediastinale Lymphknoten > 2 – 3 cm) mit extrakapsulärer Infiltration; nicht resektabel

Legende:
** klinisch ist in diesem Stadium eine weitere Unterteilung in unilevel (U) und multilevel (M) sinnvoll*

Was ist resektabel?

Lung Cancer 199 (2025) 108061

Contents lists available at ScienceDirect

Lung Cancer

journal homepage: www.elsevier.com/locate/lungcan

Check for updates

An international and multidisciplinary EORTC survey on resectability of stage III non-small cell lung cancer

Ilias Houda [a], Idris Bahce [a], Chris Dickhoff [b], Tiuri E. Kroese [c], Stephanie G.C. Kroeze [d], Alessio V. Mariolo [e], Marco Tagliamento [f,g], Laura Moliner [h], Mariana Brandão [i], Yassin Pretzenbacher [j], John Edwards [k], Isabelle Opitz [l], Alessandro Brunelli [m], Matthias Guckenberger [n], Paul E. van Schil [o], Sanjay Popat [p], Torsten Blum [q,r], Corinne Faivre-Finn [s,t], Dirk de Ruysscher [u,v], Jordi Remon [f], Thierry Berghmans [i], Anne-Marie C. Dingemans [w], Benjamin Besse [f], Lizza E.L. Hendriks [x,*]

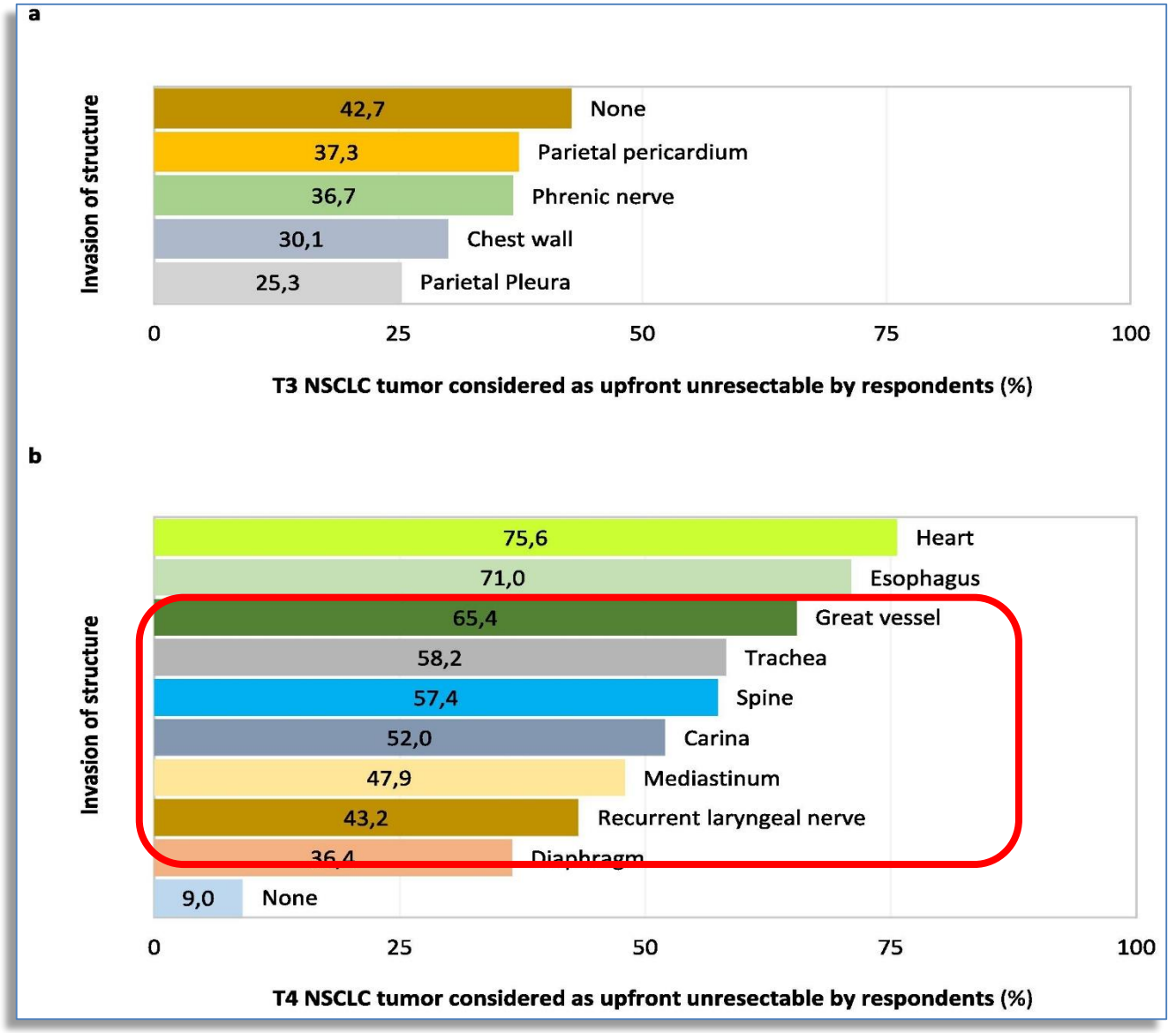
https://doi.org/10.1016/j.lungcan.2024.108061
Received 7 September 2024; Received in revised form 10 December 2024; Accepted 14 December 2024

Was ist resektabel?

	N0	N1	N2 SINGLE	N2 MULTI	N2 BULKY	N2 INVASIVE
T1-2	N/A	N/A	POTENTIALLY RESECTABLE (95%)	NO AGREEMENT (50%)	UNRESECTABLE (75%)	UNRESECTABLE (84%)
T3 SIZE	N/A	RESECTABLE (83%)[a]	POTENTIALLY RESECTABLE (87%)	NO AGREEMENT (39%)	UNRESECTABLE (80%)	UNRESECTABLE (88%)
T3 SATELLITE	N/A	POTENTIALLY RESECTABLE (94%)	POTENTIALLY RESECTABLE	NO AGREEMENT (34%)	UNRESECTABLE (84%)	UNRESECTABLE (91%)
T3 INVASION	N/A	POTENTIALLY RESECTABLE (89%)	NO AGREEMENT (71%)[b]	NO AGREEMENT (28%)[c]	UNRESECTABLE (87%)	UNRESECTABLE (92%)
T4 SIZE	POTENTIALLY RESECTABLE (94%)	POTENTIALLY RESECTABLE (90%)	NO AGREEMENT (66%)	UNRESECTABLE (77%)	UNRESECTABLE (88%)	UNRESECTABLE (93%)
T4 SATELLITE	POTENTIALLY RESECTABLE (78%)	NO AGREEMENT (71%)[b]	NO AGREEMENT (44%)	UNRESECTABLE (85%)	UNRESECTABLE (92%)	UNRESECTABLE (94%)
T4 INVASION	NO AGREEMENT (62%)[b]	NO AGREEMENT (57%)[b]	NO AGREEMENT (34%)[c]	UNRESECTABLE (90%)	UNRESECTABLE (95%)	UNRESECTABLE (94%)

