Year in Review:
Nontargeted Approaches for Lung Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, June 24, 2025
5:00 PM – 6:00 PM ET

Faculty

Benjamin Levy, MD

Moderator

Neil Love, MD

RTP Year in Review 2025

Faculty

Benjamin Levy, MD
Associate Professor, Johns Hopkins School of Medicine
Clinical Director
Medical Director, Thoracic Oncology Program
Johns Hopkins Sidney Kimmel Cancer Center
at Sibley Memorial
Washington, DC

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

Commercial Support

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Dr Love — Disclosures

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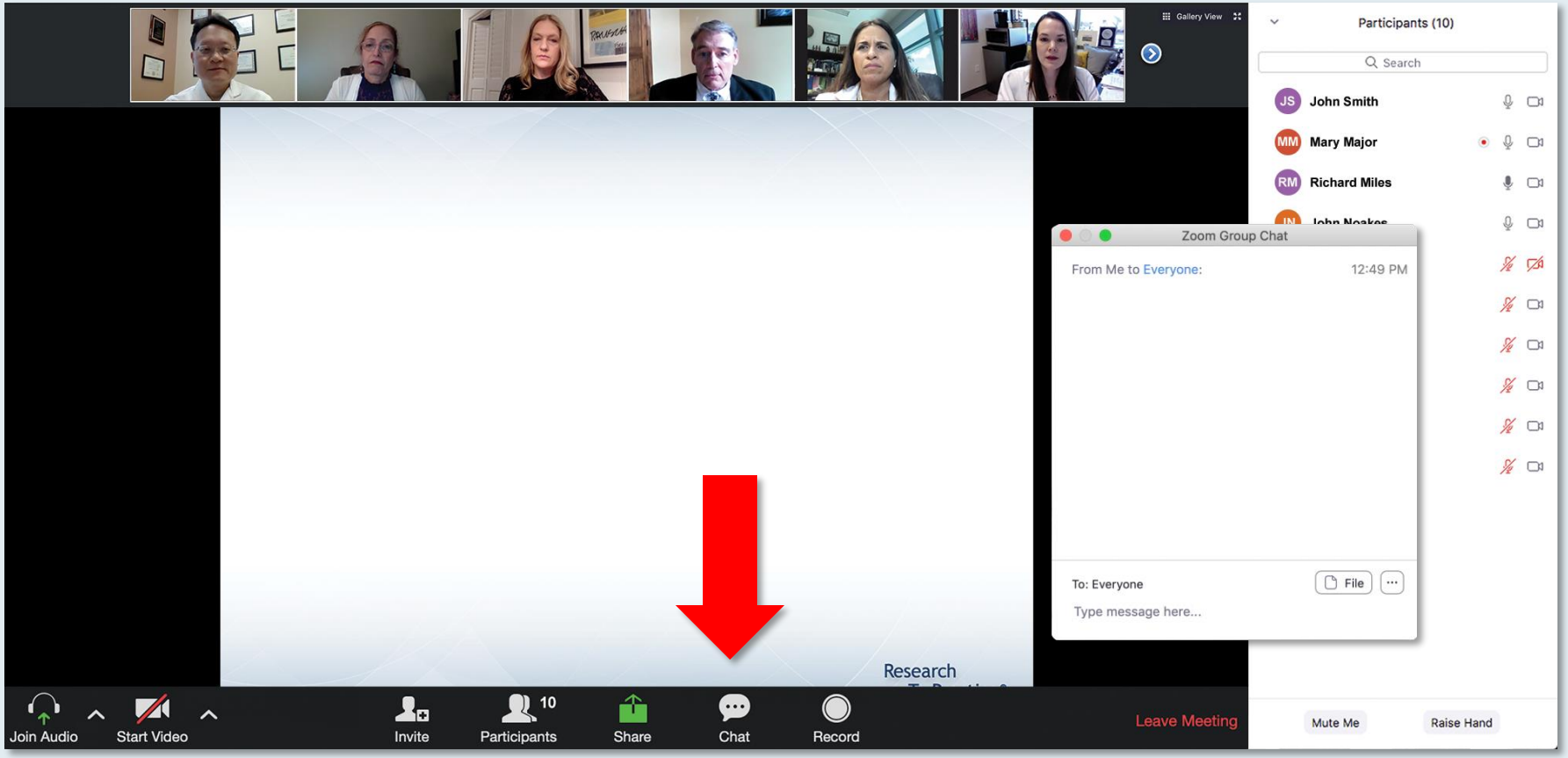

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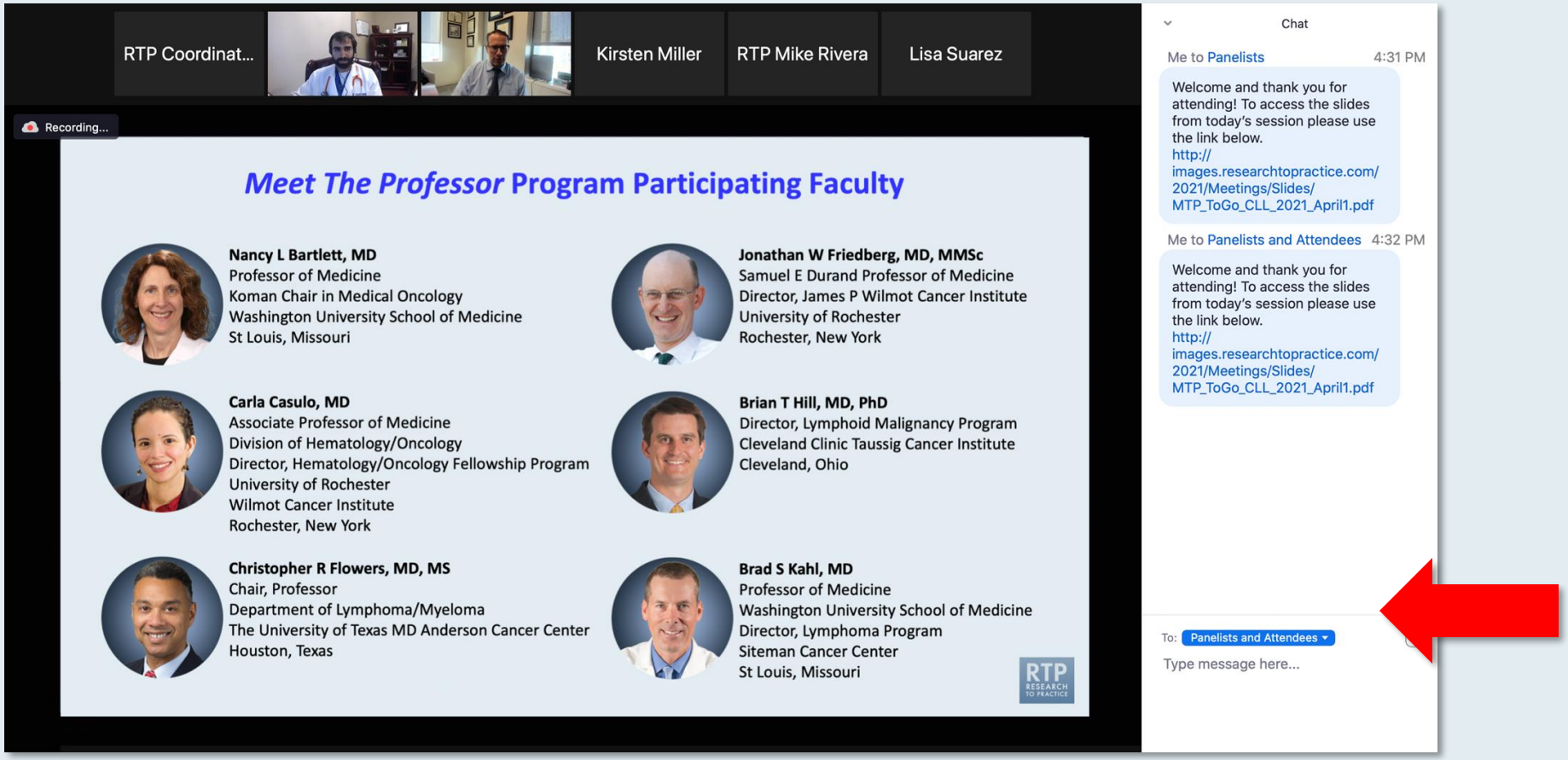

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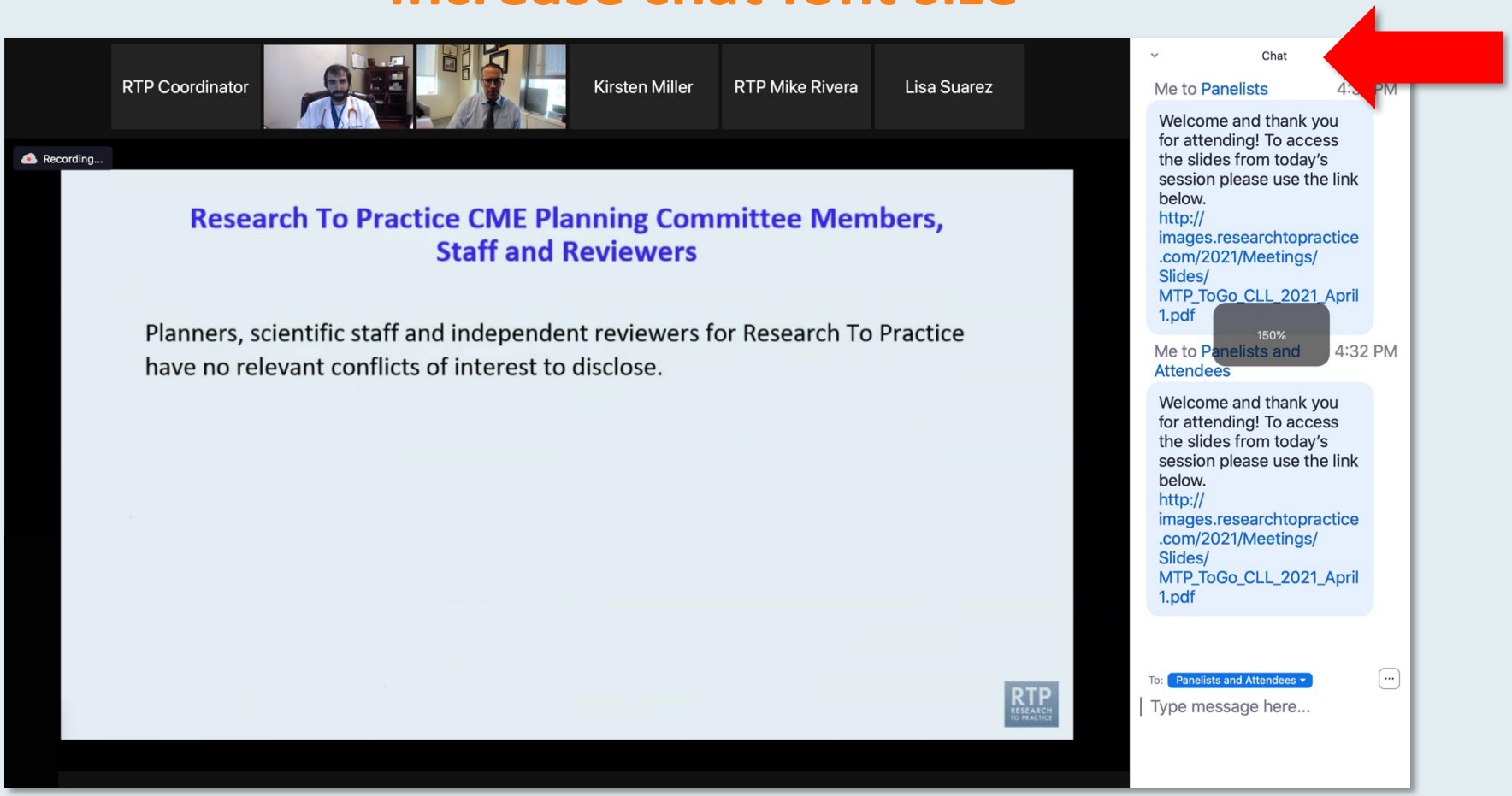

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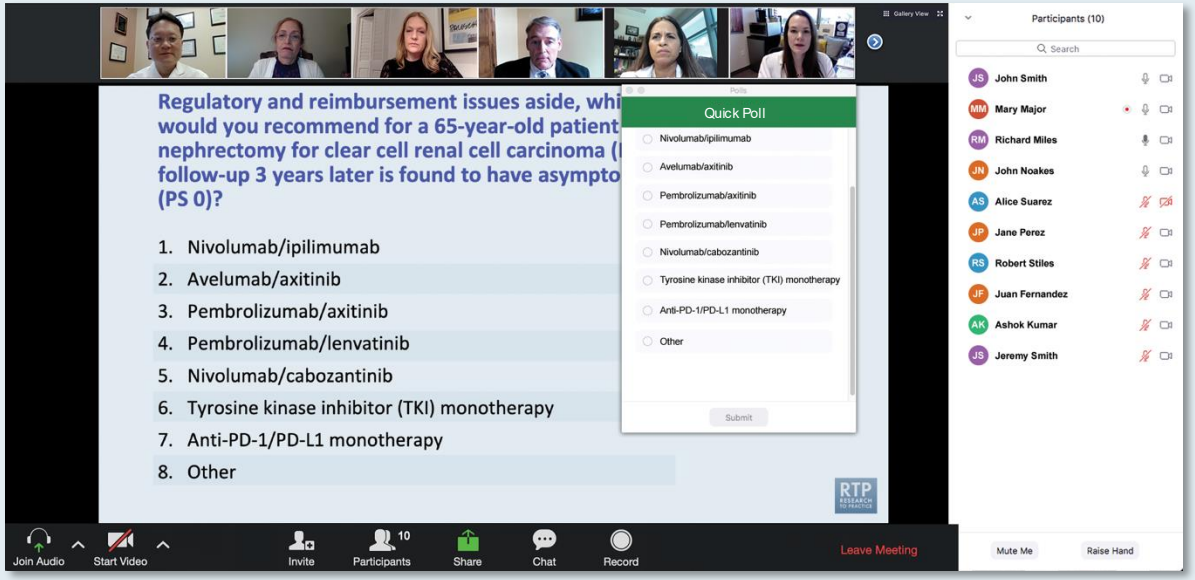

Immunotherapy and Nontargeted Approaches for NSCLC — Fourth Annual National General Medical Oncology Summit

DR RAMASWAMY GOVINDAN
WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

DR STEPHEN V LIU
GEORGETOWN UNIVERSITY HOSPITAL

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Optimizing the Selection of First-Line Therapy for Patients with Multiple Myeloma

A CME/MOC-Accredited Live Webinar

Tuesday, July 1, 2025
5:00 PM – 6:00 PM ET

Faculty

Xavier Leleu, MD, PhD
Peter Voorhees, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Practical Perspectives: Experts Review Actual Cases of Patients with Small Cell Lung Cancer

A CME/MOC-Accredited Live Webinar

Wednesday, July 16, 2025
5:00 PM – 6:00 PM ET

Faculty

Stephen V Liu, MD
Charles Rudin, MD, PhD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Cancer Q&A: Addressing Common Questions Posed by Patients with Relapsed/Refractory Multiple Myeloma

A Webinar Series for Clinicians and Patients,
Developed in Partnership with Cancer*Care*®

Patients	Clinicians
Wednesday, July 23, 2025	**Thursday, August 7, 2025**
6:00 PM – 7:00 PM ET	**5:00 PM – 6:00 PM ET**

Faculty

Natalie S Callander, MD
Sagar Lonial, MD, FACP

Moderator

Neil Love, MD

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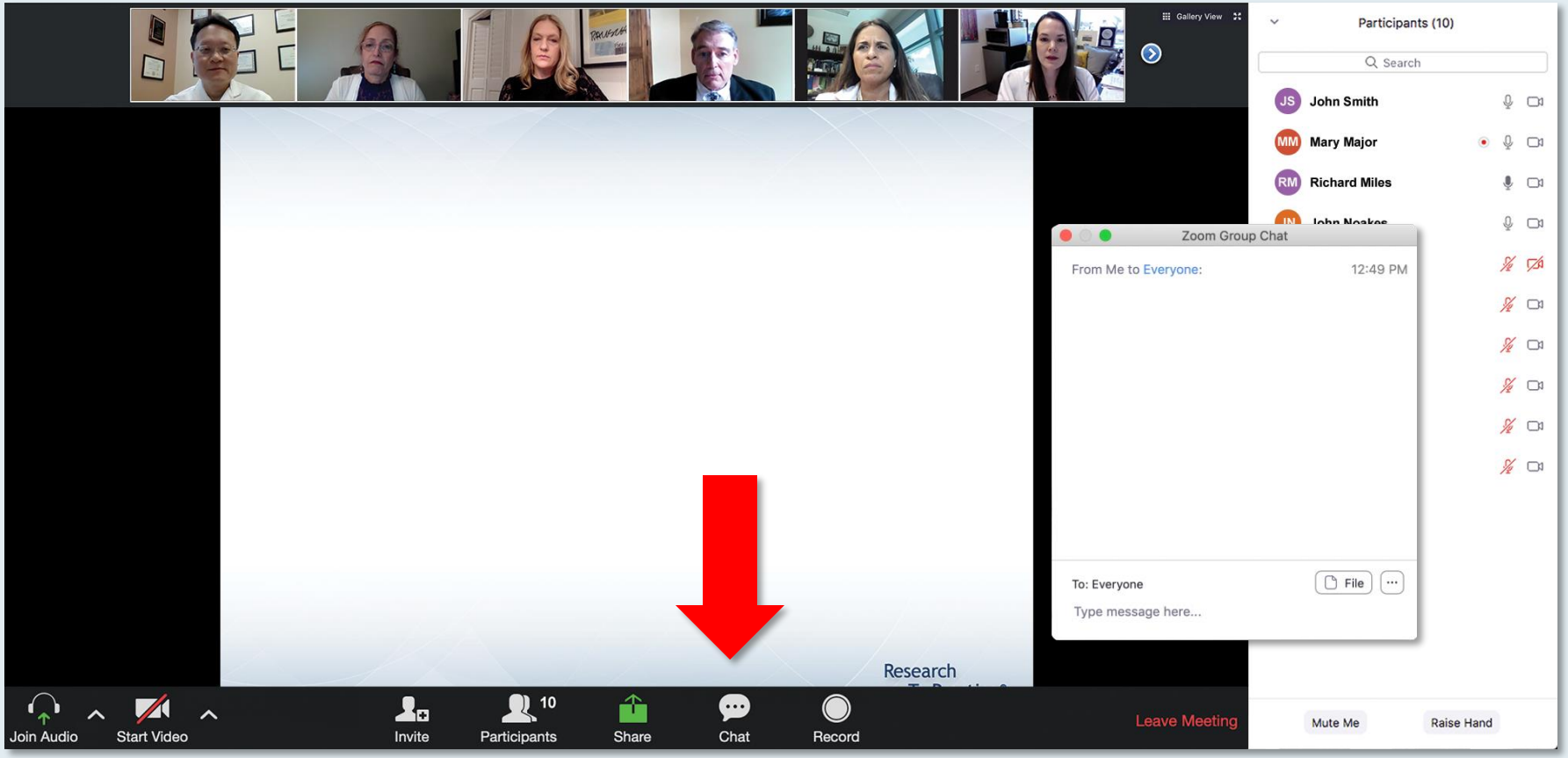

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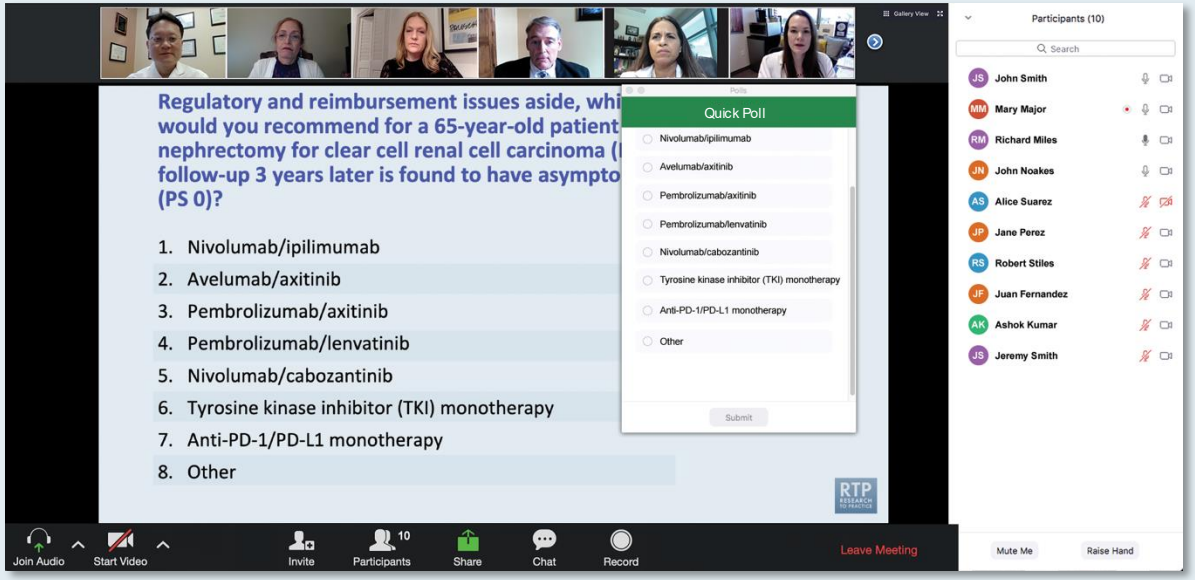

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Immunotherapy and Other Nontargeted Approaches for Lung Cancer

Benjamin Levy, MD
Associate Professor, Johns Hopkins School of Medicine
Clinical Director
Medical Director, Thoracic Oncology Program
Johns Hopkins Sidney Kimmel Cancer Center
at Sibley Memorial
Washington, DC

Key Datasets

Benjamin Levy, MD

- Forde PM et al. **Overall survival** with **neoadjuvant nivolumab (NIVO) + chemotherapy** (chemo) in patients with resectable NSCLC in **CheckMate 816**. ASCO 2025;Abstract LBA8000.
- Heymach JV et al. **Perioperative durvalumab** for resectable NSCLC (R-NSCLC): **Updated outcomes** from the Phase 3 **AEGEAN** trial. WCLC 2024;Abstract OA13.03.
- Spicer JD et al. **Neoadjuvant pembrolizumab plus chemotherapy followed by adjuvant pembrolizumab** compared with neoadjuvant chemotherapy alone in patients with early-stage non-small-cell lung cancer **(KEYNOTE-671)**: A randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet* 2024;404(10459):1240-52.
- Provencio M et al. **Perioperative nivolumab (NIVO)** vs placebo (PBO) in patients (pts) with resectable NSCLC: **Updated survival and biomarker analyses from CheckMate 77T**. ASCO 2025;Abstract LBA8010.
- Filippi AR et al. **Real-world 5-year survival outcomes** with **durvalumab (D) after chemoradiotherapy** (CRT) in unresectable, stage III NSCLC (urNSCLC): **Final data extraction** from **PACIFIC-R**. ELCC 2025;Abstract 190P.
- Reck M et al. **Five-year outcomes** with **first-line nivolumab plus ipilimumab** with **2 cycles of chemotherapy versus 4 cycles of chemotherapy** alone in patients with metastatic non-small cell lung cancer in the randomized **CheckMate 9LA** trial. *Eur J Cancer* 2024;211:114296.
- Peters S et al. **Durvalumab with or without tremelimumab** in combination **with chemotherapy** in first-line metastatic NSCLC: **Five-year overall survival** outcomes from the phase 3 **POSEIDON** trial. *J Thorac Oncol* 2025;20(1):76-93.

Key Datasets

Benjamin Levy, MD (continued)

- Garassino MC et al. **Normalized membrane ratio** of **TROP2** by quantitative continuous scoring is **predictive of clinical outcomes in TROPION-Lung 01**. WCLC 2024;Abstract PL02.11.
- Levy BP et al. **TROPION-Lung02: Datopotamab deruxtecan (Dato-DXd) plus pembrolizumab (pembro)** with or without **platinum chemotherapy** (Pt-CT) as **first-line** (1L) therapy for advanced non-small cell lung cancer (aNSCLC). ASCO 2025;Abstract 8501.
- Xiong A et al. **Ivonescimab versus pembrolizumab** for PD-L1-positive non-small cell lung cancer **(HARMONi-2)**: A randomised, double-blind, **phase 3 study in China**. *Lancet* 2025;405(10481):839-49.
- Aerts J et al. **Acasunlimab (DuoBody-PD-L1x4-1BB) alone** or in **combination with pembrolizumab** (pembro) in patients (pts) with **previously treated metastatic non-small cell lung cancer** (mNSCLC): **Initial results** of a randomized, open-label, **phase 2 trial**. ASCO 2024;Abstract 2533.
- Paz-Ares L et al. **ABBIL1TY NSCLC-06**: A global, randomized, open-label, **phase III trial of acasunlimab in combination with pembrolizumab (pembro)** vs docetaxel in **checkpoint inhibitor (CPI)-experienced patients** with **PD-L1+ metastatic non-small cell lung cancer** (mNSCLC). ELCC 2025;Abstract 128TiP.
- Mamdani H. **Bispecific antibodies in action**: Engineering immunity to target thoracic malignancies. ASCO 2025 Clinical Science Symposium.

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Superior vena cava syndrome

Metastatic NSCLC with no actionable mutation and a PD-L1 TPS (tumor proportion score) between 1% and 50%

Metastatic NSCLC with an activating EGFR mutation and brain metastases

FDA Grants Accelerated Approval to Datopotamab Deruxtecan-dlnk for EGFR-Mutated NSCLC

Press Release: June 23, 2025

"On June 23, 2025, the Food and Drug Administration granted accelerated approval to datopotamab deruxtecan-dlnk for adults with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy.

Efficacy was evaluated in a pooled subgroup of 114 patients with locally advanced or metastatic EGFR-mutated NSCLC who had received prior treatment with an EGFR-directed therapy and platinum-based chemotherapy and received datopotamab deruxtecan-dlnk at the recommended dose across two clinical trials: TROPION-Lung05 and TROPION-Lung01. TROPION-Lung05 (NCT04484142) was a multicenter, single-arm trial, while TROPION-Lung01 (NCT04656652) was a multicenter, open-label, randomized controlled trial.

The recommended datopotamab deruxtecan-dlnk dose is 6 mg/kg (up to a maximum of 540 mg for patients ≥ 90 kg), as an intravenous infusion once every 3 weeks, until disease progression or unacceptable toxicity."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-datopotamab-deruxtecan-dlnk-egfr-mutated-non-small-cell-lung-cancer

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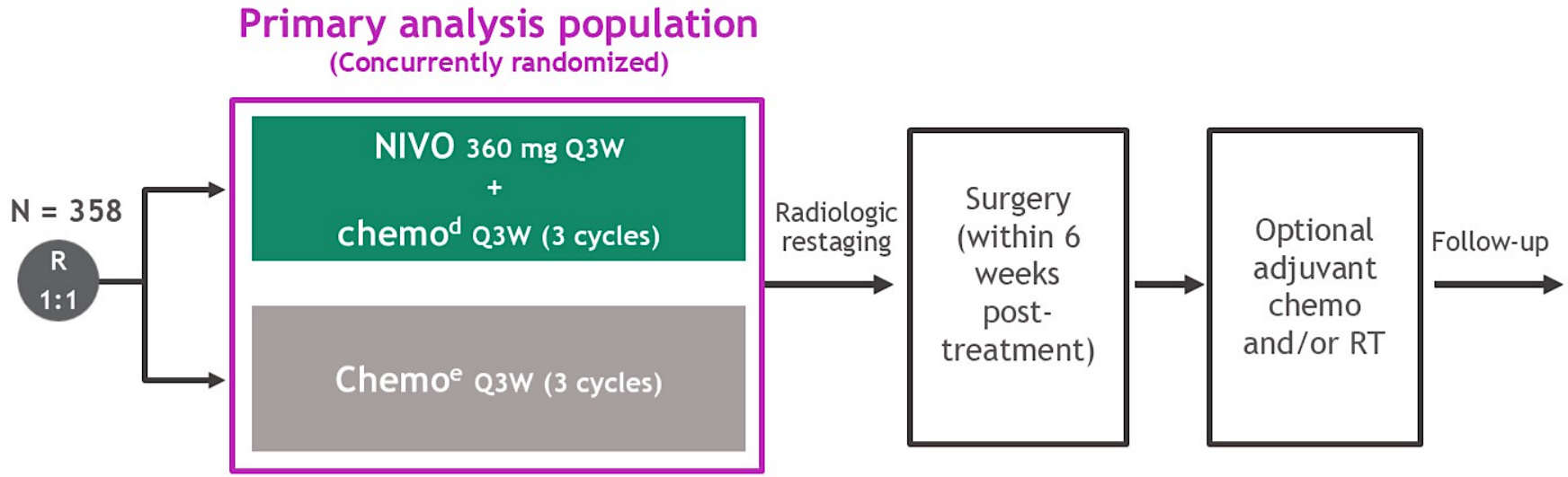
CheckMate 816 study design[a]

Key Eligibility Criteria

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

Stratified by

Stage (IB-II vs IIIA), PD-L1[b] (≥ 1% vs < 1%[c]), and sex



Minimum/median follow-up: 59.9/68.4 months

Primary endpoints

- pCR by BIPR
- EFS by BICR

Key secondary endpoints

- OS
- MPR by BIPR
- TTDM

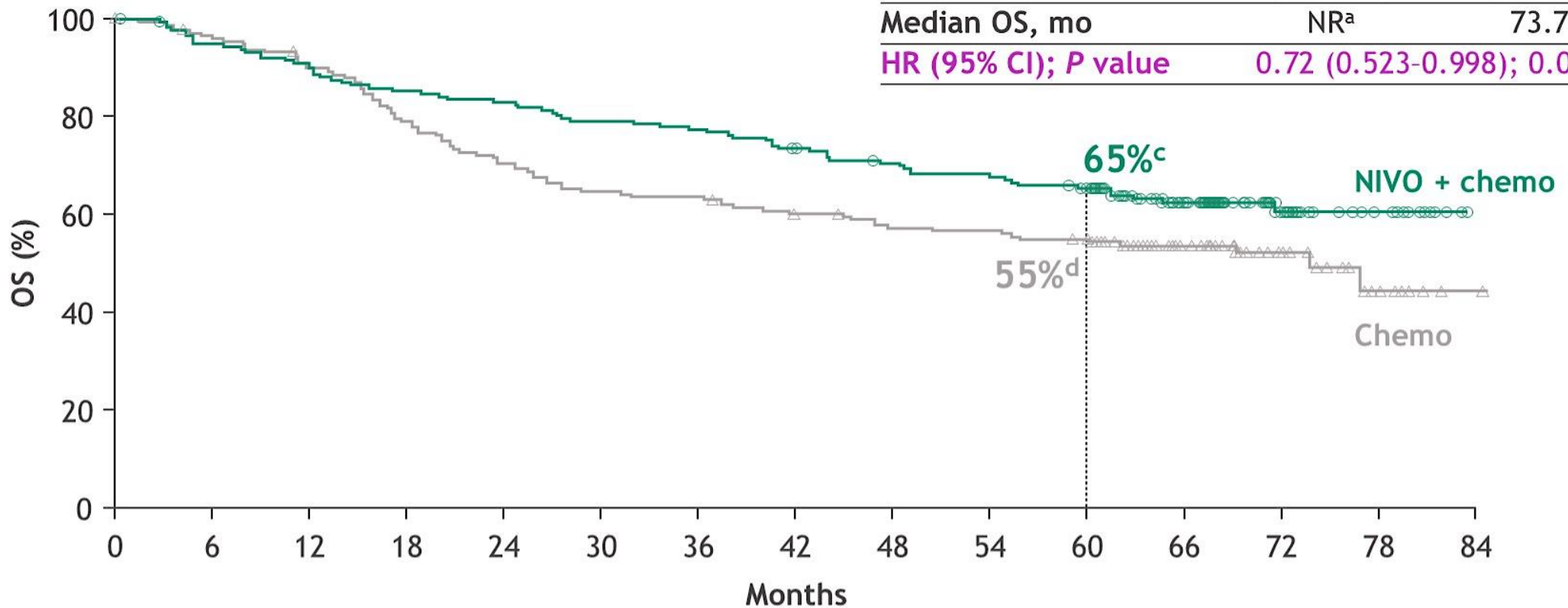
Exploratory analyses

- OS by pCR, ctDNA clearance
- Lung cancer-specific survival

Database lock: January 23, 2025. From *The New England Journal of Medicine*, Forde PM, et al, Neoadjuvant nivolumab plus chemotherapy in resectable lung cancer, 2022;386:1973-1985. [a]NCT02998528. [b]Determined by the PD-L1 IHC 28-8 pharmDx assay (Dako). [c]Included patients with PD-L1 expression status not evaluable and indeterminate. [d]Nonsquamous: pemetrexed + cisplatin or paclitaxel + carboplatin; squamous: gemcitabine + cisplatin or paclitaxel + carboplatin. [e]Vinorelbine + cisplatin, docetaxel + cisplatin, gemcitabine + cisplatin (squamous only), pemetrexed + cisplatin (nonsquamous only), or paclitaxel + carboplatin.

Final analysis: OS with neoadjuvant NIVO + chemo vs chemo

	NIVO + chemo (n = 179)	Chemo (n = 179)
Median OS, mo	NR[a]	73.7[b]
HR (95% CI); *P* value	0.72 (0.523-0.998); 0.0479	



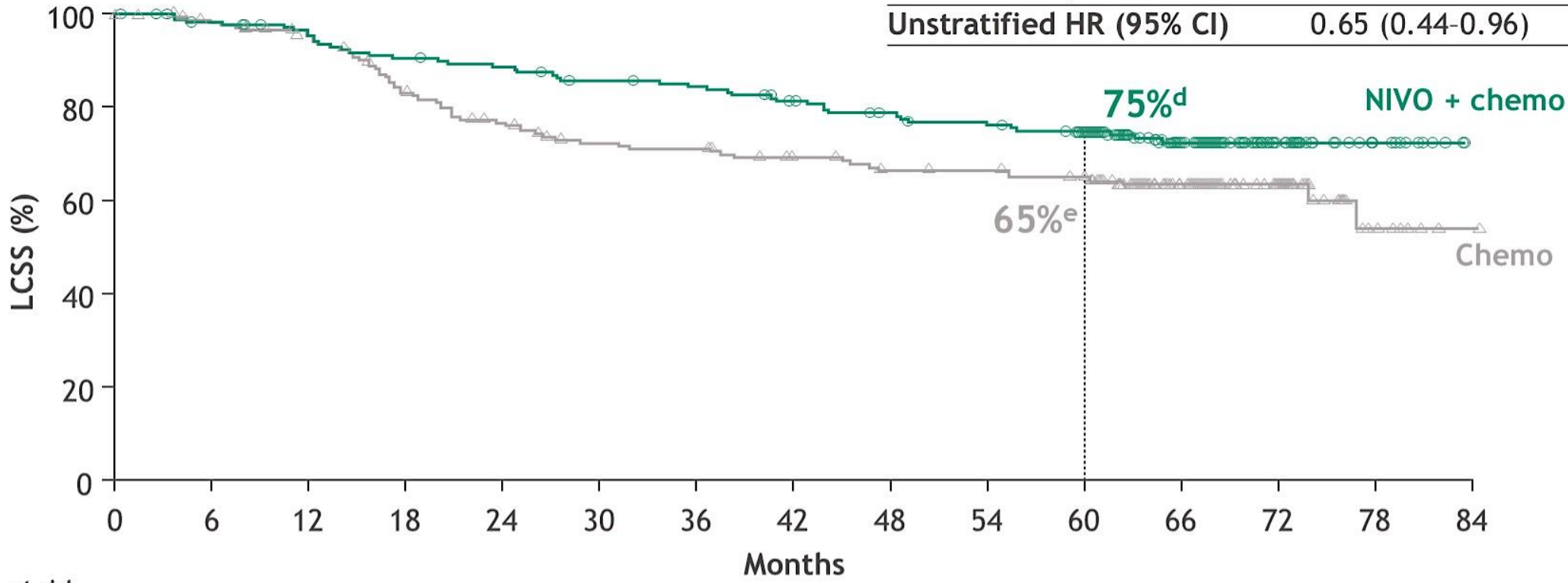
No. at risk														
NIVO + chemo	179	168	159	151	147	140	137	129	122	117	111	67	29	9	0
Chemo	179	170	159	139	124	114	112	104	98	97	91	58	29	6	1

Minimum/median follow-up: 59.9/68.4 months.

[a-d]95% CI: [a]NR; [b]47.3-NR; [c]58-72; [d]47-62.

Lung cancer–specific survival[a]

	NIVO + chemo (n = 179)	Chemo (n = 179)
Median LCSS, mo	NR[b]	NR[c]
Unstratified HR (95% CI)	0.65 (0.44-0.96)	



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Chemo	179	170	159	139	124	114	112	104	98	97	91	58	29	6	1

Minimum/median follow-up: 59.9/68.4 months.

[a]Included deaths due to disease per investigator assessment (n = 44 in the NIVO + chemo arm; n = 61 in the chemo arm). [b-e]95% CI: [b]NR; [c]73.7-NR; [d]68-81; [e]57-72.