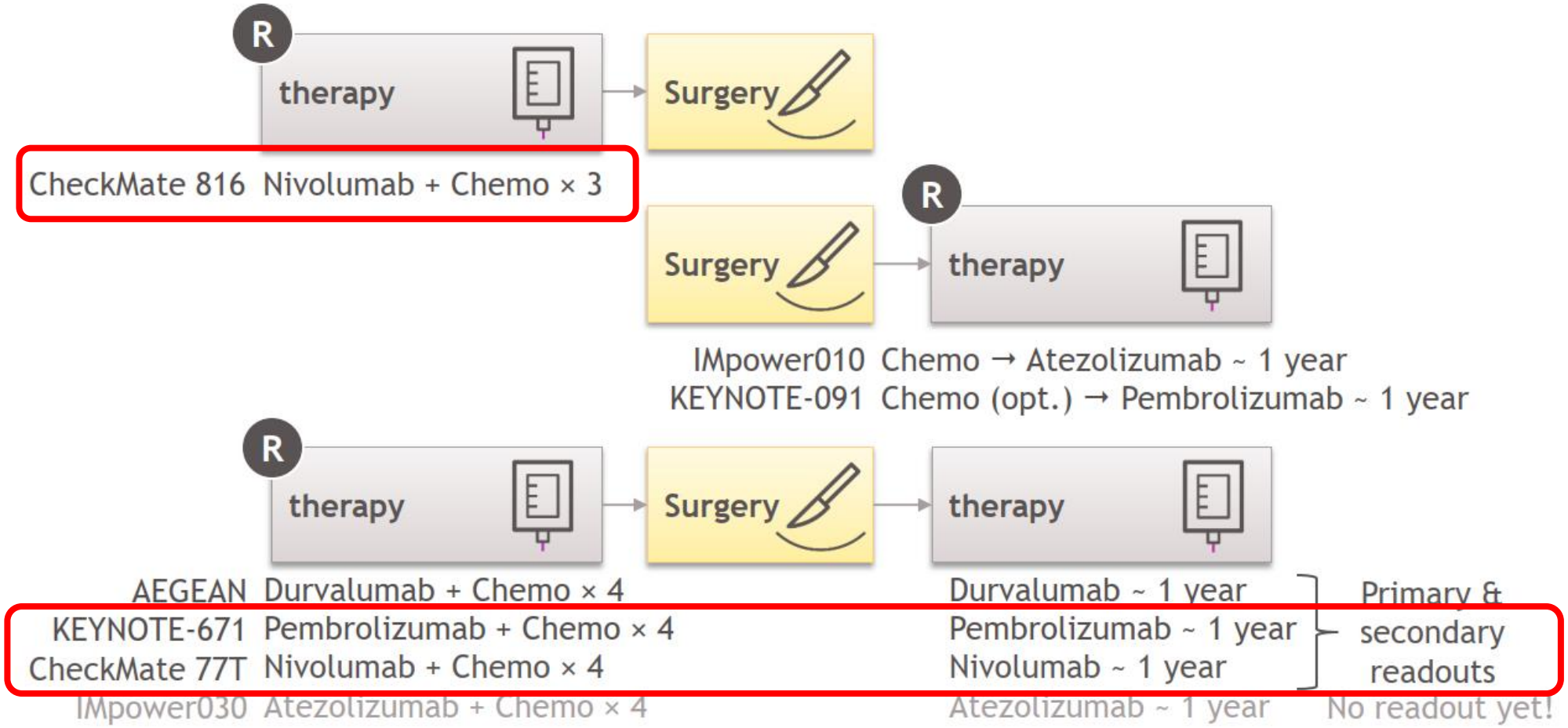
https://doi.org/10.1016/j.lungcan.2024.108061
Received 7 September 2024; Received in revised form 10 December 2024; Accepted 14 December 2024

Was ist resektabel?



https://doi.org/10.1016/j.lungcan.2024.108061
Received 7 September 2024; Received in revised form 10 December 2024; Accepted 14 December 2024

Neoadjuvant bzw. Perioperativ



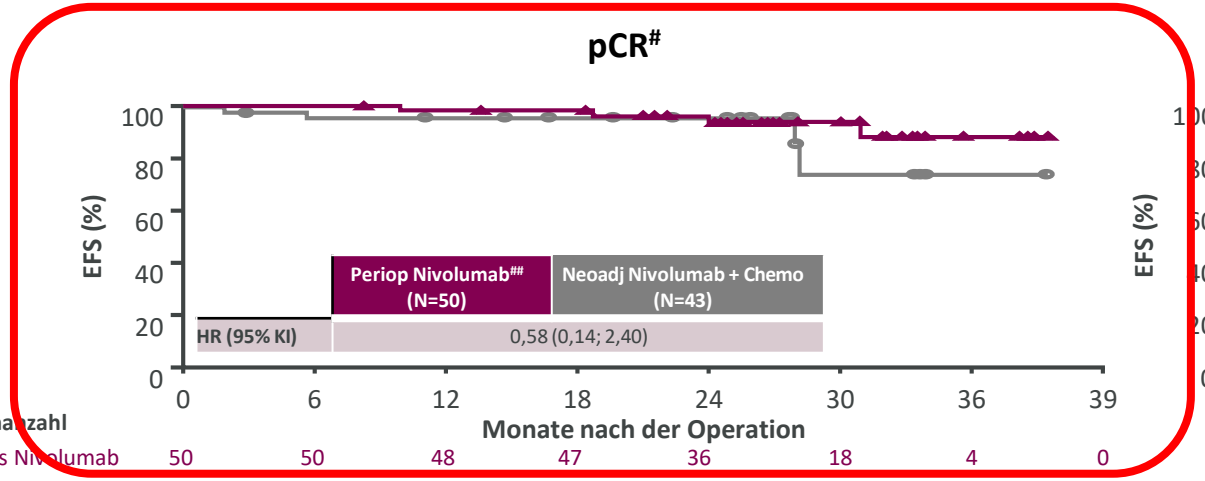
Neoadjuvant bzw. Perioperativ

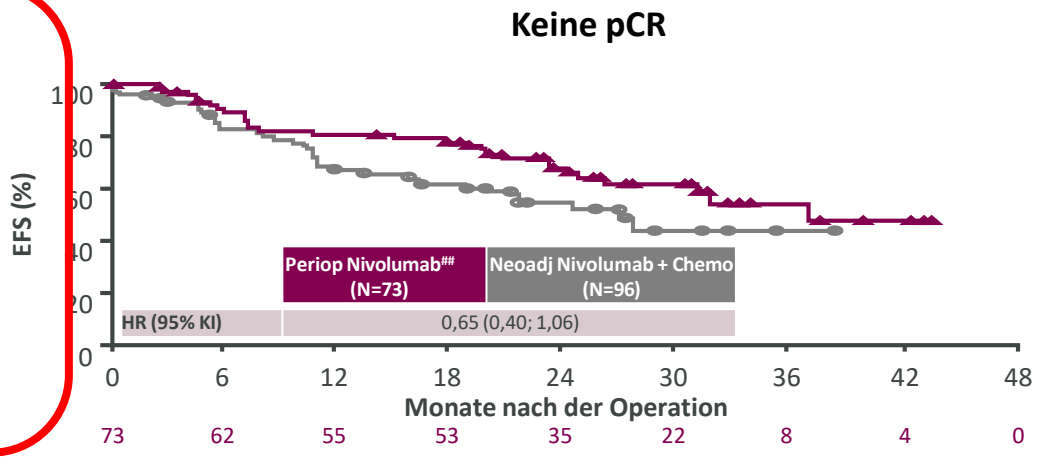
- **CM 816: neoadjuvant** Nivolumab + Histologie-basierte Platin-CHT 3 Zyklen
- **EMA zugelassen bei PD-L1 > 1%**

- **CM 77T: „perioperativ“**: neoadjuvant Nivolumab + Histologie-basierte Platin-CHT 4 Zyklen
- postoperativ Nivolumab für bis zu 1 Jahr
- EMA nicht zugelassen

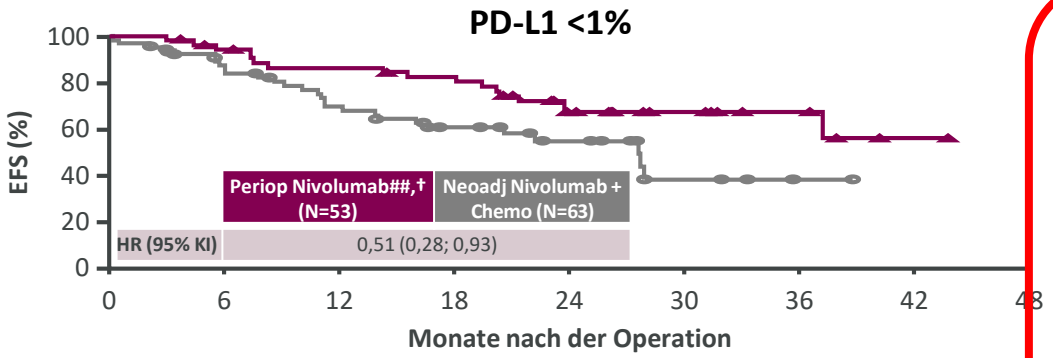
- **KN 671 „perioperativ“**: präoperativ Pembrolizumab + Histologie-basierte Platin-CHT
- postoperativ Pembrolizumab für bis zu 1 Jahr
- **EMA zugelassen bei PD-L1 > 1%**

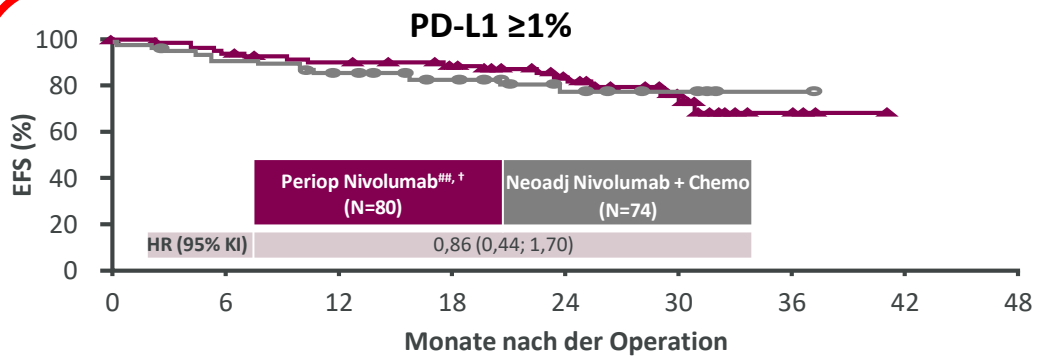
Nivolumab Vergleich neoadjuvant vs. perioperativ





Patient:innenanzahl									
Perioperatives Nivolumab	50	50	48	47	36	18	4	0	
Neoadjuvantes Nivolumab+CT	43	40	39	35	19	6	2	0	
Perioperatives Nivolumab	73	62	55	53	35	22	8	4	0
Neoadjuvantes Nivolumab+CT	96	75	60	47	19	7	1	0	0





Patient:innenanzahl									
Perioperatives Nivolumab	53	48	43	40	27	15	7	1	
Neoadjuvantes Nivolumab+CT	63	49	39	29	15	6	2	0	0
Perioperatives Nivolumab	80	74	68	66	48	26	6	2	0
Neoadjuvantes Nivolumab+CT	74	66	61	53	24	7	1	0	0

Medianes Follow-Up: CheckMate 816 29,5 Monate; CheckMate 77T 33,3 Monate. *Patient:innen mit nicht auswertbarem pCR-Status oder nicht auswertbarer PD-L1-Expression wurden ausgeschlossen; **Ungewichtete Analysen; #pCR-Raten in dieser Analysepopulation: perioperatives Nivolumab 40,7%, neoadjuvantes Nivolumab + Chemo 30,5%; ##Umfasst nur Patient:innen, die ≥1 Dosis adjuvantes Nivolumab erhielten; †Abgeschlossene adjuvante Behandlung ab: <1%, 33 Patient:innen (62%) und ≥1%, 51 Patient:innen (64%). Mediane Anzahl an Dosen (Bereich): <1%, 13 (1-13) und ≥1%, 13 (1-13).

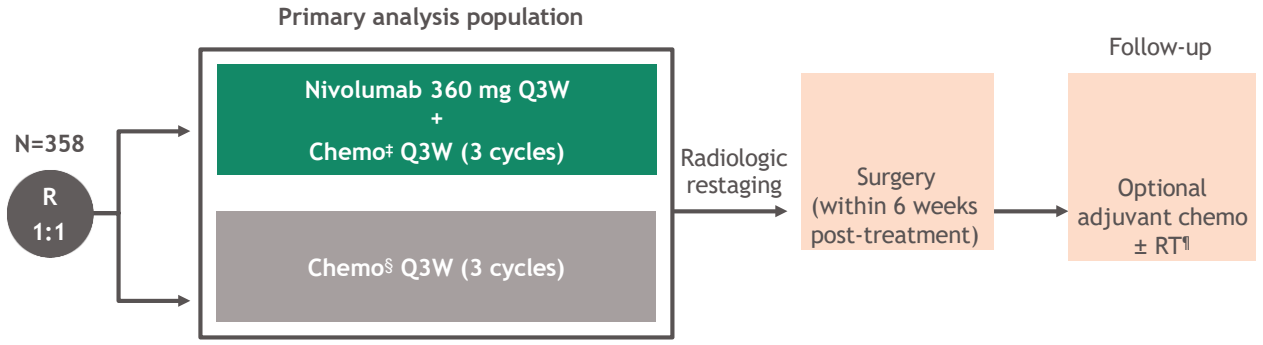
Forde PM et al. WCLC 2024, San Diego & virtuell, PL02.08