AEGEAN: A phase 3, global, randomized, double-blind, placebo-controlled study

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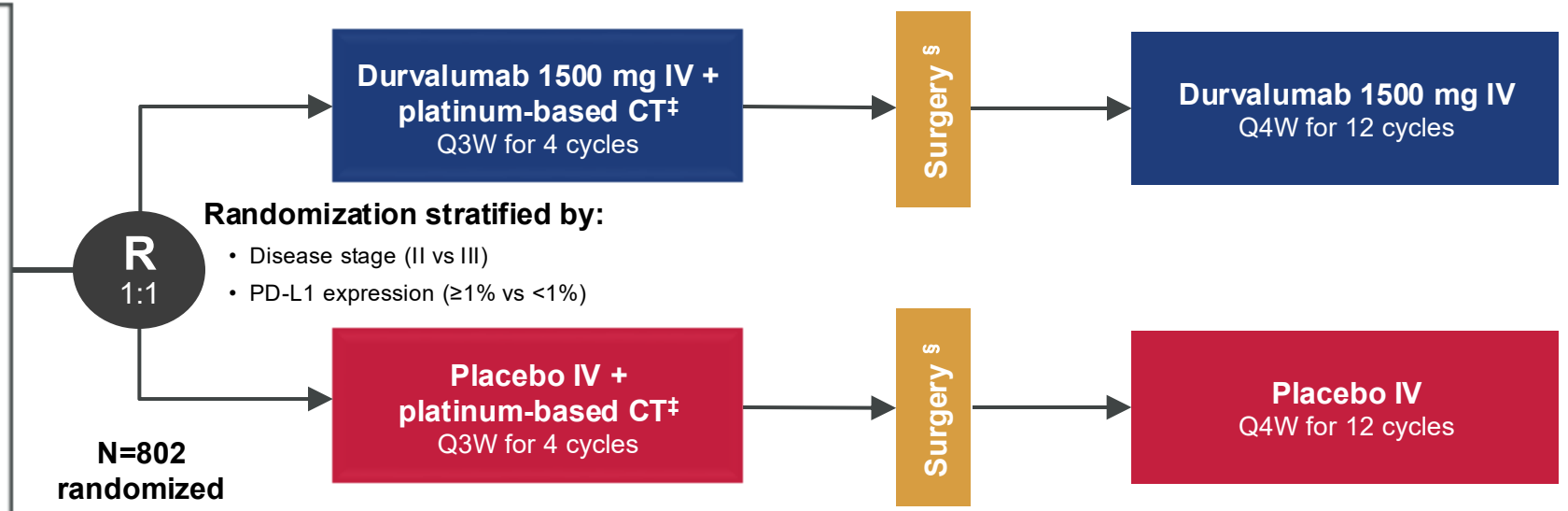
Study population

- Treatment-naïve
- ECOG PS 0 or 1
- Resectable NSCLC* (stage IIA–IIIB[N2]; AJCC 8th ed)
- Lobectomy, sleeve resection, or bilobectomy as planned surgery*
- Confirmed PD-L1 status†
- No documented *EGFR/ALK* aberrations*



Endpoints: All efficacy analyses performed on a modified population that excludes patients with documented *EGFR/ALK* aberrations¶

Primary:

- pCR by central lab (per IASLC 2020[1])
- EFS using BICR (per RECIST v1.1)

Key secondary:

- MPR by central lab (per IASLC 2020[1])
- DFS using BICR (per RECIST v1.1)
- OS

*The protocol was amended while enrollment was ongoing to exclude (1) patients with tumors classified as T4 for any reason other than size; (2) patients with planned pneumonectomies; and (3) patients with documented *EGFR/ALK* aberrations. †Ventana SP263 immunohistochemistry assay. ‡Choice of CT regimen determined by histology and at the investigator's discretion. For non-squamous: cisplatin + pemetrexed or carboplatin + pemetrexed. For squamous: carboplatin + paclitaxel or cisplatin + gemcitabine (or carboplatin + gemcitabine for patients who have comorbidities or who are unable to tolerate cisplatin per the investigator's judgment). §Post-operative radiotherapy (PORT) was permitted where indicated per local guidance. ¶All efficacy analyses reported in this presentation were performed on the mITT population, which includes all randomized patients who did not have documented *EGFR/ALK* aberrations. AJCC, American Joint Committee on Cancer; BICR, blinded independent central review; DFS, disease-free survival; EFS, event-free survival; mITT, modified intent-to-treat; MPR, major pathologic response; pCR, pathologic complete response.

[1]Travis WD, et al. *J Thorac Oncol* 2020;15:709-40.

AEGEAN: Pathologic response per IASLC 2020 methodology* (mITT)

Final analysis

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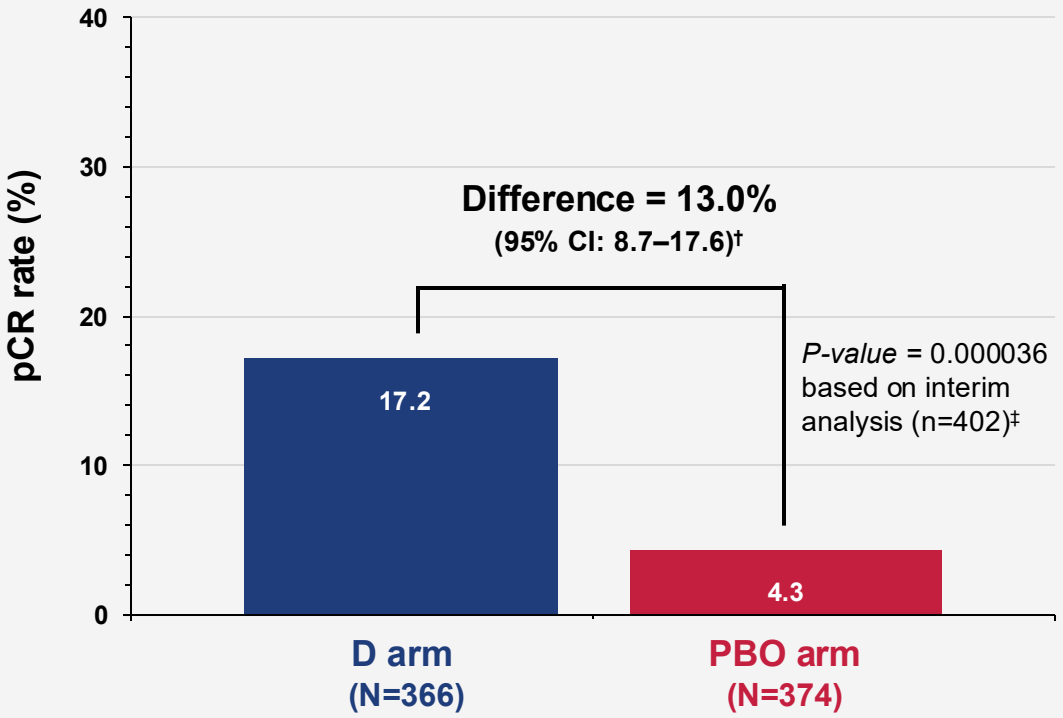
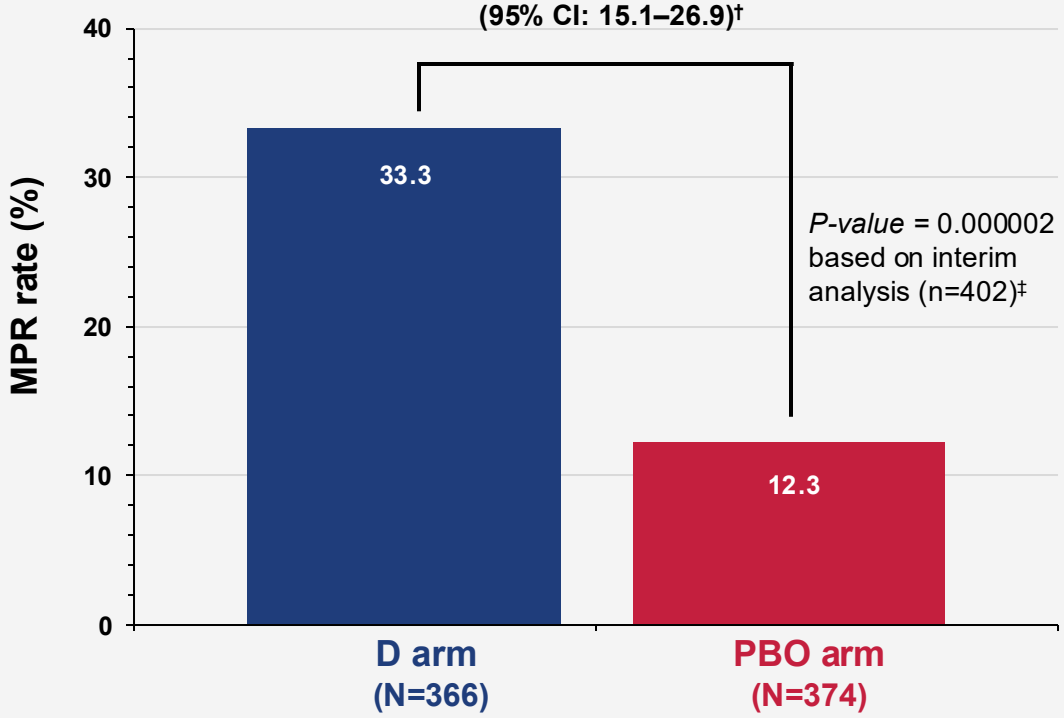
pCR (central lab)



MPR (central lab)



Heymach AACR 2023; Abstract CT005

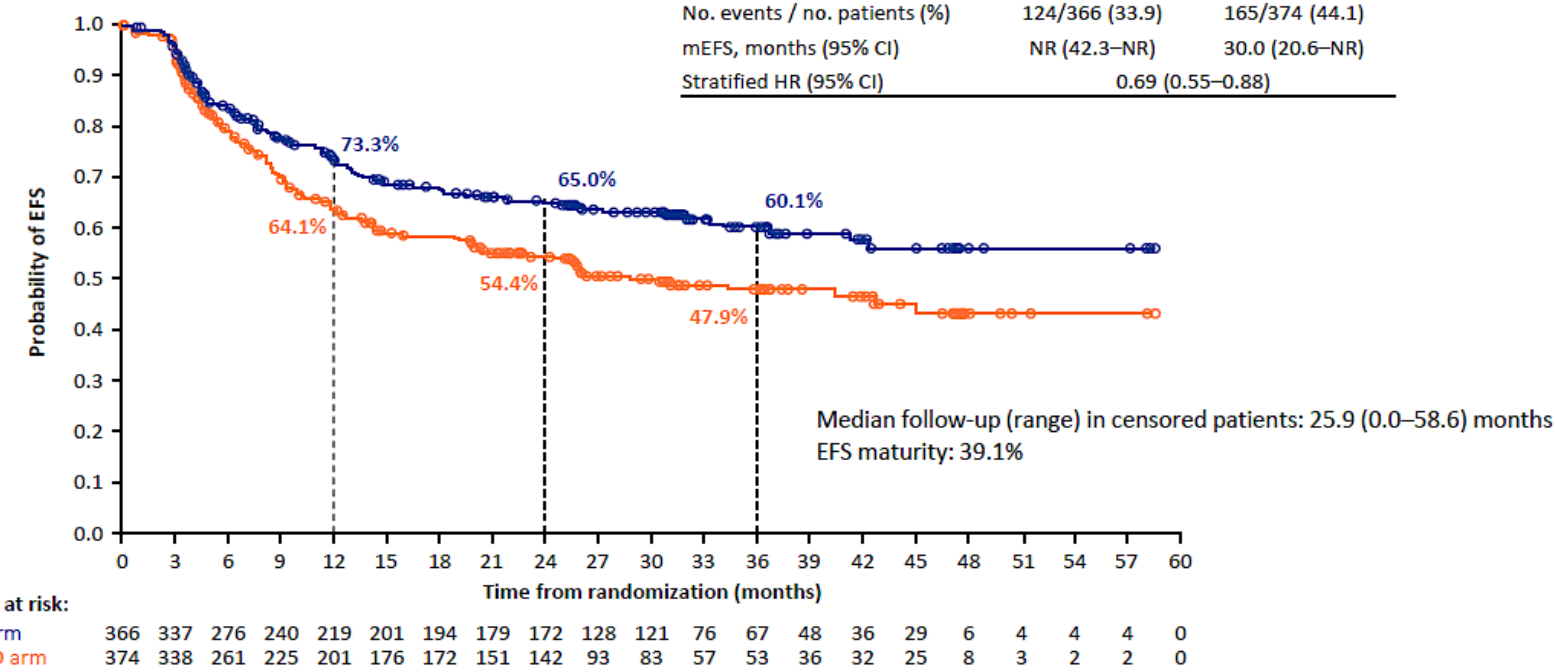
*Using IASLC recommendations for pathologic assessment of response to therapy, including gross assessment and processing of tumor bed (Travis WD, et al. *J Thorac Oncol* 2020;15:709-40). pCR = a lack of any viable tumor cells after complete evaluation of the resected lung cancer specimen and all sampled regional lymph nodes. MPR = less than or equal to 10% viable tumor cells in lung primary tumor after complete evaluation of the resected lung cancer specimen. To be eligible for pathologic assessment, patients needed tohave received three cycles of neoadjuvant study Tx per protocol. Patients who were not evaluable were classified as non-responders. †CIs calculated by stratified Miettinen and Nurminen method. ‡No formal statistical testing was performed at the pCR final analysis (DCO: Nov 10, 2022; n=740 [data shown]). Statistical significance was achieved at the interim pCR analysis (DCO: Jan 14, 2022; n=402; *P*-value for pCR/MPR calculated using a stratified Cochran-Mantel-Haenszel test with a significance boundary = 0.000082 calculated using a Lan-DeMets alpha spending function with O'Brien Fleming boundary).

AEGEAN: Updated Event Free Survival

Updated EFS (second planned interim analysis; mITT)

- EFS benefit favoring the durvalumab arm was maintained and consistent with that reported previously[1]

	D arm	PBO arm
No. events / no. patients (%)	124/366 (33.9)	165/374 (44.1)
mEFS, months (95% CI)	NR (42.3–NR)	30.0 (20.6–NR)
Stratified HR (95% CI)	0.69 (0.55–0.88)	



John V. Heymach | Perioperative Durvalumab for Resectable NSCLC: Updated Outcomes from the Phase 3 AEGEAN Trial

[1]Heymach JV, et al. *N Engl J Med* 2023;389:1672–84.

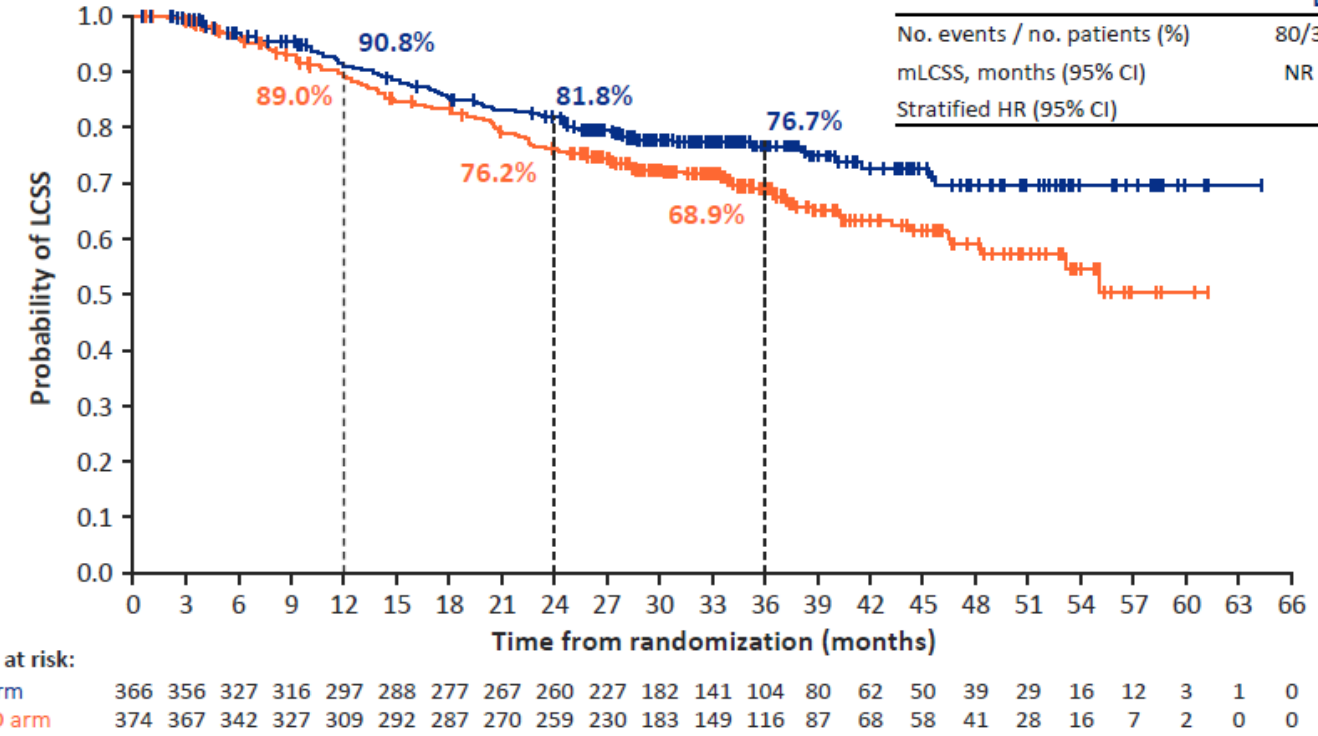
DCO = May 10, 2024. mEFS, median EFS; NR, not reached.

Heymach JV et al. Perioperative Durvalumab for Resectable NSCLC (R-NSCLC): Updated Outcomes from the Phase 3 AEGEAN Trial WCLC 2024;Abstract OA13.03.