CheckMate 816: Neoadjuvant nivolumab + chemo in patients with resectable stage IB-IIIA NSCLC

Key Eligibility Criteria

- Newly diagnosed, resectable, stage IB (≥4 cm)–IIIA NSCLC (per AJCC 7th edition)
- ECOG performance status 0–1
- No known sensitizing *EGFR* mutations or *ALK* alterations

Stratified by
Stage (IB–II vs IIIA),
PD-L1* (≥1% vs <1%†), and sex



Primary endpoints
- pCR by BIPR
- EFS by BICR

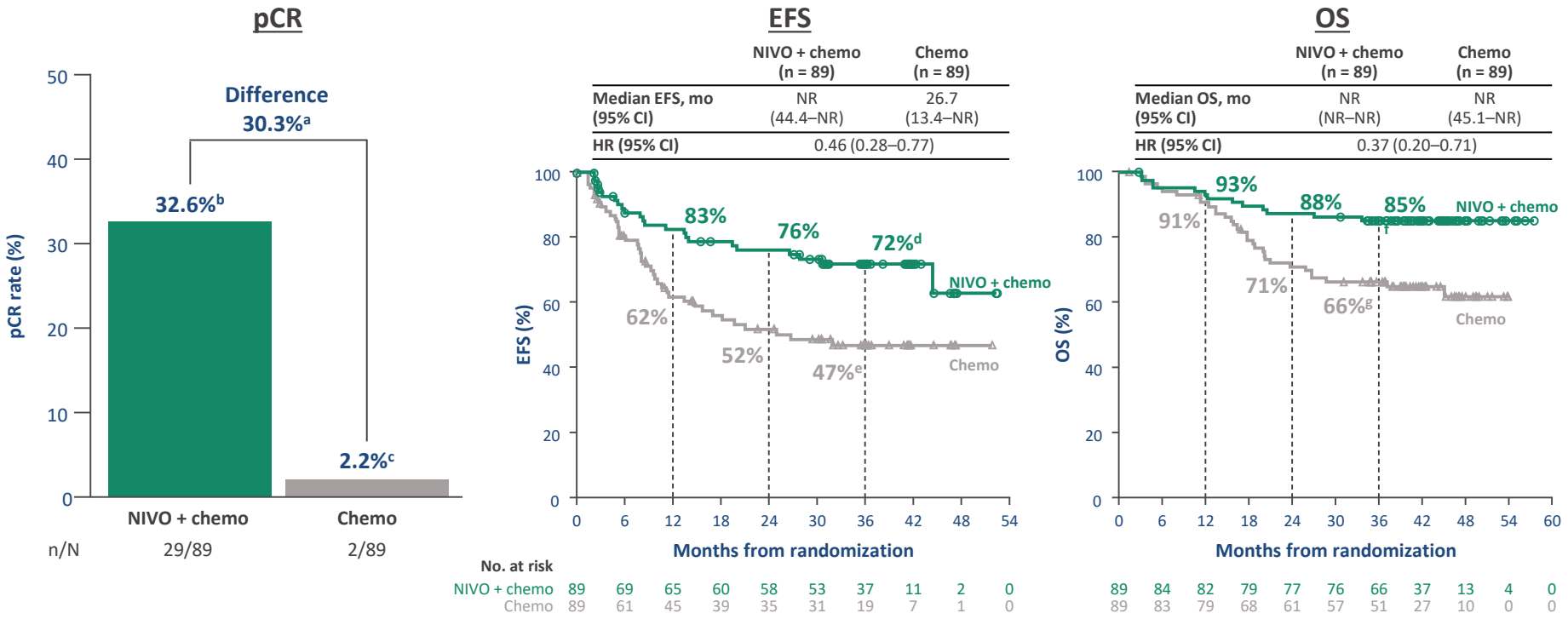
Secondary endpoints
- MPR by BIPR
- OS
- Time to death or distant metastases

- **pCR:** 0% residual viable tumor in both the primary tumor (lung) and sampled lymph nodes
- **EFS:** Time from randomization to disease progression that precludes surgery, disease progression/recurrence after surgery, progression for patients without surgery, or death due to any cause

*Determined by the PD-L1 IHC 28-8 pharmDx assay (Dako). †Included patients with PD-L1 expression status not evaluable and indeterminate. ‡NSQ: pemetrexed + cisplatin or paclitaxel + carboplatin; SQ: gemcitabine + cisplatin or paclitaxel + carboplatin. §Vinorelbine + cisplatin, docetaxel + cisplatin, gemcitabine + cisplatin (SQ only), pemetrexed + cisplatin (NSQ only), or paclitaxel + carboplatin. ‖Randomized exploratory arm (enrollment closed early). ¶Per healthcare professional choice. AJCC=American Joint Committee on Cancer; ALK=anaplastic lymphoma kinase; BICR=blinded independent central review; BIPR=blinded independent pathological review; ctDNA=circulating tumor deoxyribonucleic acid; ECOG=Eastern Cooperative Oncology Group; EFS=event-free survival; EGFR=epidermal growth factor receptor; MPR=major pathologic response; NSCLC=non-small cell lung cancer; ORR=overall response rate; OS=overall survival; pCR=pathologic complete response; PD- L1=programmed death ligand 1; Q3W=every 3 weeks; R=randomization; RT=radiotherapy.

Forde PM et al. *N Engl J Med*. 2022;386(21):1973-1985.

Efficacy outcomes in patients with tumor PD-L1 ≥ 1%



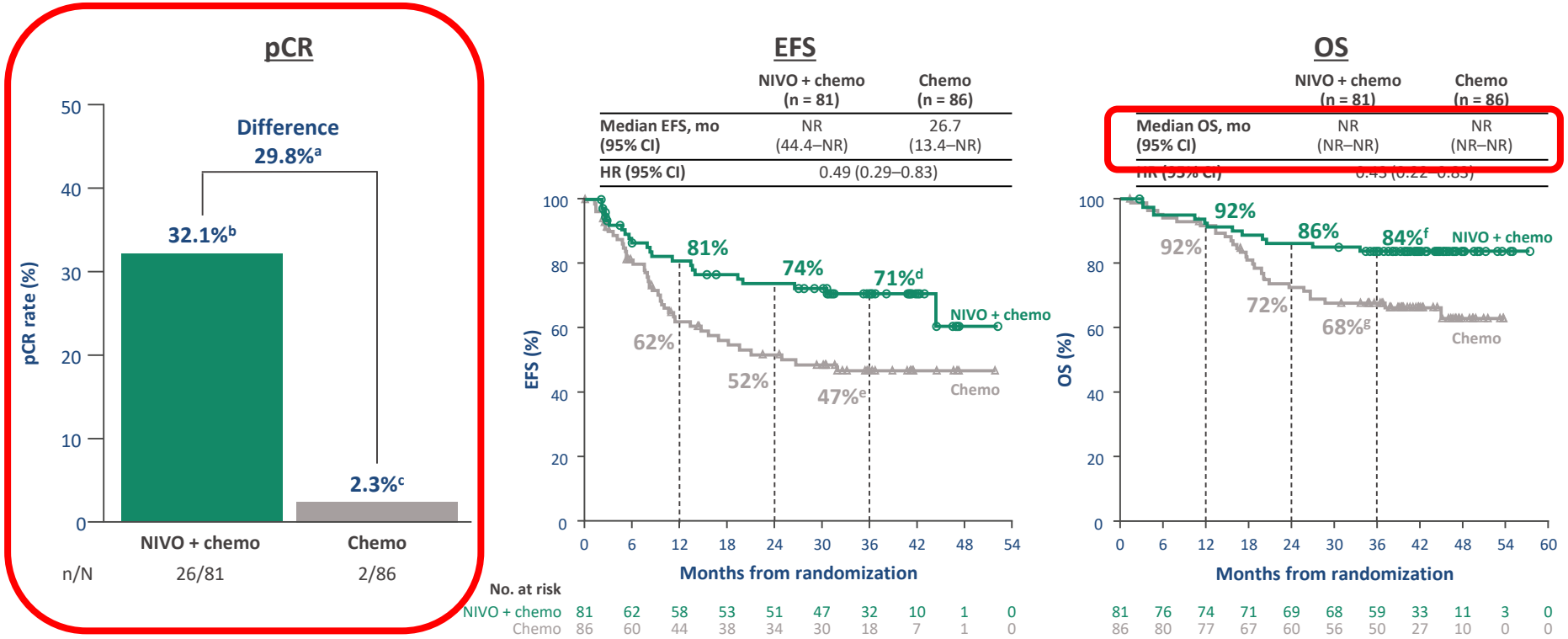
- Median TTDM (95% CI) in months was NR vs NR (18.8–NR) for NIVO + chemo vs chemo (HR, 0.35; 95% CI, 0.19–0.62); 3-year TTDM rates were 82%[h] vs 53%[i]

Minimum/median follow-up: 32.9/41.4 months.

MPR rates were 44.9% (95% CI, 34.4–55.9) with NIVO + chemo and 5.6% (95% CI, 1.8–12.6) with chemo (difference, 39.3%; 95% CI, 27.3–50.1). Unweighted differences in pCR and MPR rates between treatment arms were calculated using the Newcombe method. [a–g]95% CI: [a]19.9–40.7; [b]23.0–43.3; [c]0.3–7.9; [d]61–81; [e]35–58; [f]76–91; [g]56–75; [h]71–88; [i]41–63.

Provencio Pulla M et al. Oral presentation at ESMO 2023. Presentation LBA57.

Efficacy outcomes in patients with tumor PD-L1 ≥ 1% and stage II–IIIA disease



- Median TTDM (95% CI) in months was NR (44.4–NR) vs NR (18.8–NR) for NIVO + chemo vs chemo (HR, 0.40; 95% CI, 0.22–0.72)

Minimum/median follow-up: 32.9/41.4 months.

MPR rates were 45.7% (95% CI, 34.6–57.1) with NIVO + chemo and 5.8% (95% CI, 1.9–13.0) with chemo (difference, 39.9%; 95% CI, 27.3–51.2). Unweighted differences in pCR and MPR rates between treatment arms were calculated using the Newcombe method. [a–g]95% CI: [a]19.0–40.7; [b]22.2–43.4; [c]0.3–8.1; [d]59–80; [e]35–58; [f]74–90; [g]56–77.

Provencio Pulla M et al. Oral presentation at ESMO 2023. Presentation LBA57

Keynote 671: perioperativ

Haupteinschlusskriterien
- Pathologisch bestätigtes, resezierbares NSCLC im Stadium II, IIIA oder IIIB (N2) gemäß AJCC v8
- Keine vorherige Therapie
- Geeignet für eine Operation
- Tumorgewebe zur PD-L1-Analyse vorhanden*
- ECOG PS 0 oder 1

R 1:1

~786

Pembrolizumab 200 mg i.v. Q3W
+
Cisplatin und Gemcitabin**
oder
Cisplatin und Pemetrexed#

für bis zu 4 Zyklen

Operation##

Pembrolizumab 200 mg i.v. Q3W

für bis zu 13 Zyklen

Placebo i.v. Q3W
+
Cisplatin und Gemcitabin**
oder
Cisplatin und Pemetrexed#

für bis zu 4 Zyklen

Operation##

Placebo i.v. Q3W

für bis zu 13 Zyklen

Stratifizierungsfaktoren
- Krankheitsstadium (II vs III)
- PD-L1-TPS* (<50% vs ≥50%)
- Histologie (Plattenepithel- vs Nicht-Plattenepithelkarzinom)
- Geographische Region (Ostasien vs Nicht-Ostasien)

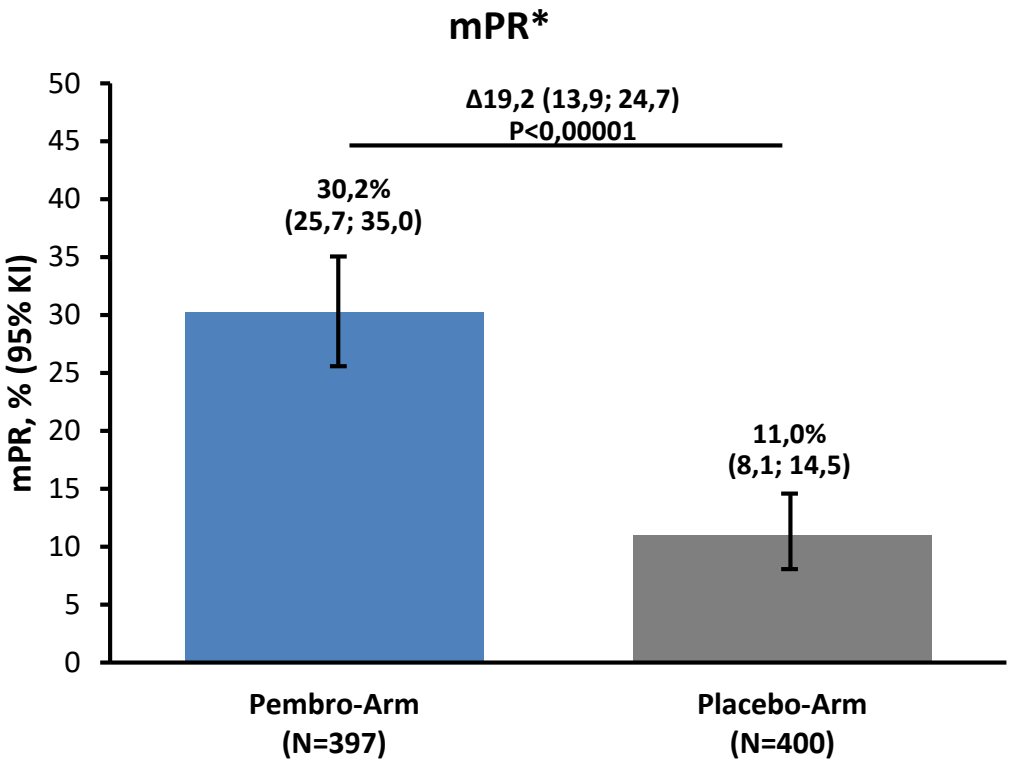
Duale primäre Endpunkte
- EFS gemäß Prüfarzt/-ärztin-Beurteilung und OS