AEGEAN: Updated Overall Survival

Lung cancer-specific survival (exploratory analysis; mITT)

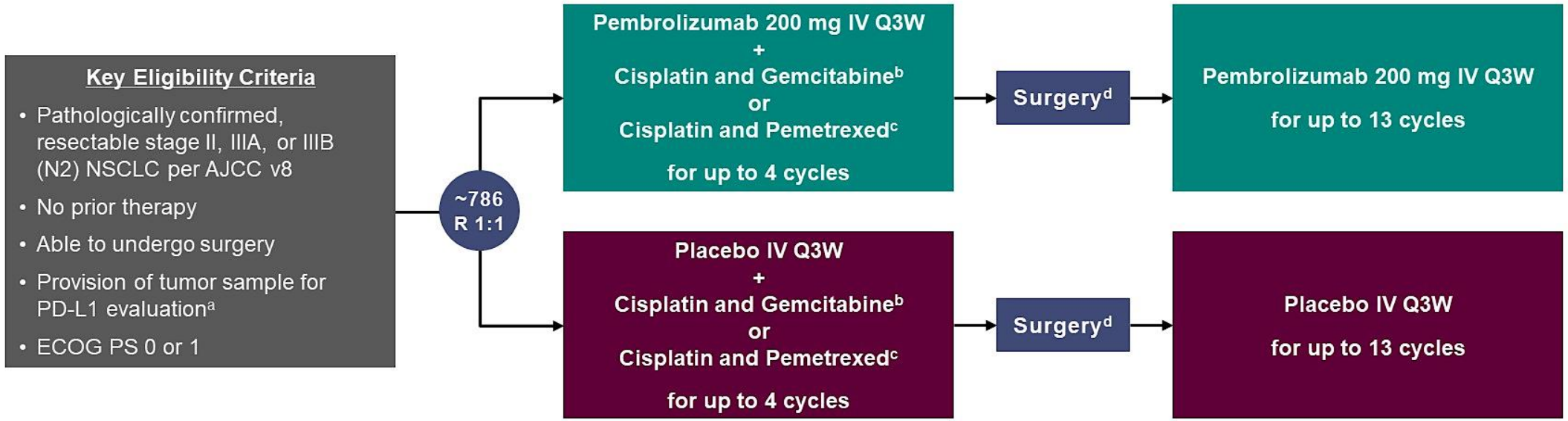
- Improvement in lung cancer-specific survival also favored the durvalumab arm



	D arm	PBO arm
No. events / no. patients (%)	80/366 (21.9)	117/374 (31.3)
mLCSS, months (95% CI)	NR (NR–NR)	NR (48.3–NR)
Stratified HR (95% CI)	0.70 (0.52–0.93)	

DCO = May 10, 2024. Lung cancer specific survival included deaths reported to be related to 'disease under investigation' per investigator assessment. LCSS, lung cancer specific survival; mLCSS, median LCSS.

KEYNOTE-671 Study Design
Randomized, Double-Blind, Phase 3 Trial



Stratification Factors
- Disease stage (II vs III)
- PD-L1 TPS[a] (<50% vs ≥50%)
- Histology (squamous vs nonsquamous)
- Geographic region (east Asia vs not east Asia)

Dual primary end points: EFS per investigator review and OS

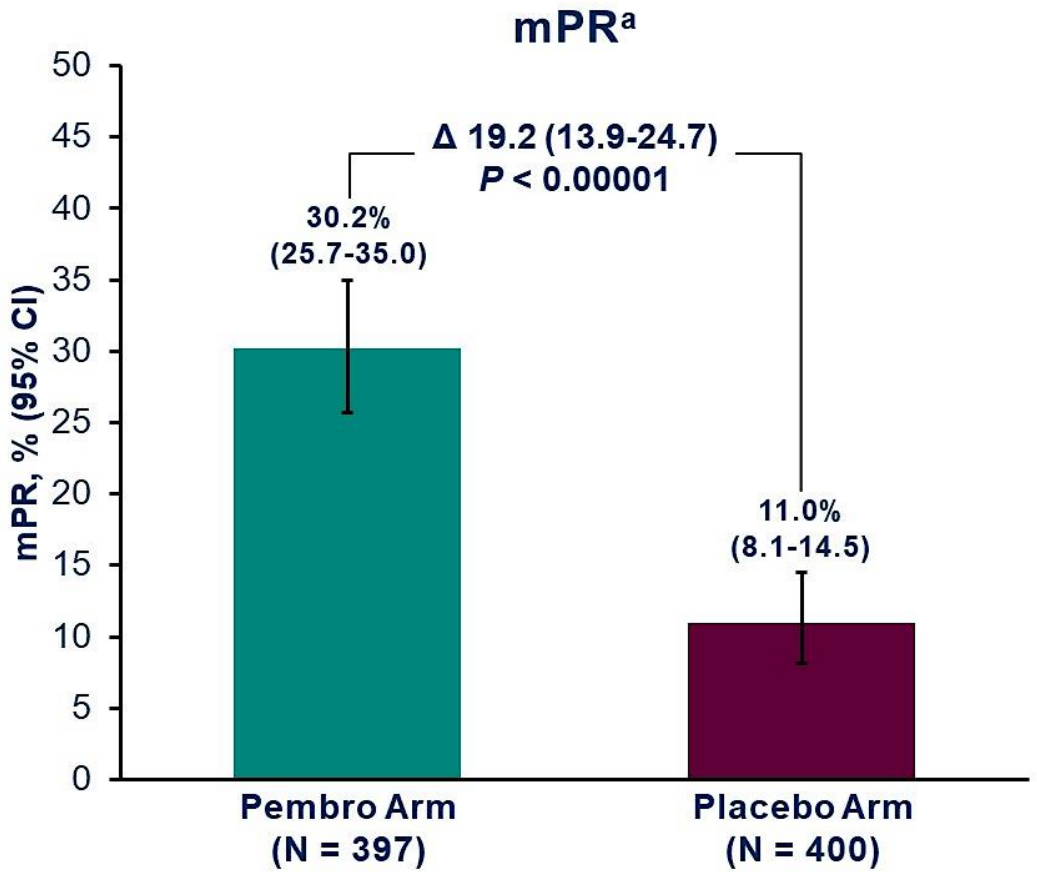
Key secondary end points: mPR and pCR per blinded, independent pathology review, and safety

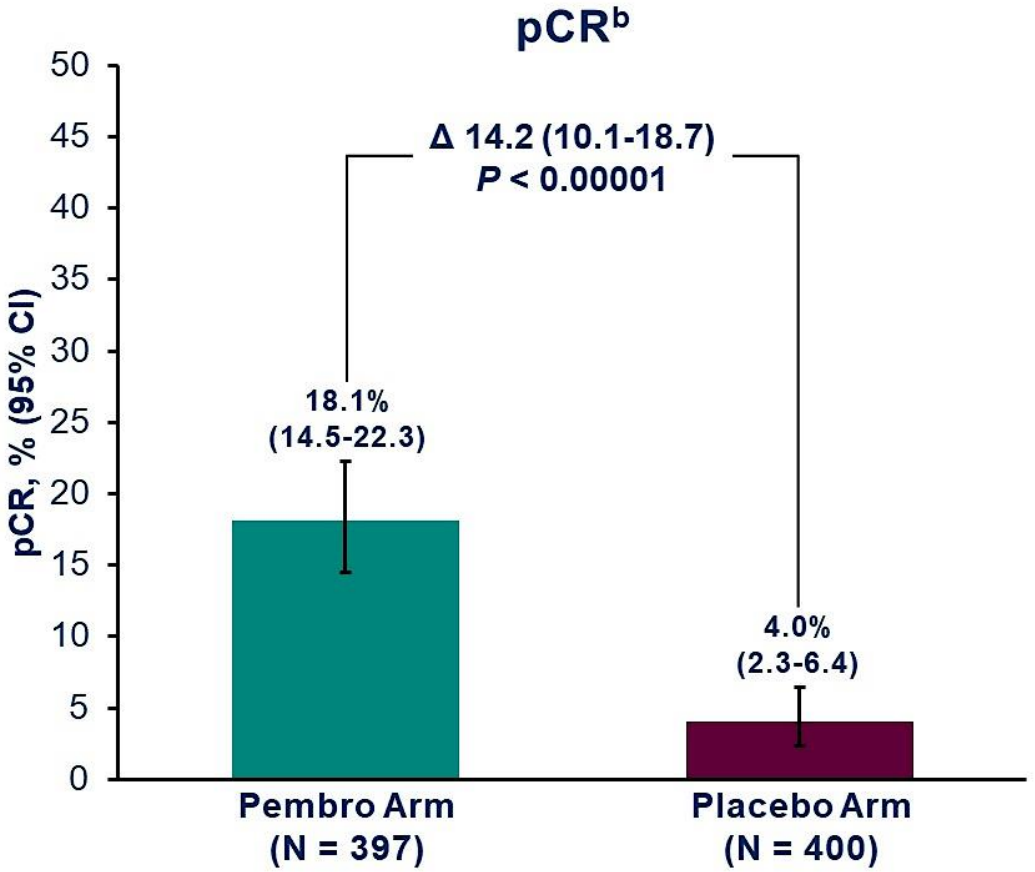
[a] Assessed at a central laboratory using PD-L1 IHC 22C3 pharmDx. [b] Cisplatin 75 mg/m^2 IV Q3W + gemcitabine 1000 mg/m^2 IV on days 1 and 8 Q3W was permitted for squamous histology only. [c] Cisplatin 75 mg/m^2 IV Q3W + pemetrexed 500 mg/m^2 IV Q3W was permitted for nonsquamous histology only. [d] Radiotherapy was to be administered to participants with microscopic positive margins, gross residual disease, or extracapsular nodal extension following surgery and to participants who did not undergo planned surgery for any reason other than local progression or metastatic disease. ClinicalTrials.gov identifier: NCT03425643.

Wakelee ASCO 2023; Abstract LBA1000

Pathological Response

Assessed per Blinded, Independent Pathologist Review

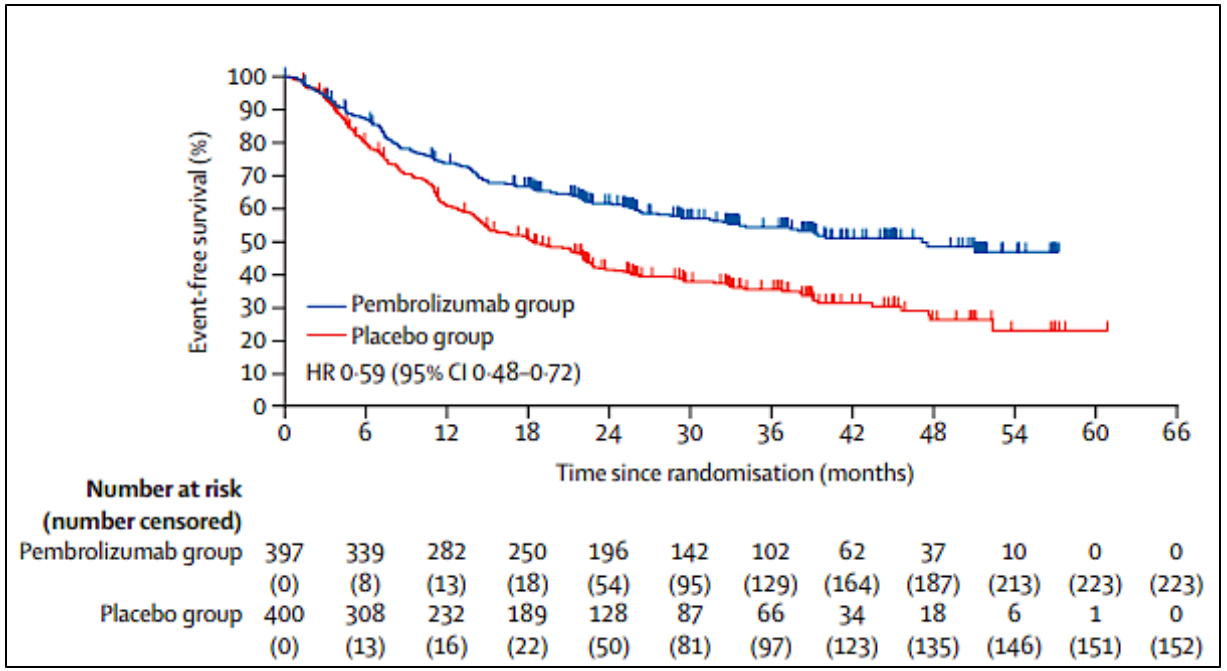




[a] Per IASLC criteria, defined as ≤10% viable tumor cells in resected primary tumor and lymph nodes. [b] Per IASLC criteria, defined as absence of residual invasive cancer in resected primary tumor and lymph nodes (ypT0/Tis ypN0). Data cutoff date for IA1: July 29, 2022.

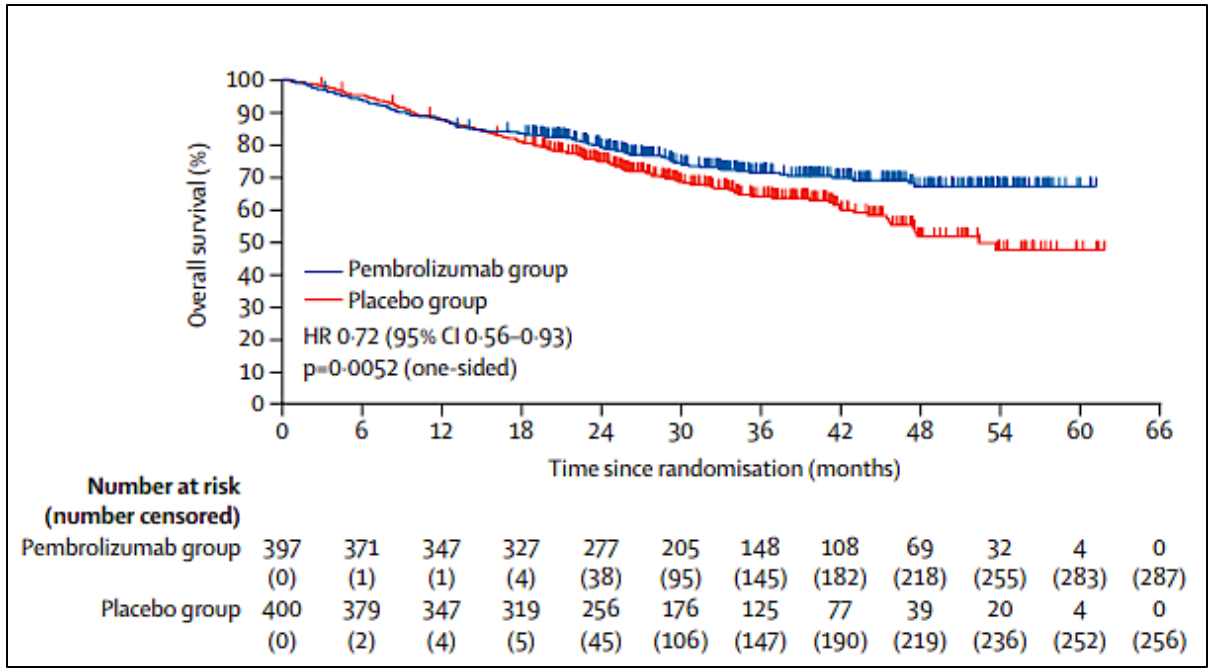
KEYNOTE-671: Updated Overall Survival

Event Free Survival



Number at risk (number censored)												
Pembrolizumab group	397	339	282	250	196	142	102	62	37	10	0	0
	(0)	(8)	(13)	(18)	(54)	(95)	(129)	(164)	(187)	(213)	(223)	(223)
Placebo group	400	308	232	189	128	87	66	34	18	6	1	0
	(0)	(13)	(16)	(22)	(50)	(81)	(97)	(123)	(135)	(146)	(151)	(152)

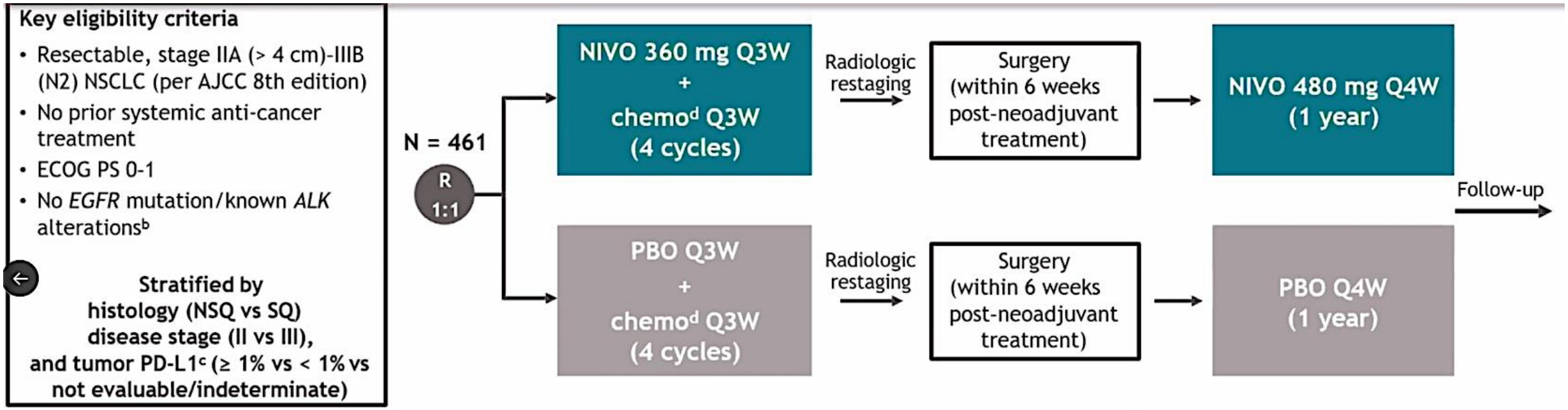
Overall Survival



Number at risk (number censored)												
Pembrolizumab group	397	371	347	327	277	205	148	108	69	32	4	0
	(0)	(1)	(1)	(4)	(38)	(95)	(145)	(182)	(218)	(255)	(283)	(287)
Placebo group	400	379	347	319	256	176	125	77	39	20	4	0
	(0)	(2)	(4)	(5)	(45)	(106)	(147)	(190)	(219)	(236)	(252)	(256)

Spicer JD et al. Neoadjuvant pembrolizumab plus chemotherapy followed by adjuvant pembrolizumab compared with neoadjuvant chemotherapy alone in patients with early-stage non-small-cell lung cancer (KEYNOTE-671): A randomised, double-blind, placebo-controlled, phase 3 trial. Lancet 2024;404(10459):1240-52