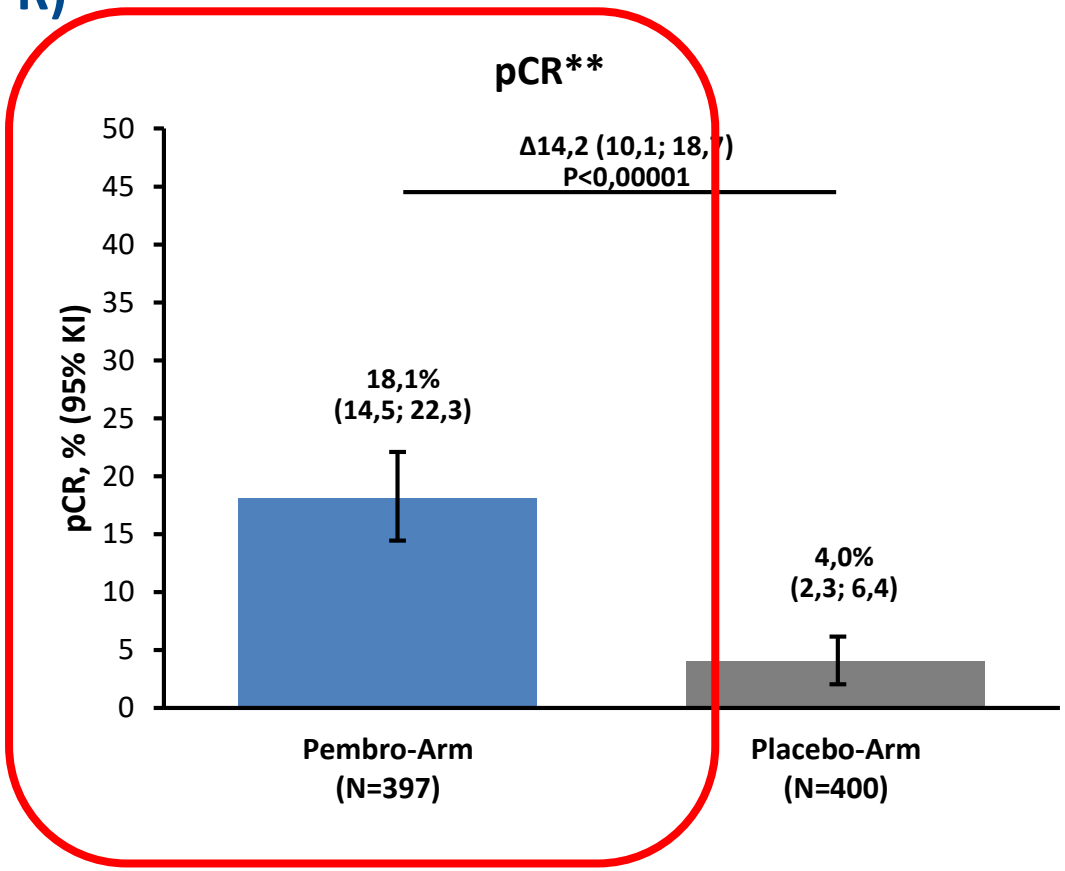
Wichtige sekundäre Endpunkte
- mPR und pCR gemäß verblindeter, unabhängiger pathologischer Beurteilung und Sicherheit

*Bestimmt in einem Zentrallabor mittels PD-L1 IHC 22C3 pharmDX; **Cisplatin 75 mg/m^2 i.v. Q3W + Gemcitabin 1000 mg/m^2 i.v. an den Tagen 1 und 8 Q3W war nur erlaubt bei Plattenepithelhistologie; #Cisplatin 75 mg/m^2 Q3W + Pemetrexed 500 mg/m^2 i.v. Q3W war nur erlaubt bei Nicht-Plattenepithelhistologie; ##Radiotherapie sollte bei Teilnehmer:innen mit mikroskopisch-positiven Tumorrändern, Resterkrankung oder extrakapsulärer nodaler Beteiligung nach Operation und bei Teilnehmer:innen, aufgrund von lokale Progression oder metastasierte Erkrankung nicht der geplanten Operation unterzogen, verabreicht werden. ClinicalTrials.gov Identifizierung: NCT03425643.

Wakelee HA et al. J Clin Oncol 41, 2023 (suppl 17; abstr LBA100)

Keynote 671: Pathologisches Ansprechen (gemäß BIPR)

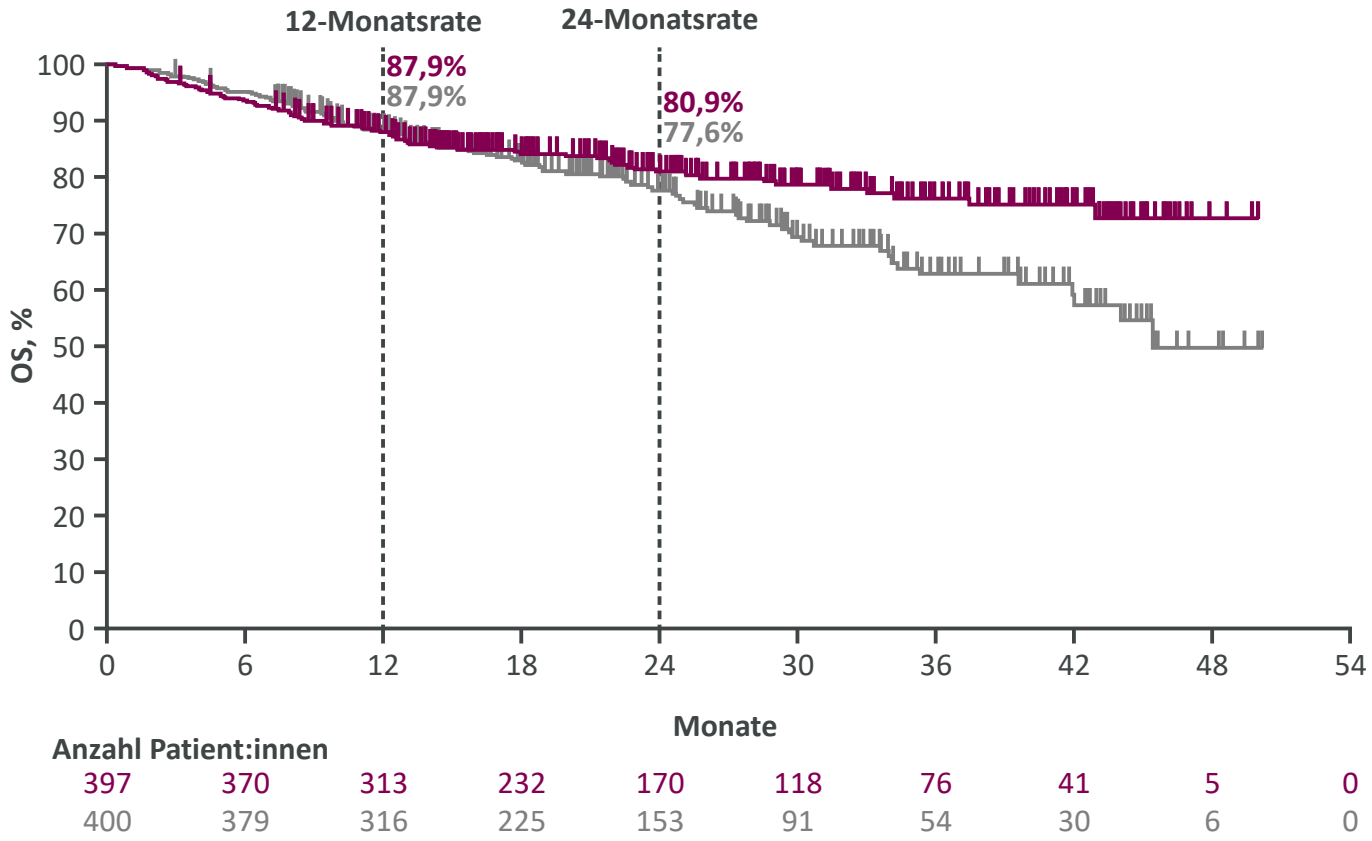




*Definiert als ≤10% lebende Tumorzellen in reseziertem primärem Tumor und Lymphknoten; **Definiert als Nicht-Vorhandensein von invasiven Tumorzellen in reseziertem primärem Tumor und Lymphknoten (ypT0/Tis ypN0). Daten-Cut-Off für IA1: 29. Juli 2022.
BIPR, verblindete unabhängige pathologische Überprüfung

Wakelee HA et al. J Clin Oncol 41, 2023 (suppl 17; abstr LBA100)

Keynote 671: OS positiv!!



	Pembro-Arm	Placebo-Arm
Patient:innen mit Ereignis, %	19,1	25,3
Median (95% KI), Monate	NR (NR-NR)	45,5 (42,0; NR)

HR 0,73 (95% KI, 0,54; 0,99)
P<0,02124*

OS ist definiert als Zeit von Randomisierung bis zum Tod durch beliebige Ursache. *Signifikanzgrenze nicht erreicht bei IA1; OS wird entsprechend des Analyseplans weiterhin untersucht.
Daten-Cut-Off für IA1: 29. Juli 2022 (medianes Follow-Up: 25,2 Monate [Bereich: 7,5; 50,6]).

Wakelee HA et al. J Clin Oncol 41, 2023 (suppl 17; abstr LBA100)

CM 816: OS positiv!!

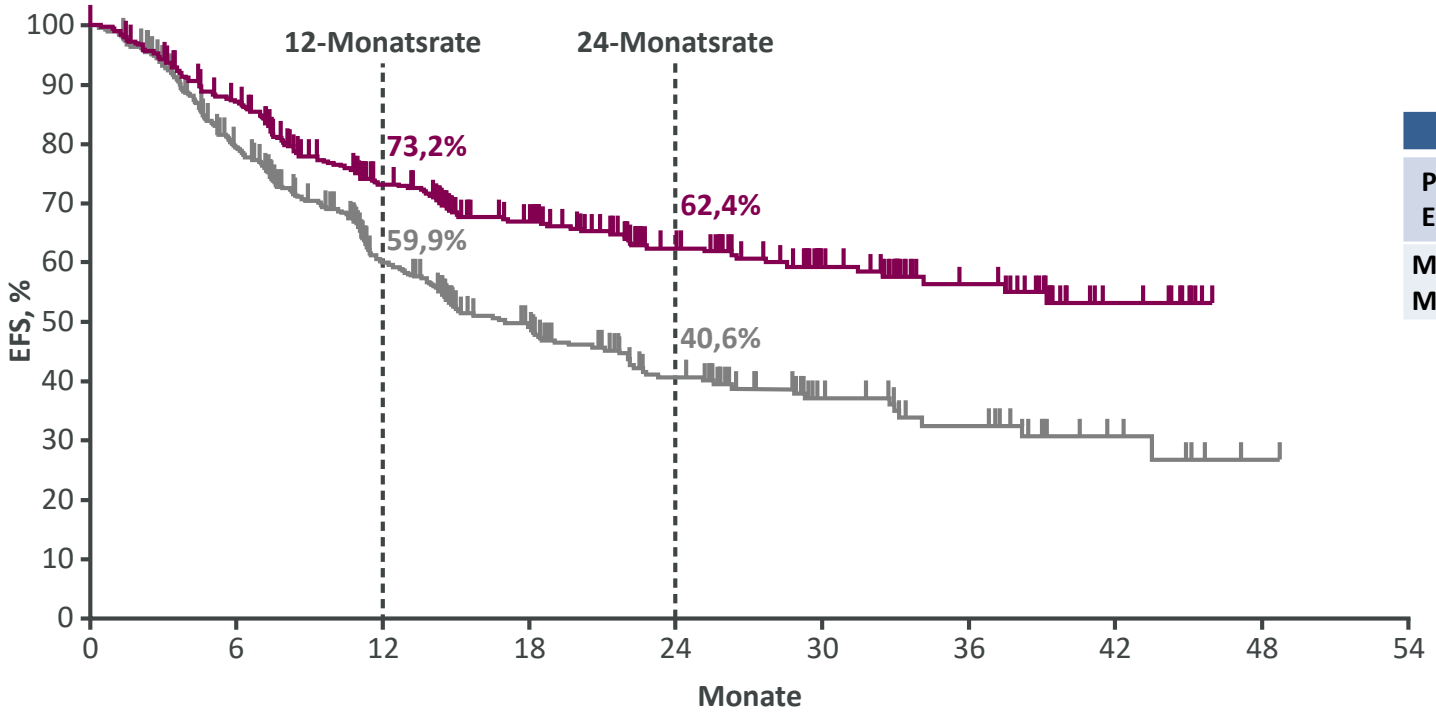
February 19, 2025

See all press releases Sign up for email alerts

Bristol Myers Squibb Announces Opdivo® Plus Chemotherapy as the First and Only Neoadjuvant-Only Immuno-Oncology Therapy to Demonstrate Statistically Significant and Clinically Meaningful Overall Survival in Resectable Non-Small Cell Lung Cancer