CHECKMATE-77T

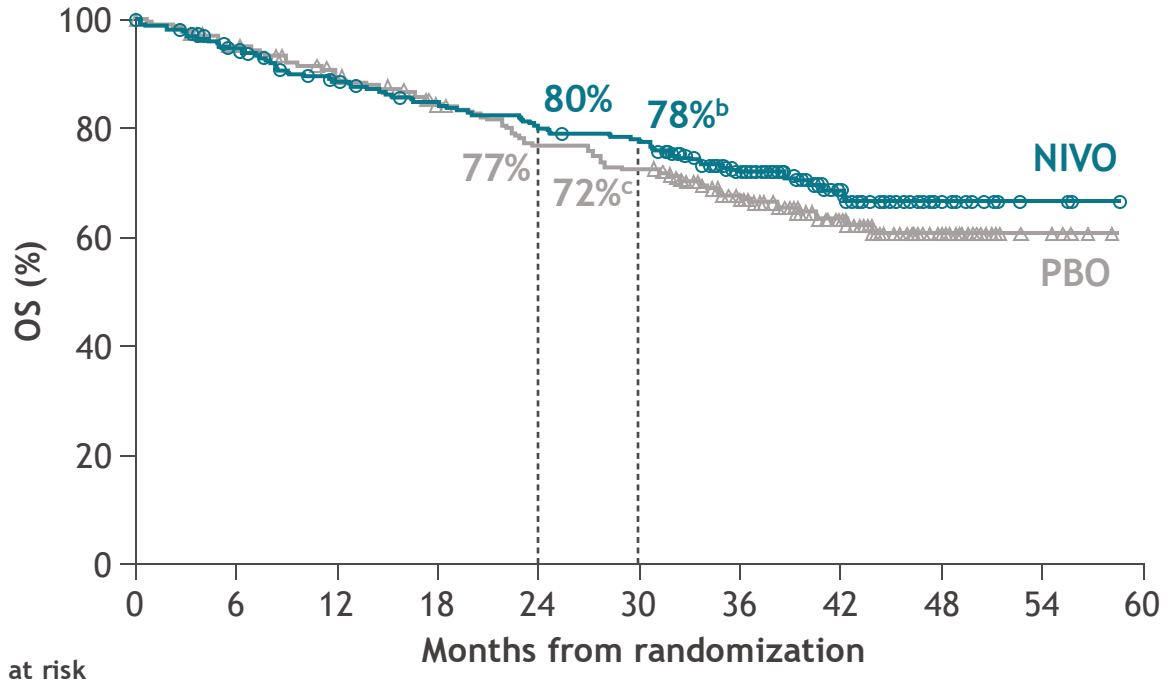


Cascone ESMO 2023; Abstract LBA1

OS and lung cancer-specific survival

OS

	NIVO (n = 229)	PBO (n = 232)
Median OS, mo (95% CI)	NR (NR–NR)	NR (NR–NR)
HR (97.63% CI)[a]	0.85 (0.58–1.25)	

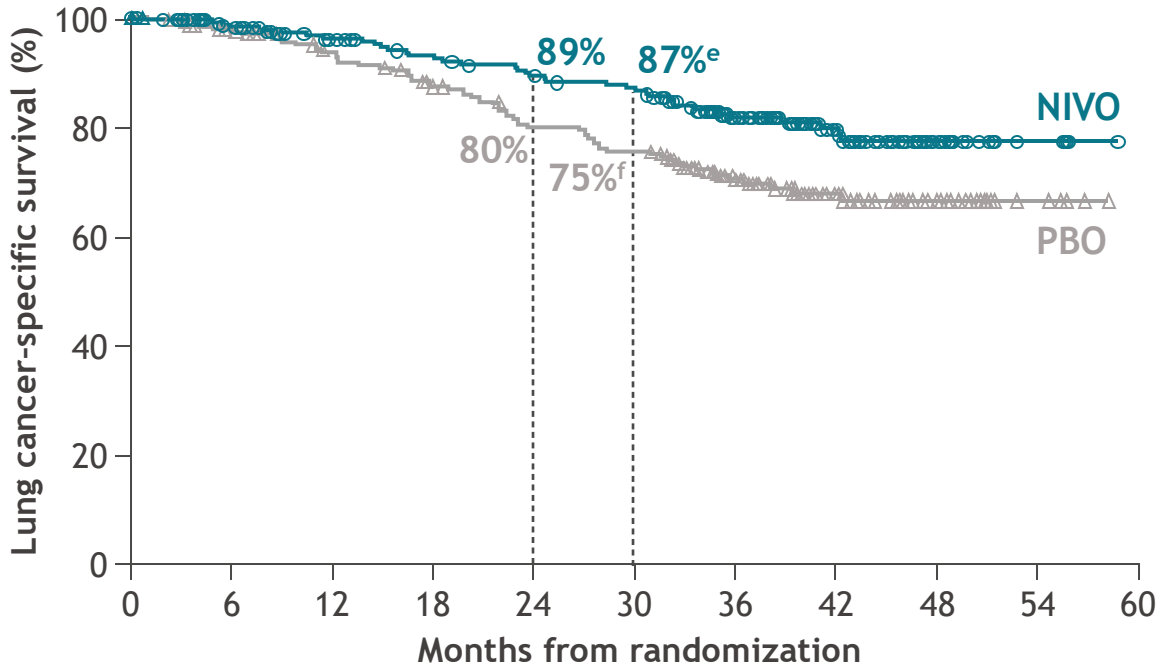


No. at risk

NIVO	229	206	187	176	166	161	114	66	23	6	0
PBO	232	216	197	178	161	152	103	52	20	7	0

Lung cancer-specific survival[d]

	NIVO (n = 229)	PBO (n = 232)
Median lung cancer-specific survival, mo (95% CI)	NR (NR–NR)	NR (NR–NR)
HR (95% CI)	0.60 (0.40–0.89)	



	229	206	187	176	166	161	114	66	23	6	0
	232	216	197	178	161	152	103	52	20	7	0

Median follow-up (range): 41.0 months (31.3-59.8).
67 (29%) patients in the NIVO arm and 101 (44%) patients in the PBO arm received subsequent therapy of any type; 50 (22%) and 87 (38%) patients, respectively, received subsequent systemic therapy.
[a]HR (95% CI), 0.85 (0.61–1.18). Significance boundary for OS was not met at this interim analysis. [b,c]95% CI: [b]72–83; [c]66–78. [d]Exploratory analysis; events were deaths with noted reason of "disease" per investigator assessment. [e,f]95% CI: [e]82–91; [f]69–81.

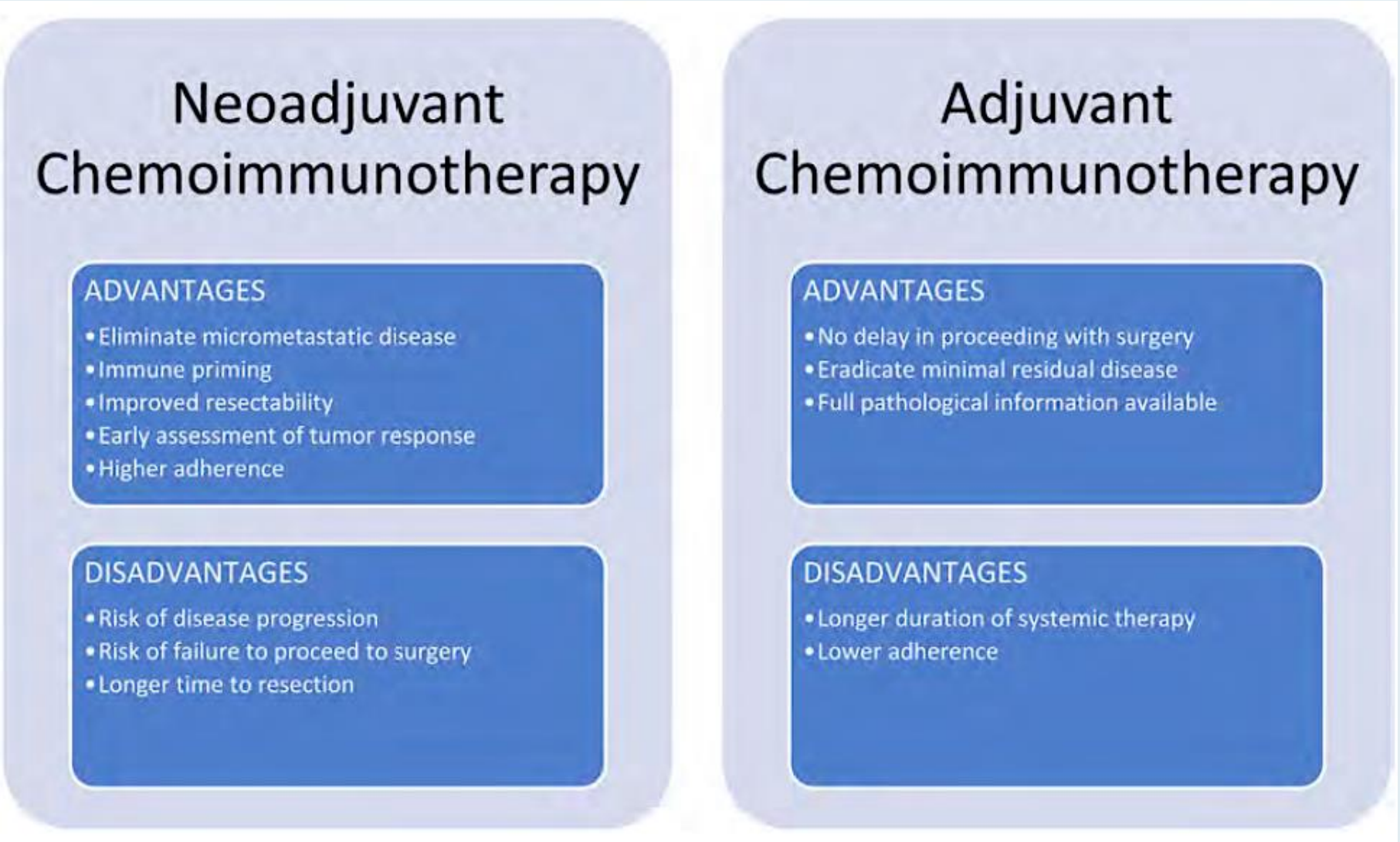
Review Article

Perioperative Immunotherapy for Non-Small Cell Lung Cancer: Practical Application of Emerging Data and New Challenges

Angelica D'Aiello,[1] Brendon Stiles,[2] Nitin Ohri,[3] Benjamin Levy,[4] Perry Cohen,[5] Balazs Halmos[1]

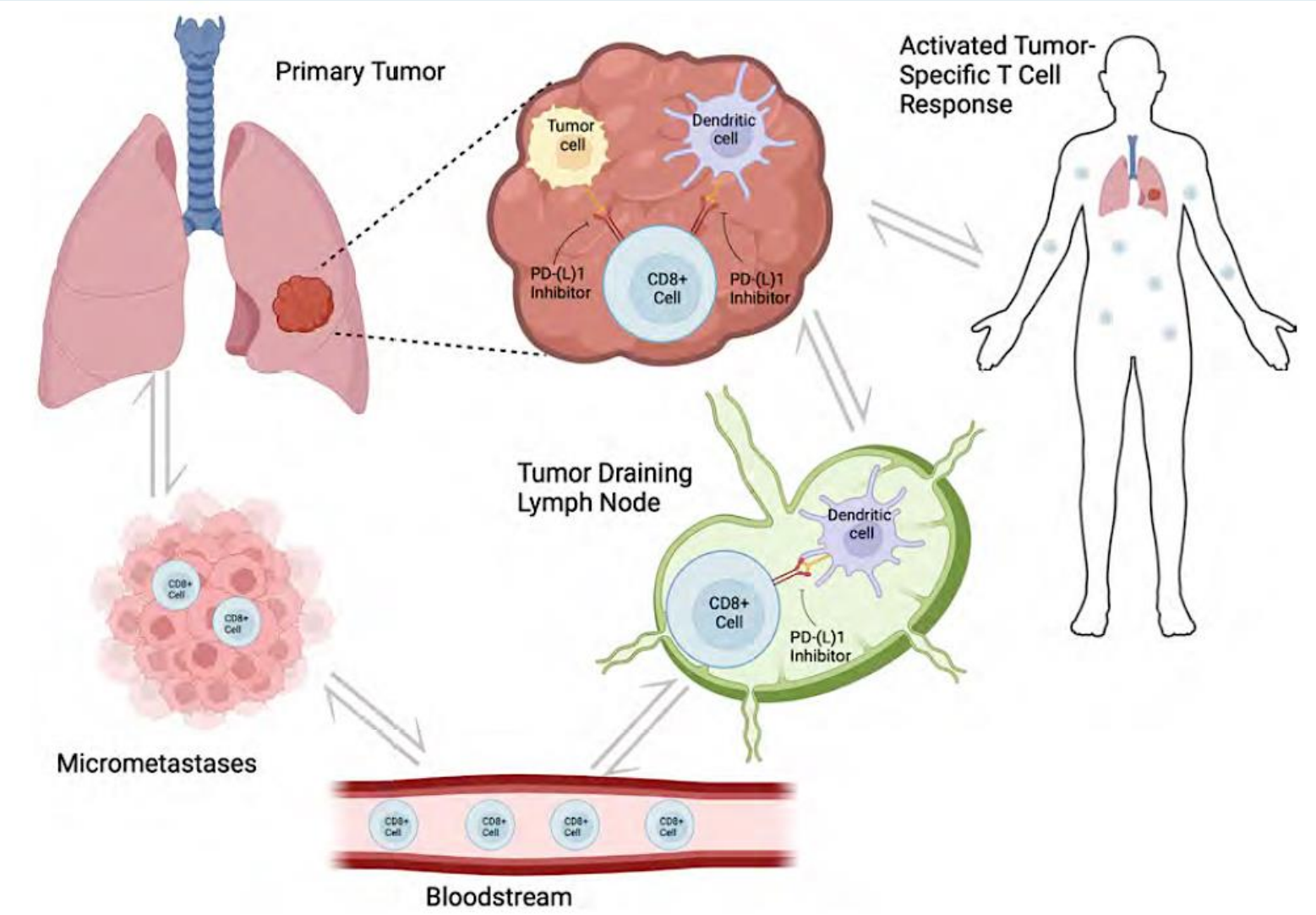
Clin Lung Cancer 2024;25(3):197-214.

Neoadjuvant and Adjuvant Advantages and Disadvantages



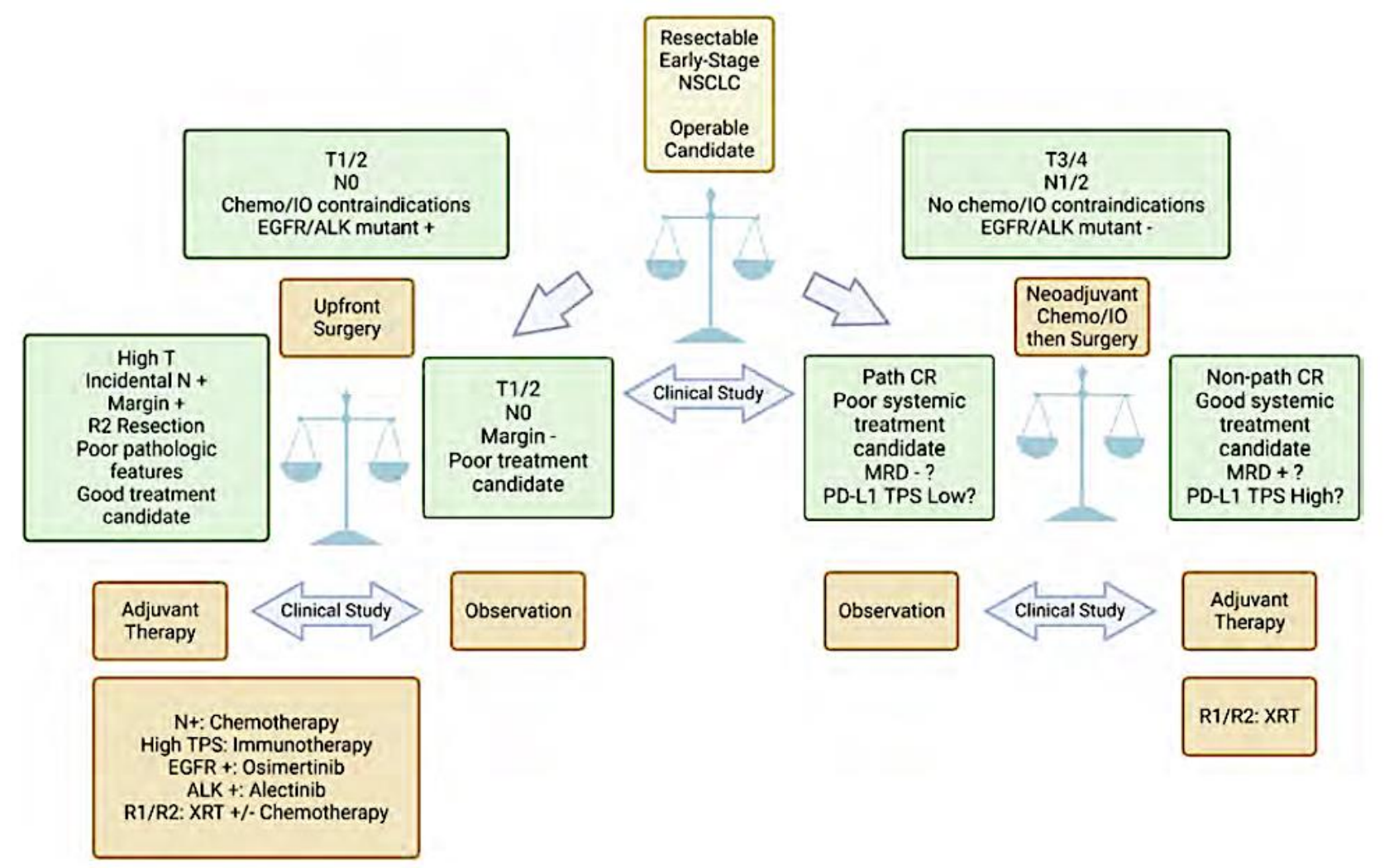
D'Aiello A et al. *Clin Lung Cancer* 2024;25(3):197-214.

Neoadjuvant Biology



D'Aiello A et al. *Clin Lung Cancer* 2024;25(3):197-214.

Practical Implementation and Patient Navigation for Perioperative Immunotherapy in NSCLC



D'Aiello A et al. *Clin Lung Cancer* 2024;25(3):197-214.

Epidemiology

RMD Open
Rheumatic & Musculoskeletal Diseases

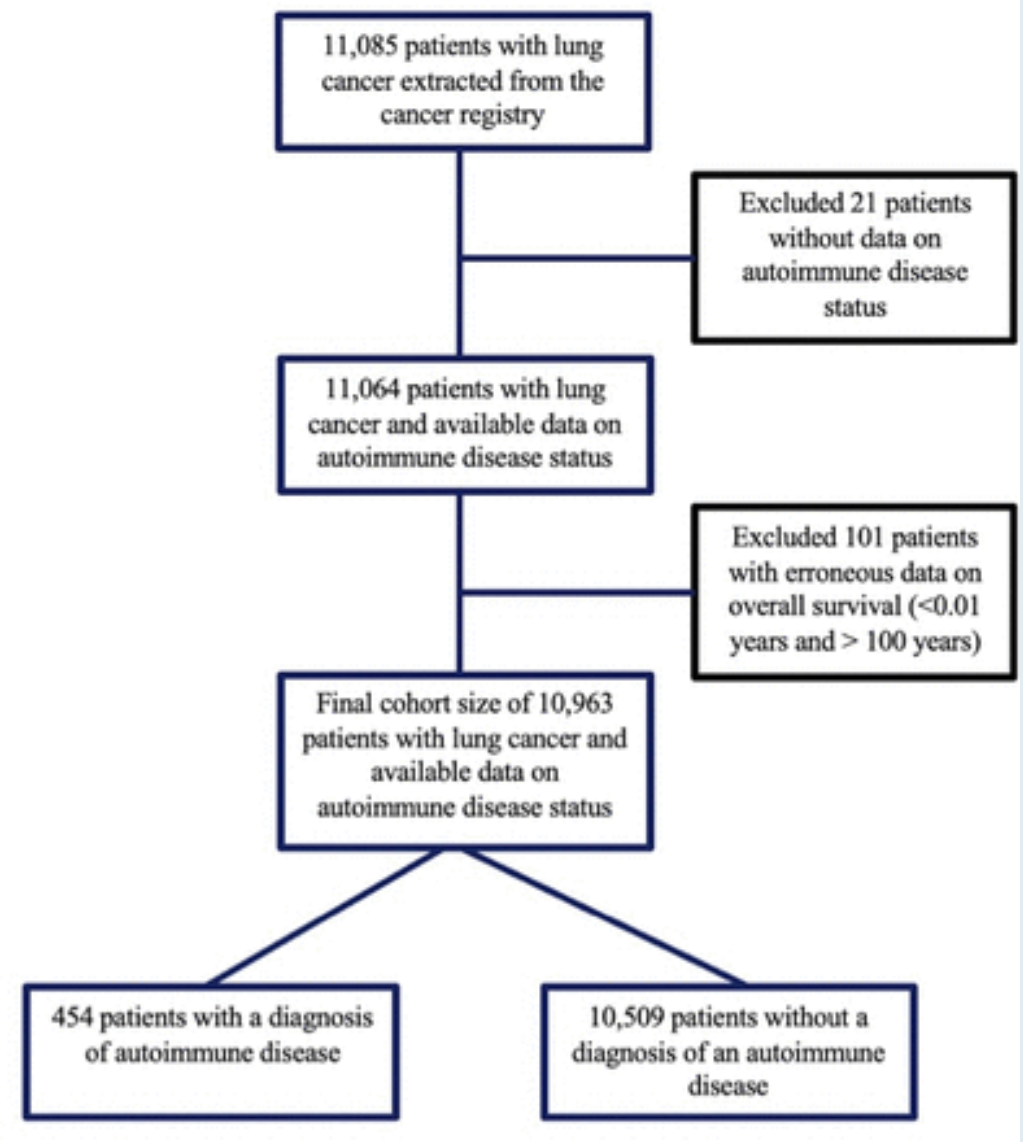
ORIGINAL RESEARCH

Improved lung cancer clinical outcomes in patients with autoimmune rheumatic diseases

Paola Ghanem,[1] Joseph C Murray,[1] Kristen A Marrone,[1] Susan C Scott,[1] Josephine L Feliciano,[1] Vincent K Lam,[1] Christine L Hann,[1] David S Ettinger,[1] Benjamin P Levy,[1] Patrick M Forde,[1] Ami A Shah,[2] Christopher Mecoli,[2] Julie Brahmer,[1] Laura C Cappelli [2]

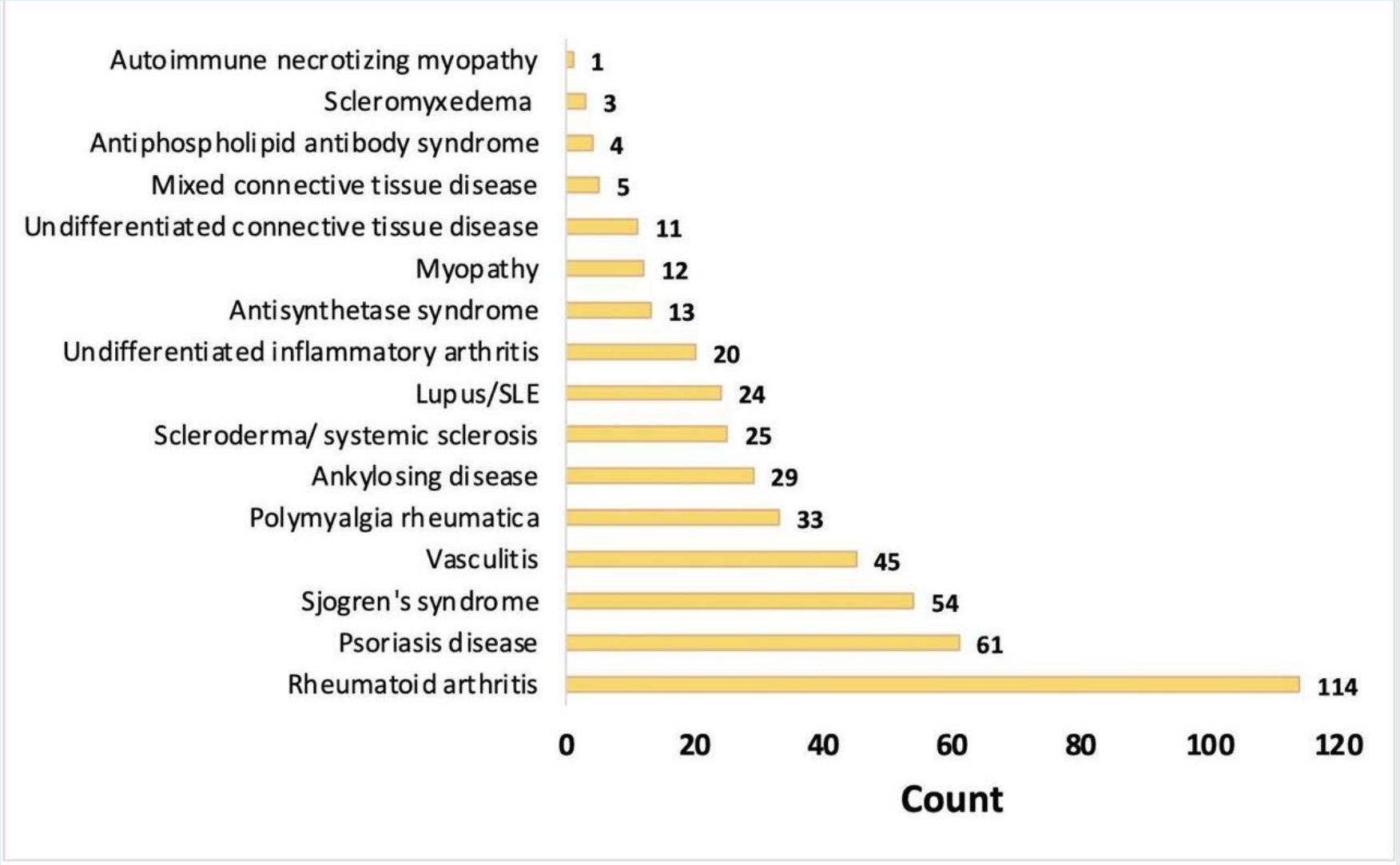
2023;9(4):e003471.

Flow Diagram of Cohort Selection



Ghanem P et al. *RMD Open* 2023;9(4):e003471.

Distribution of Autoimmune Diseases



Ghanem P et al. *RMD Open* 2023;9(4):e003471.

Nature 2024;635(8038):462-71.

Article

CTLA4 blockade abrogates *KEAP1/STK11*-related resistance to PD-(L)1 inhibitors

https://doi.org/10.1038/s41586-024-07943-7

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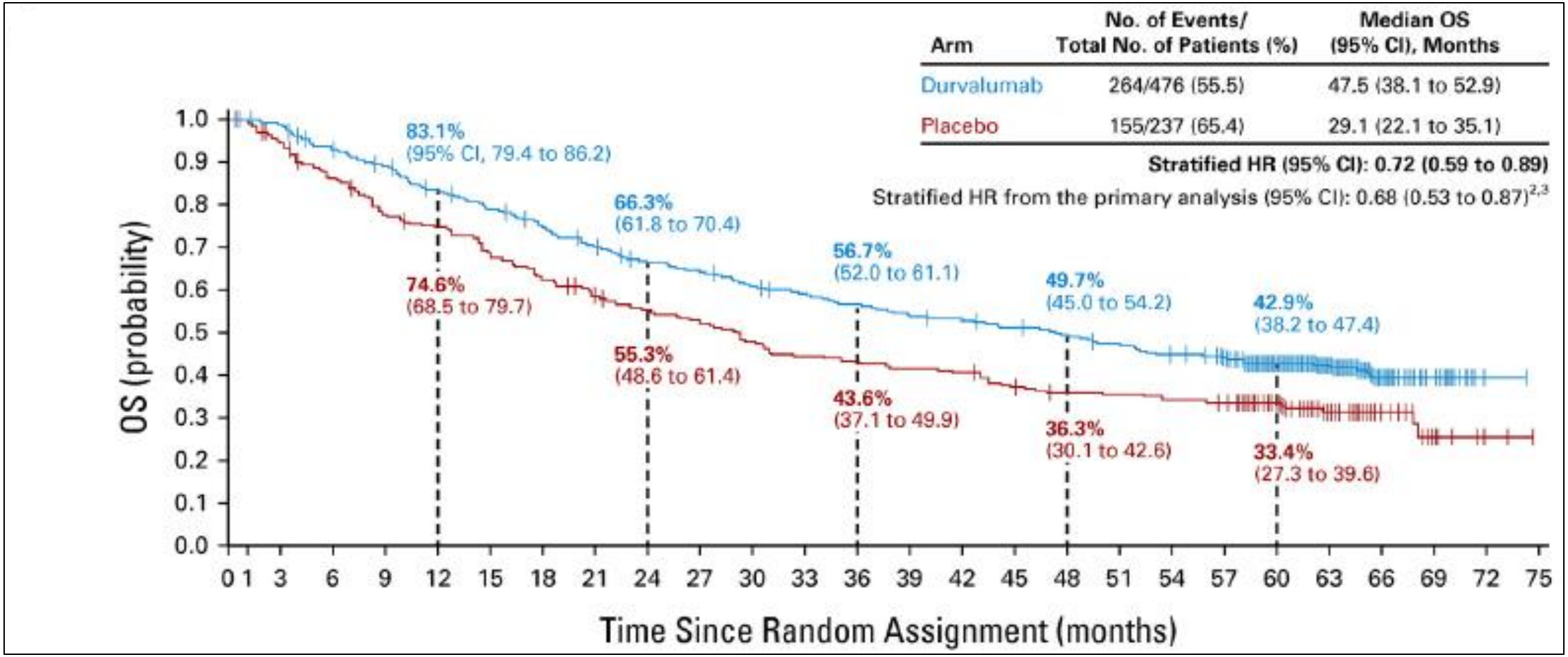
Ferdinandos Skoulidis[1,53] ✉, Haniel A. Araujo[1,52], Minh Truong Do[1,52], Yu Qian[1], Xin Sun[1], Ana Galan Cobo[1], John T. Le[1], Meagan Montesion[2], Rachael Palmer[3], Nadine Jahchan[3], Joseph M. Juan[4], Chengyin Min[5], Yi Yu[5], Xuewen Pan[5], Kathryn C. Arbour[6], Natalie Vokes[1], Stephanie T. Schmidt[7], David Molkentine[1], Dwight H. Owen[8], Regan Memmott[8], Pradnya D. Patil[9], Melina E. Marmarelis[10], Mark M. Awad[11], Joseph C. Murray[12], Jessica A. Hellyer[13], Justin F. Gainor[14], Anastasios Dimou[15], Christine M. Bestvina[16], Catherine A. Shu[17], Jonathan W. Riess[18], Collin M. Blakely[19], Chad V. Pecot[20], Laura Mezquita[21], Fabrizio Tabbó[22], Matthias Scheffler[23], Subba Digumarthy[24], Meghan J. Mooradian[14], Adrian G. Sacher[25], Sally C. M. Lau[26], Andreas N. Saltos[27], Julia Rotow[11], Rocio Perez Johnson[28], Corinne Liu[28], Tyler Stewart[29], Sarah B. Goldberg[30], Jonathan Killam[31], Zenta Walther[32], Kurt Schalper[32], Kurtis D. Davies[33], Mark G. Woodcock[20], Valsamo Anagnostou[12], Kristen A. Marrone[12], Patrick M. Forde[12], Biagio Ricciuti[11], Deepti Venkatraman[11], Eliezer M. Van Allen[11], Amy L. Cummings[34], Jonathan W. Goldman[34], Hiram Shaish[17], Melanie Kier[35], Sharyn Katz[10], Charu Aggarwal[10], Ying Ni[9], Joseph T. Azok[9], Jeremy Segal[36], Lauren Ritterhouse[2], Joel W. Neal[13], Ludovic Lacroix[37], Yasir Y. Elamin[1], Marcelo V. Negrao[1], Xiuning Le[1], Vincent K. Lam[12], Whitney E. Lewis[1], Haley N. Kemp[1], Brett Carter[38], Jack A. Roth[39], Stephen Swisher[39], Richard Lee[1], Teng Zhou[1], Alissa Poteete[1], Yifan Kong[1], Tomohiro Takehara[1], Alvaro Guimaraes Paula[1], Edwin R. Parra Cuentas[40], Carmen Behrens[40], Ignacio I. Wistuba[40], Jianjun Zhang[1], George R. Blumenschein[1], Carl Gay[1], Lauren A. Byers[1], Don L. Gibbons[1], Anne Tsao[1], J. Jack Lee[41], Trever G. Bivona[19], D. Ross Camidge[42], Jhannelle E. Gray[27], Natasha B. Leighl[25], Benjamin Levy[12], Julie R. Brahmer[12], Marina C. Garassino[16], David R. Gandara[18], Edward B. Garon[34], Naiyer A. Rizvi[43], Giorgio Vittorio Scagliotti[44], Jürgen Wolf[23], David Planchard[37], Benjamin Besse[37], Roy S. Herbst[30], Heather A. Wakelee[13], Nathan A. Pennell[9], Alice T. Shaw[45], Pasi A. Jänne[11], David P. Carbone[5], Matthew D. Hellmann[46], Charles M. Rudin[6], Lee Albacker[2], Helen Mann[47], Zhou Zhu[47], Zhongwu Lai[47], Ross Stewart[47], Solange Peters[48], Melissa L. Johnson[49], Kwok K. Wong[50], Alan Huang[5], Monte M. Winslow[4,53], Michael J. Rosen[4], Ian P. Winters[4], Vassiliki A. Papadimitrakopoulou[51], Tina Cascone[1], Philip Jewsbury[47] & John V. Heymach[1,53] ✉

PACIFIC: 5 YEAR OUTCOMES



Spigel et al. JCO 2022

Poster 190P

Real-world 5-year survival outcomes with durvalumab after chemoradiotherapy in unresectable, stage III NSCLC: final data extraction from PACIFIC-R

Figure 1. PACIFIC-R (NCT03798535), an observational, retrospective chart review study

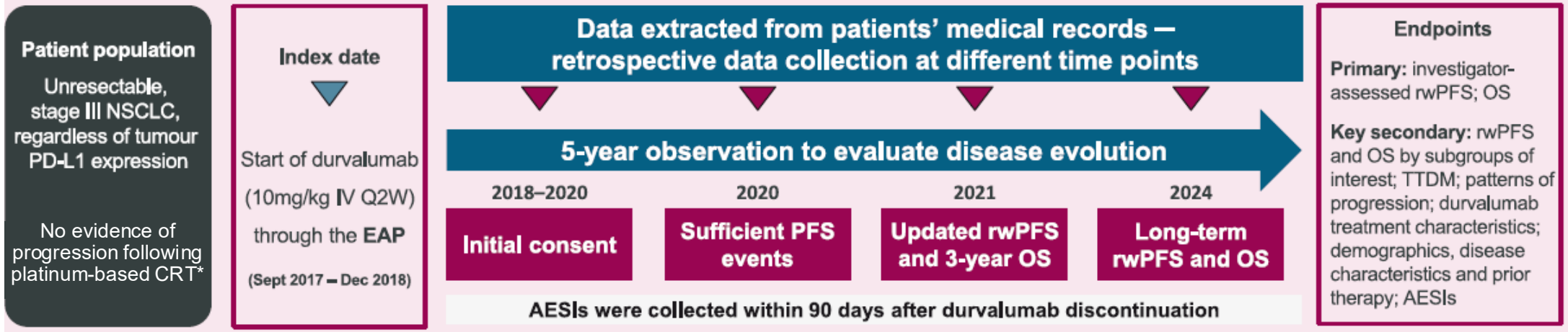
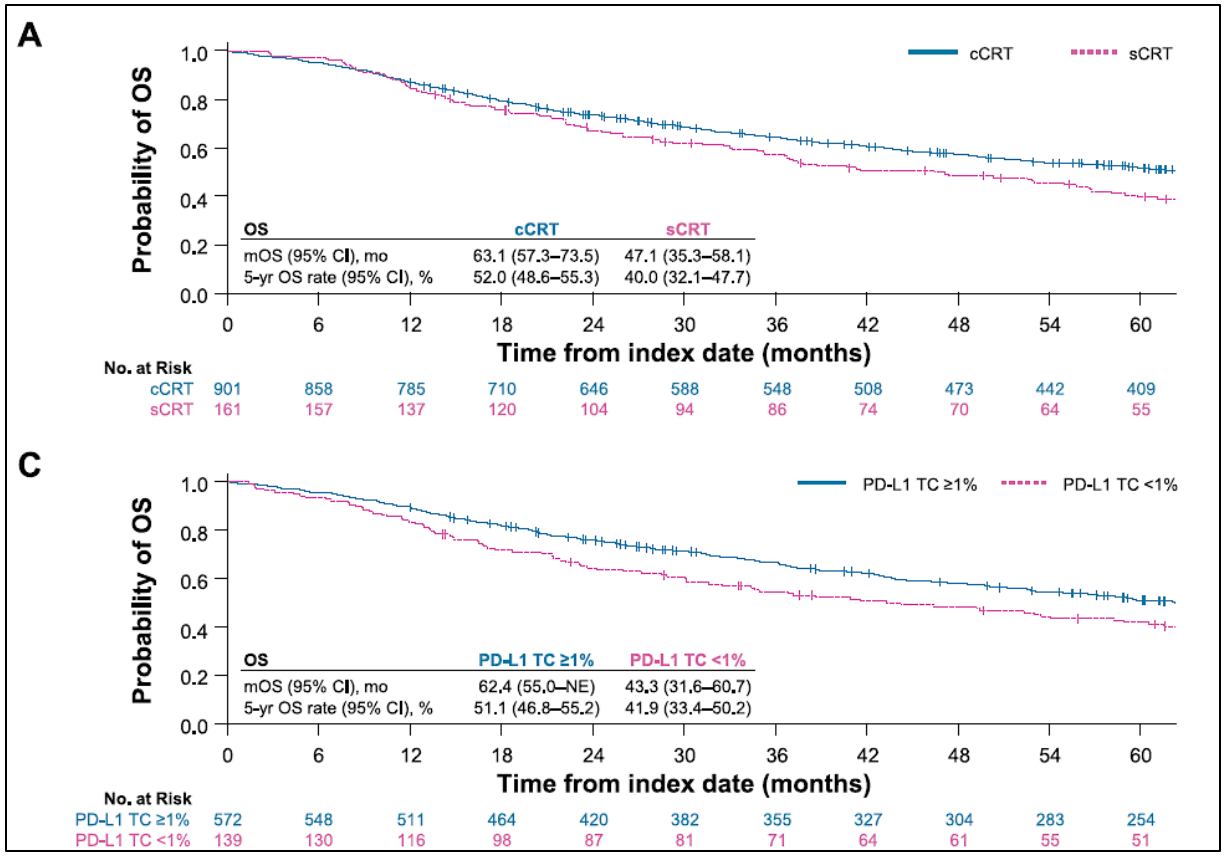
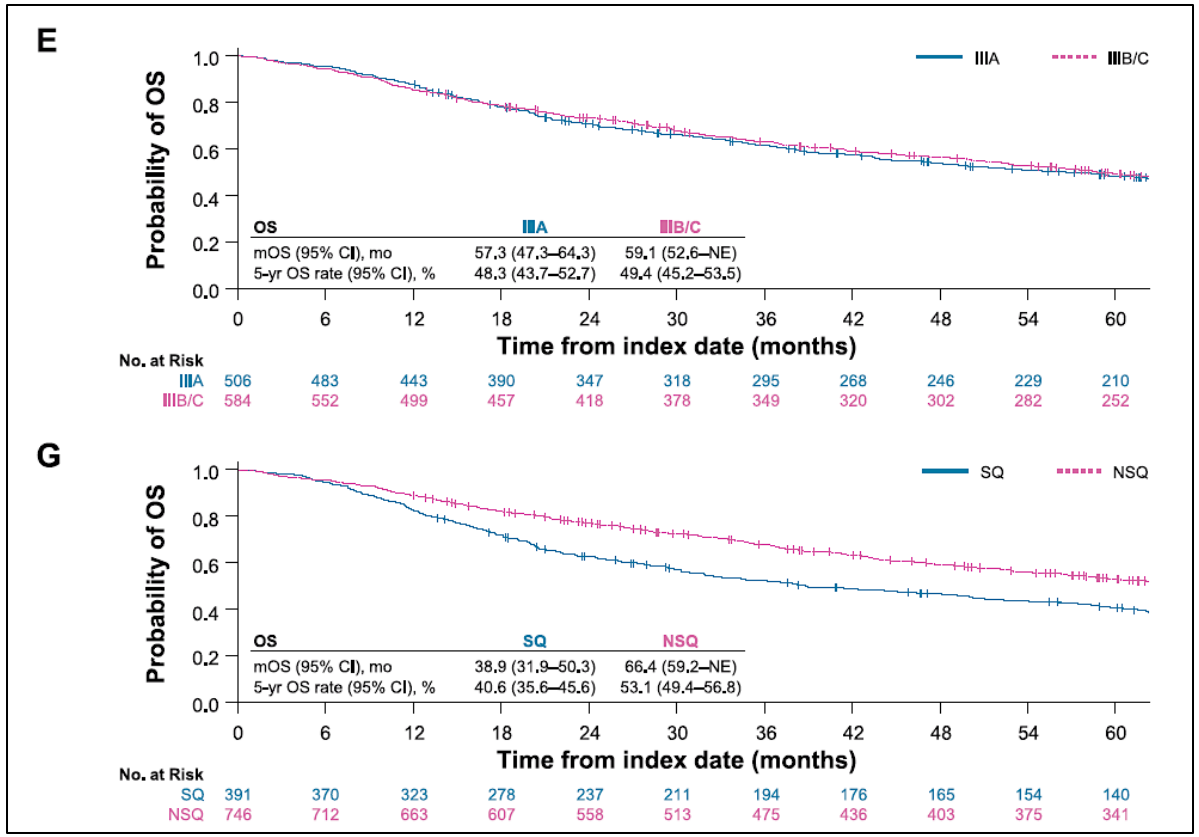