PRINCETON, N.J.--(BUSINESS WIRE)-- Bristol Myers Squibb (NYSE: BMY) today announced the final analysis of overall survival (OS) from the Phase 3 CheckMate -816 study, which evaluated *Opdivo*® (nivolumab) in combination with platinum-doublet chemotherapy as a neoadjuvant treatment for adult patients with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer (NSCLC). The results showed a statistically significant and clinically meaningful improvement in OS, a key secondary endpoint, compared to neoadjuvant chemotherapy alone. The results build on the previously reported primary endpoints of event-free survival (EFS) and pathological complete response (pCR), which also met statistical significance.

Keynote 671: EFS



Anzahl Patient:innen									
397	330	236	172	117	72	42	11	0	0
400	294	183	124	74	38	24	9	1	0

	Pembro-Arm	Placebo-Arm
Patient:innen mit Ereignis, %	35,0	51,3
Median (95% KI), Monate	NR (34,2; NR)	17,0 (14,3; 22,0)

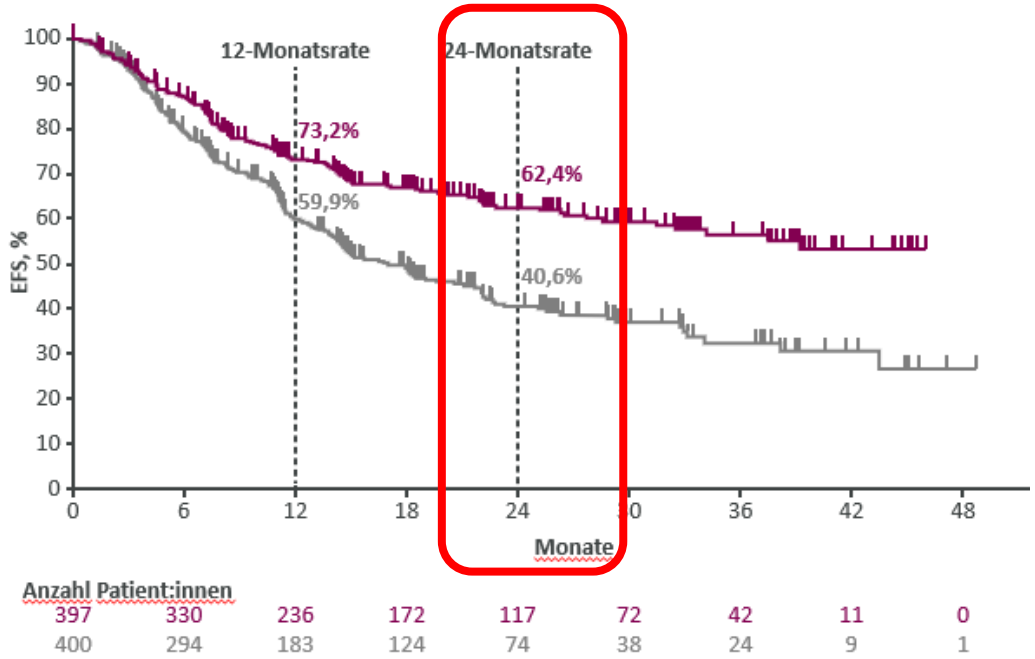
HR 0,58 (95% KI, 0,46; 0,72)
P<0,00001

EFS ist definiert als Zeit von Randomisierung bis zum ersten Auftreten einer lokalen Progression unter Ausschluss einer geplanten Operation, eines nicht-resezierbaren Tumors, einer Progression oder Rezidivs gemäß RECIST v1.1 nach Beurteilung des/-r Prüfarztes/-ärztin oder Tod durch beliebige Ursache. Daten-Cut-Off für IA1: 29. Juli 2022 (medianes Follow-Up: 25,2 Monate [Bereich: 7,5; 50,6]).

Wakelee HA et al. J Clin Oncol 41, 2023 (suppl 17; abstr LBA100)

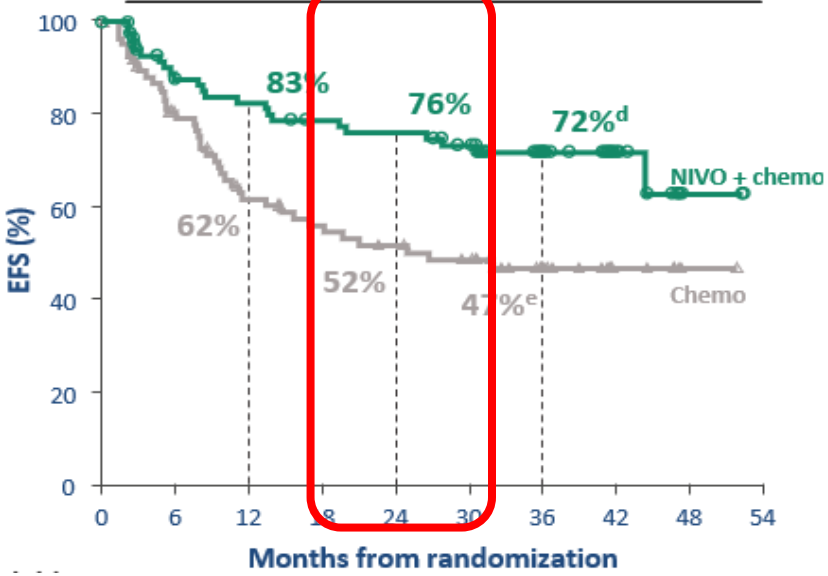
Perioperativ vs. Neoadjuvant??

Keynote 671: EFS



CheckMate 816: EFS

	NIVO + chemo (n = 89)	Chemo (n = 89)
Median EFS, mo (95% CI)	NR (44.4–NR)	26.7 (13.4–NR)
HR (95% CI)	0.46 (0.28–0.77)	



Neoadjuvante Chemo-Immuntherapie beim funktionell resektablen Stadium IIIA NSCLC??

- Welches Stadium IIIA??
- Wer sagt mir was resektabel ist??
- (wie fit ist meine Thoraxchirurgie??) 

- In dubio pro reo:

- **„präoperative CHT-IO“: unbedingt!!!!**

VIELEN DANK FÜR IHRE AUFMERKSAMKEIT UND IHR ENGAGEMENT!

PETER ERRHALT UK KREMS PNEUMOLOGIE