Table 1. OS, rwPFS, and TTDM in the FAS

Category		N=1153
OS	Median (95% CI), months	59.0 (52.7–64.3)
	5-year rate (95% CI), %	49.2 (46.2–52.2)
rwPFS	Median (95% CI), months	24.3 (20.3–28.4)
	5-year rate (95% CI), %	35.2 (32.4–38.1)
TTDM	Median (95% CI), months	37.2 (33.3–43.0)
	5-year rate (95% CI), %	40.2 (37.3–43.2)

PACIFIC-RW OUTCOMES





Filippi ELCC 2025;Abstract 190P

QUESTIONS?

RTP Year in Review 2025

Year in Review:
Nontargeted Approaches for Lung Cancer

INTRODUCTION: The Boards

MODULE 1: Immune Checkpoint Inhibition for Localized Non-Small Cell Lung Cancer (NSCLC)

MODULE 2: Immunotherapy for Metastatic NSCLC

MODULE 3: Antibody-Drug Conjugates

MODULE 4: Novel Bispecific Antibodies

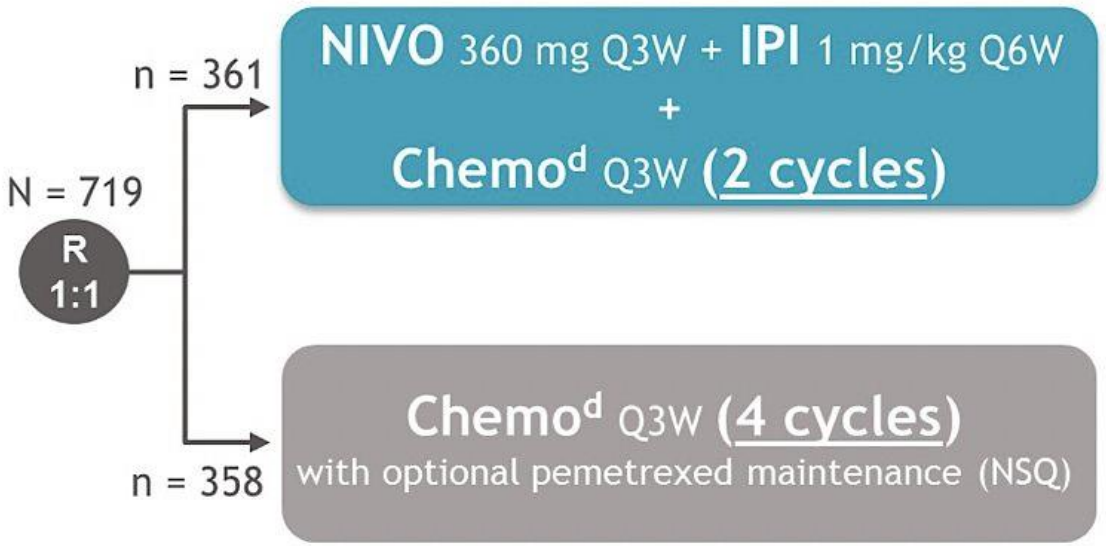
MODULE 5: Journal Club with Dr Levy

CheckMate 9LA study design[a]

Key Eligibility Criteria

- Stage IV or recurrent NSCLC
- No prior systemic therapy
- No sensitizing *EGFR* mutations or known *ALK* alterations
- ECOG PS 0-1

Stratified by PD-L1[b] (< 1%[c] vs ≥ 1%), sex, and histology (SQ vs NSQ)



Until disease progression, unacceptable toxicity, *or* for 2 years for immunotherapy

Primary endpoint

- OS

Secondary endpoints

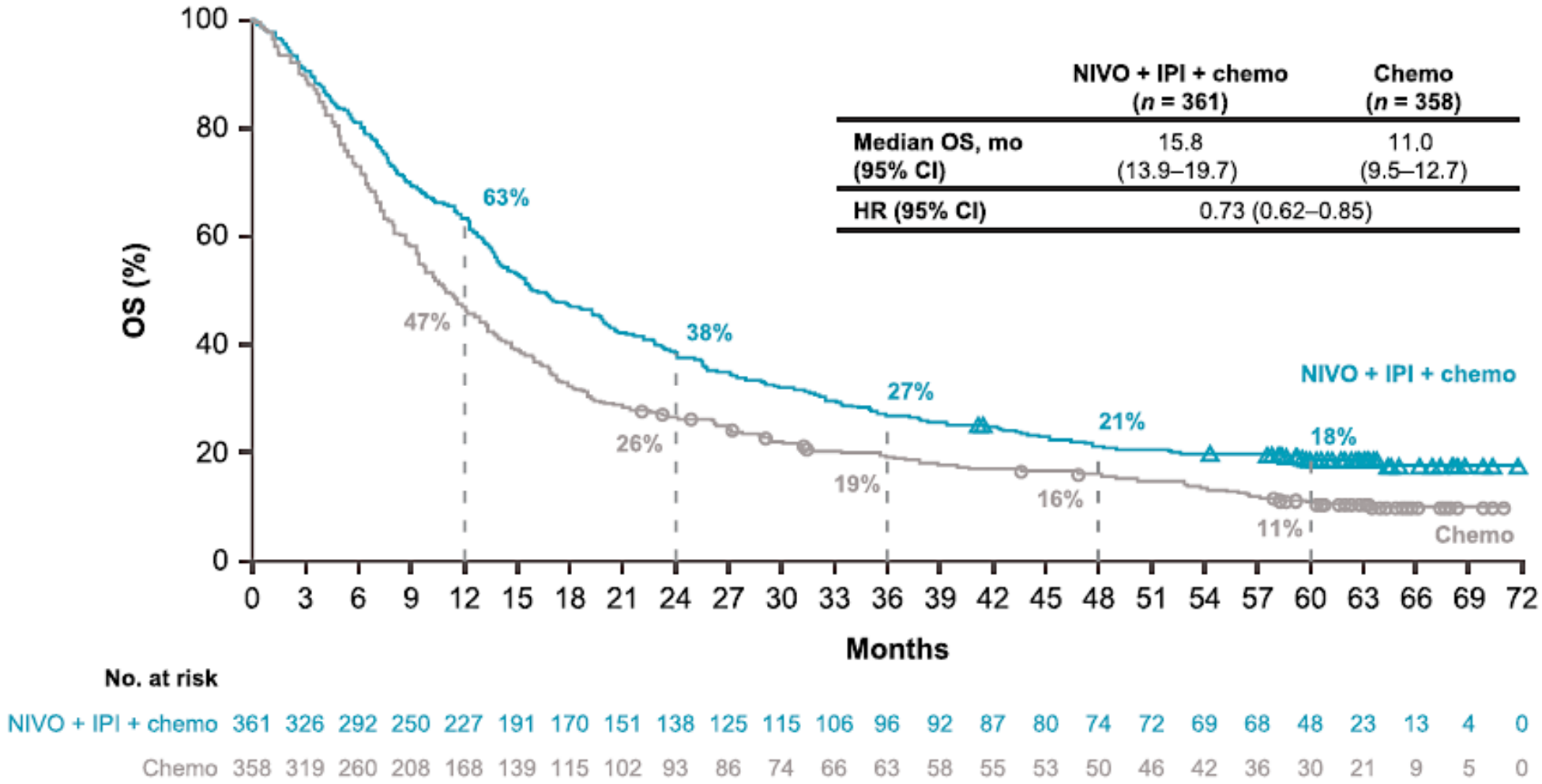
- PFS by BICR[e]
- ORR by BICR[e]
- Efficacy by tumor PD-L1 expression

Interim database lock: October 3, 2019; minimum follow-up: 8.1 months for OS and 6.5 months for all other endpoints.
Updated database lock: March 9, 2020; minimum follow-up: 12.7 months for OS and 12.2 months for all other endpoints.

[a]NCT03215706; [b]Determined by the PD-L1 IHC 28-8 pharmDx assay (Dako); [c]Patients unevaluable for PD-L1 were stratified to PD-L1 < 1% and capped to 10% of all randomized patients; [d]**NSQ**: pemetrexed + cisplatin or carboplatin; SQ: paclitaxel + carboplatin; [e]Hierarchically statistically tested.

Reck ASCO 2024;Abstract 8560

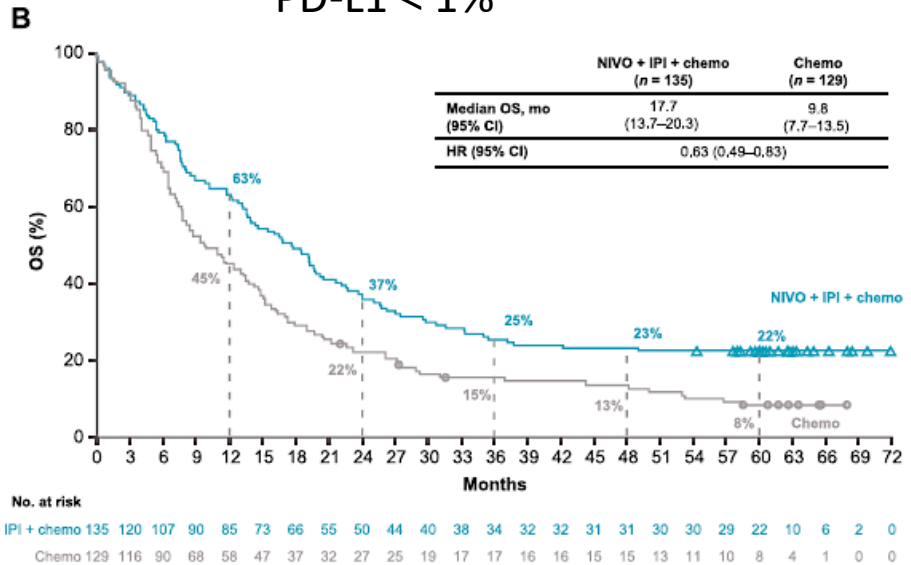
CheckMate 9LA: IIT UPDATED OS



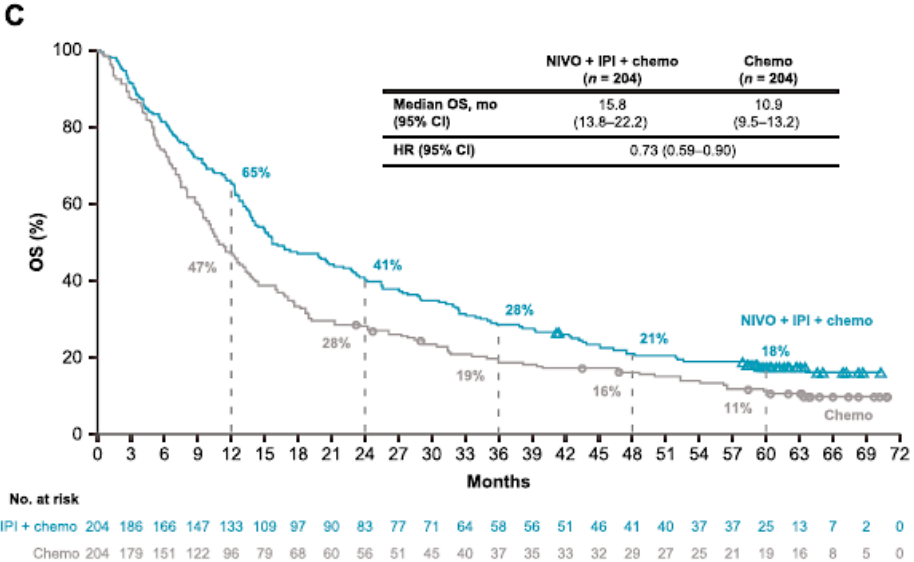
Reck Eur J Cancer 2024

CheckMate 9LA: UPDATED OS

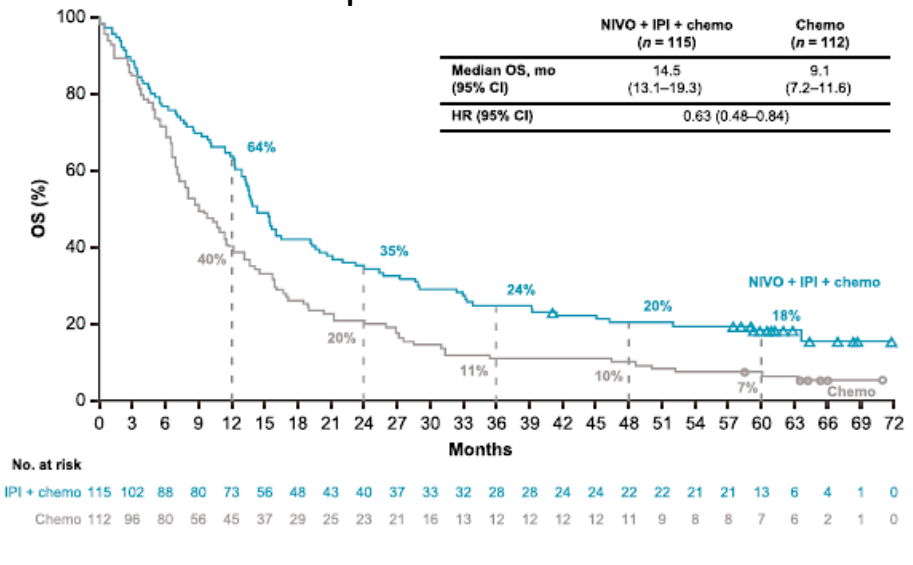
PD-L1 < 1%



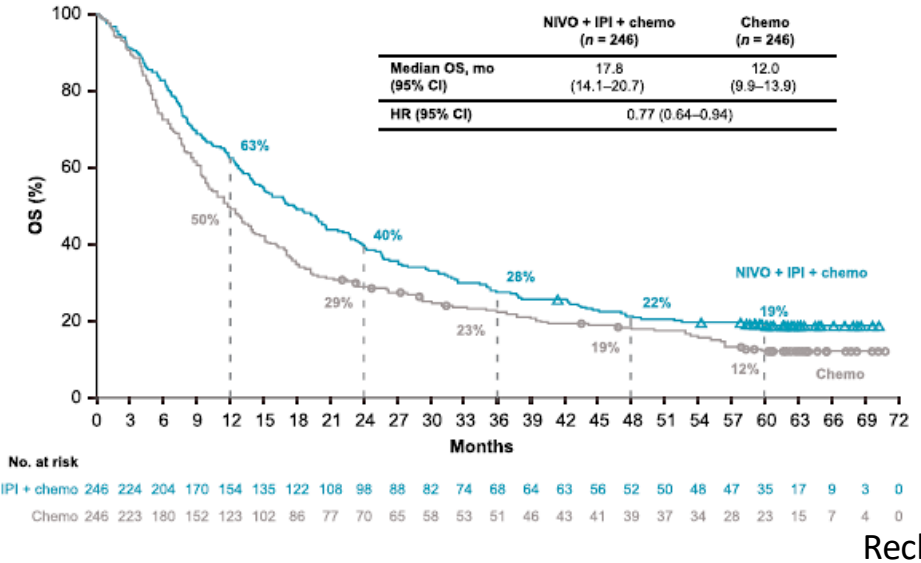
PD-L1 > 1%



Squamous

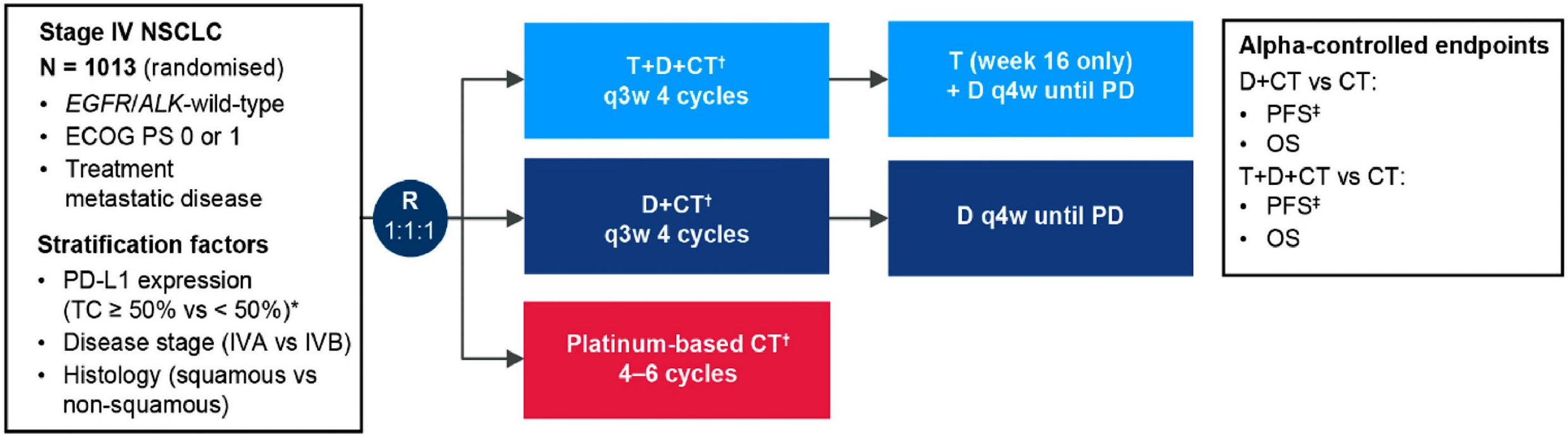


Non-Squamous



Reck Eur J Cancer 2024

POSEIDON STUDY DESIGN



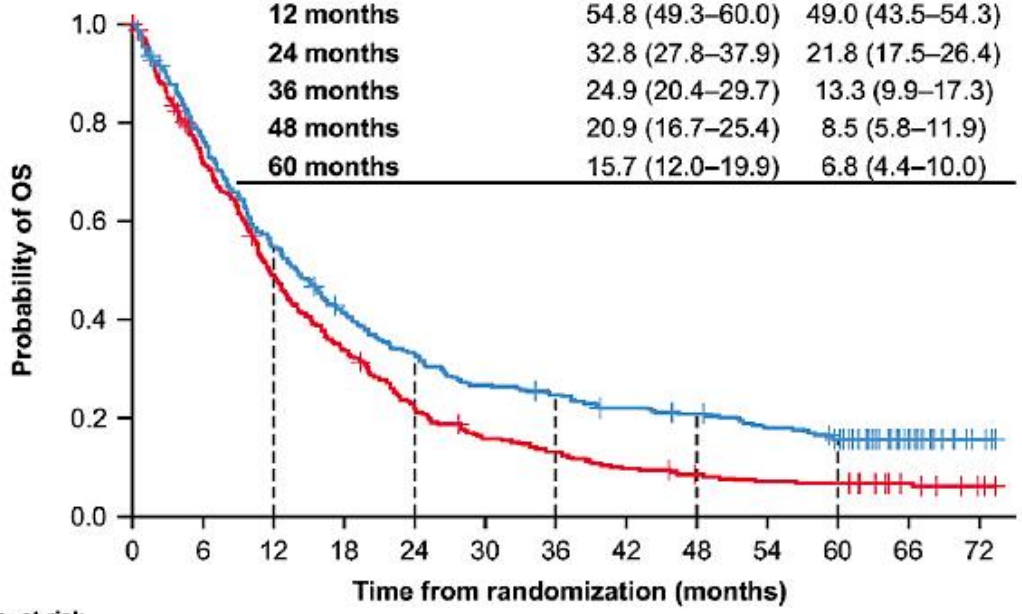
Garon Clin Lung Cancer 2024

POSEIDON: UPDATED OS

January 2025

A

	T+D+CT	CT
Events/patients, n/N	279/338 (82.5)	304/337 (90.2)
mOS, months (95% CI)	14.0 (11.7–16.1)	11.6 (10.5–13.1)
HR (95% CI)	0.76 (0.64–0.89)	
Landmark OS, % (95% CI)		
12 months	54.8 (49.3–60.0)	49.0 (43.5–54.3)
24 months	32.8 (27.8–37.9)	21.8 (17.5–26.4)
36 months	24.9 (20.4–29.7)	13.3 (9.9–17.3)
48 months	20.9 (16.7–25.4)	8.5 (5.8–11.9)
60 months	15.7 (12.0–19.9)	6.8 (4.4–10.0)



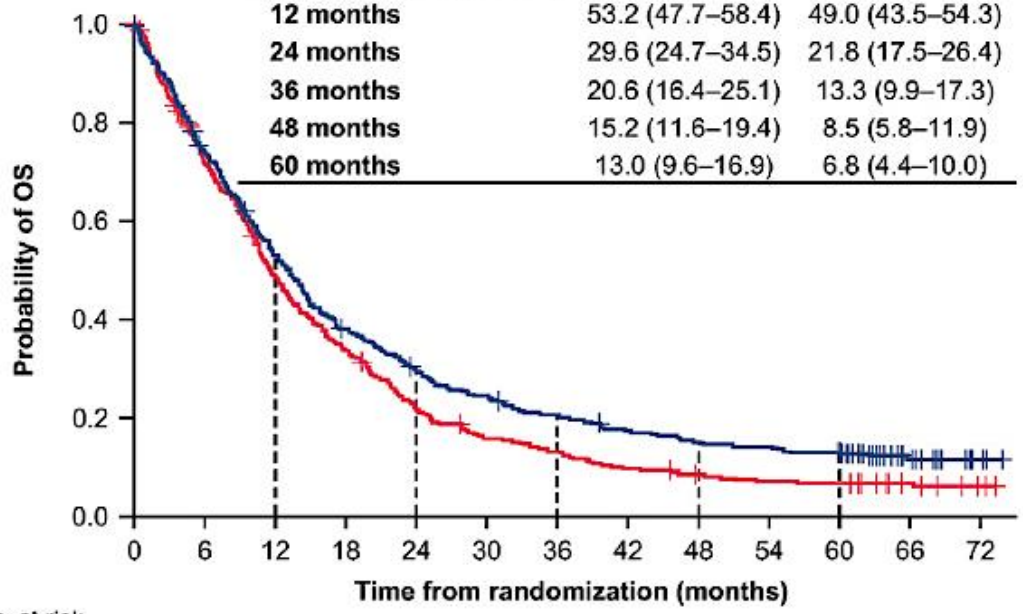
No. at risk

T+D+CT	338	256	183	136	108	88	81	71	66	56	47	21	3
CT	337	235	159	110	70	50	42	31	25	21	20	10	2

Durable mNSCLC OS With T+D+CT After >5 years

B

	D+CT	CT
Events/patients, n/N	290/338 (85.8)	304/337 (90.2)
mOS, months (95% CI)	13.3 (11.4–14.7)	11.6 (10.5–13.1)
HR (95% CI)	0.84 (0.72–1.00)	
Landmark OS, % (95% CI)		
12 months	53.2 (47.7–58.4)	49.0 (43.5–54.3)
24 months	29.6 (24.7–34.5)	21.8 (17.5–26.4)
36 months	20.6 (16.4–25.1)	13.3 (9.9–17.3)
48 months	15.2 (11.6–19.4)	8.5 (5.8–11.9)
60 months	13.0 (9.6–16.9)	6.8 (4.4–10.0)



No. at risk

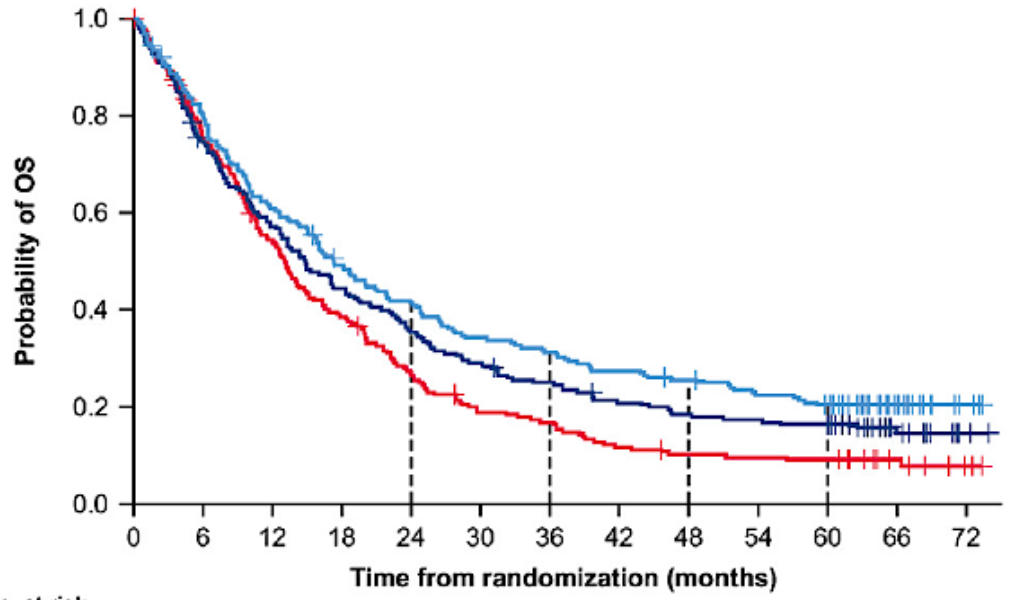
D+CT	338	247	176	125	96	80	66	55	48	45	40	18	3
CT	337	235	159	110	70	50	42	31	25	21	20	10	2

Peters J Thorac Oncol 2025

POSEIDON: UPDATED OS

A

Nonsquamous	T+D+CT	D+CT	CT
Events/patients, n/N	167/214	172/209	186/214
mOS, months (95% CI)	17.2 (14.9–21.8)	14.8 (11.8–18.3)	13.0 (10.6–15.1)
HR (95% CI) vs CT	0.69 (0.56–0.85)	0.81 (0.66–1.00)	–
Landmark OS, % (95% CI)			
24 months	41.3 (34.6–47.9)	35.4 (28.9–42.0)	26.5 (20.6–32.7)
36 months	31.2 (25.1–37.6)	25.0 (19.3–31.1)	16.9 (12.1–22.4)
48 months	25.5 (19.8–31.5)	18.4 (13.4–24.1)	10.2 (6.5–14.9)
60 months	20.5 (15.3–26.2)	16.4 (11.6–21.8)	9.1 (5.6–13.6)

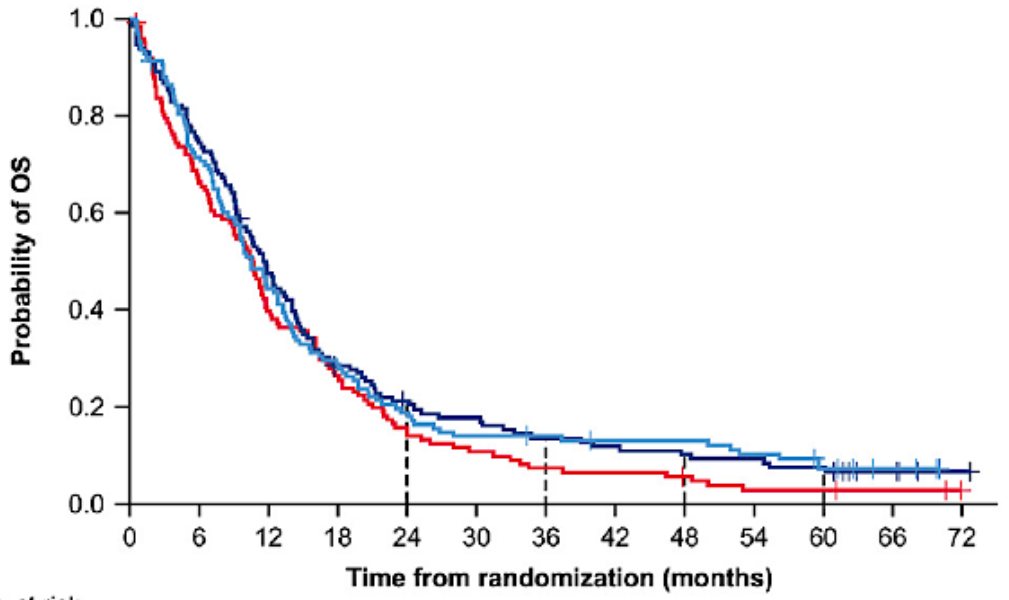


No. at risk

T+D+CT	214	169	129	102	86	71	65	57	52	45	40	17	3
D+CT	209	152	116	90	72	59	50	41	36	34	31	14	2
CT	214	154	110	78	53	37	33	23	19	18	17	8	2

B

Squamous	T+D+CT	D+CT	CT
Events/patients, n/N	112/124	117/128	117/122
mOS, months (95% CI)	10.4 (8.4–12.7)	11.5 (9.4–14.0)	10.5 (8.0–11.7)
HR (95% CI) vs CT	0.85 (0.65–1.10)	0.82 (0.64–1.07)	–
Landmark OS, % (95% CI)			
24 months	18.1 (11.8–25.4)	20.3 (13.8–27.8)	14.1 (8.6–20.9)
36 months	14.0 (8.5–20.7)	13.6 (8.2–20.2)	7.4 (3.7–13.0)
48 months	13.1 (7.8–19.7)	10.2 (5.6–16.3)	5.8 (2.6–10.9)
60 months	7.3 (3.4–13.1)	7.6 (3.8–13.2)	2.9 (0.8–7.3)



No. at risk

T+D+CT	124	87	54	34	22	17	16	14	14	11	7	4	0
D+CT	128	95	60	35	24	21	16	14	12	11	9	4	1
CT	122	80	48	32	17	13	9	8	6	3	3	2	0

Peters J Thorac Oncol 2025

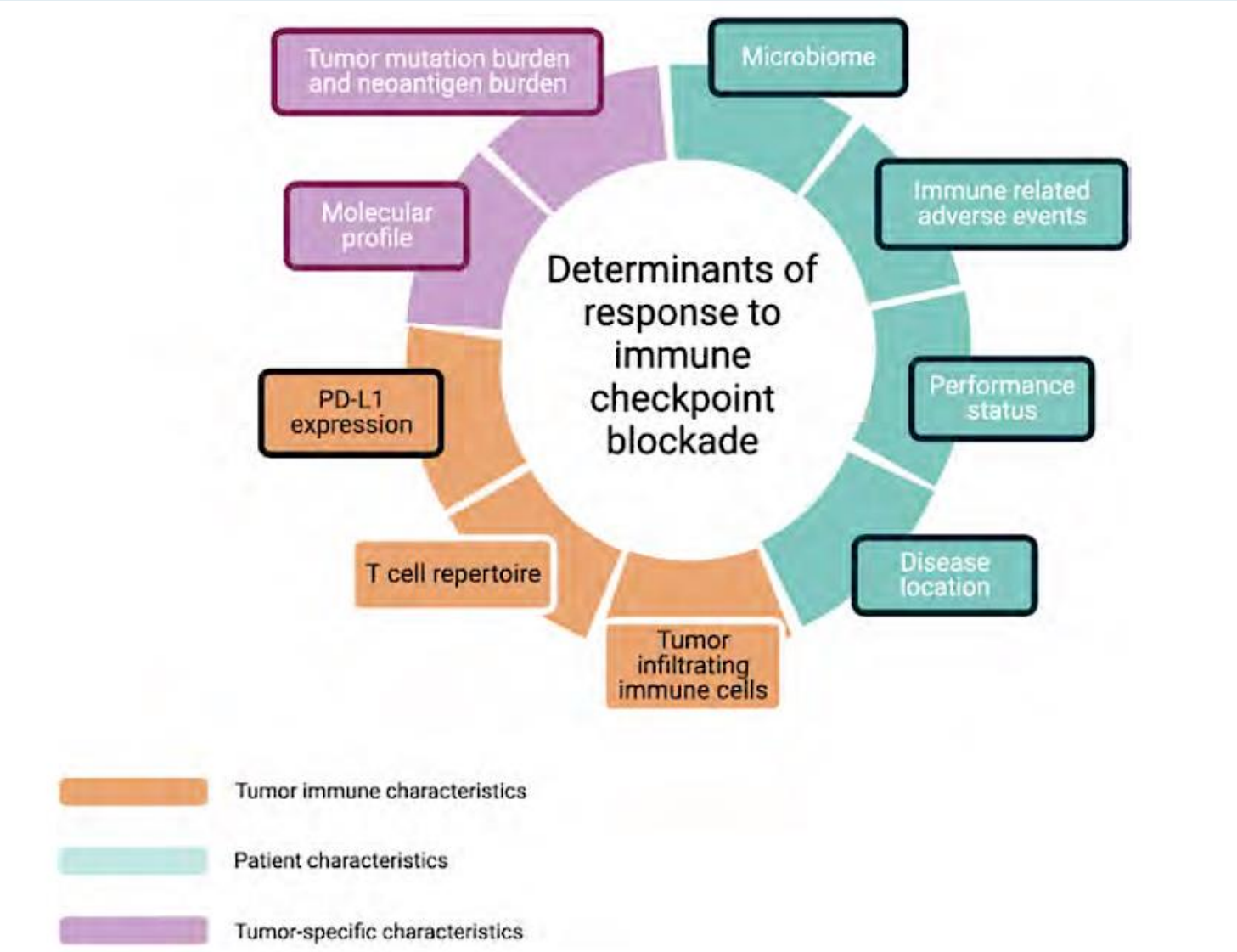
Original Study

Clinical and Genomic Characterization of Long-Term Responders Receiving Immune Checkpoint Blockade for Metastatic Non–Small-Cell Lung Cancer

Paola Ghanem,[1] Joseph C. Murray,[2] Melinda Hsu,[3] Matthew Z. Guo,[1] David S. Ettinger,[2] Josephine Feliciano,[2] Patrick Forde,[2] Christine L. Hann,[2] Vincent K. Lam,[2] Benjamin Levy,[2] Valsamo Anagnostou,[2] Julie R. Brahmer,[2] Kristen A. Marrone[2]

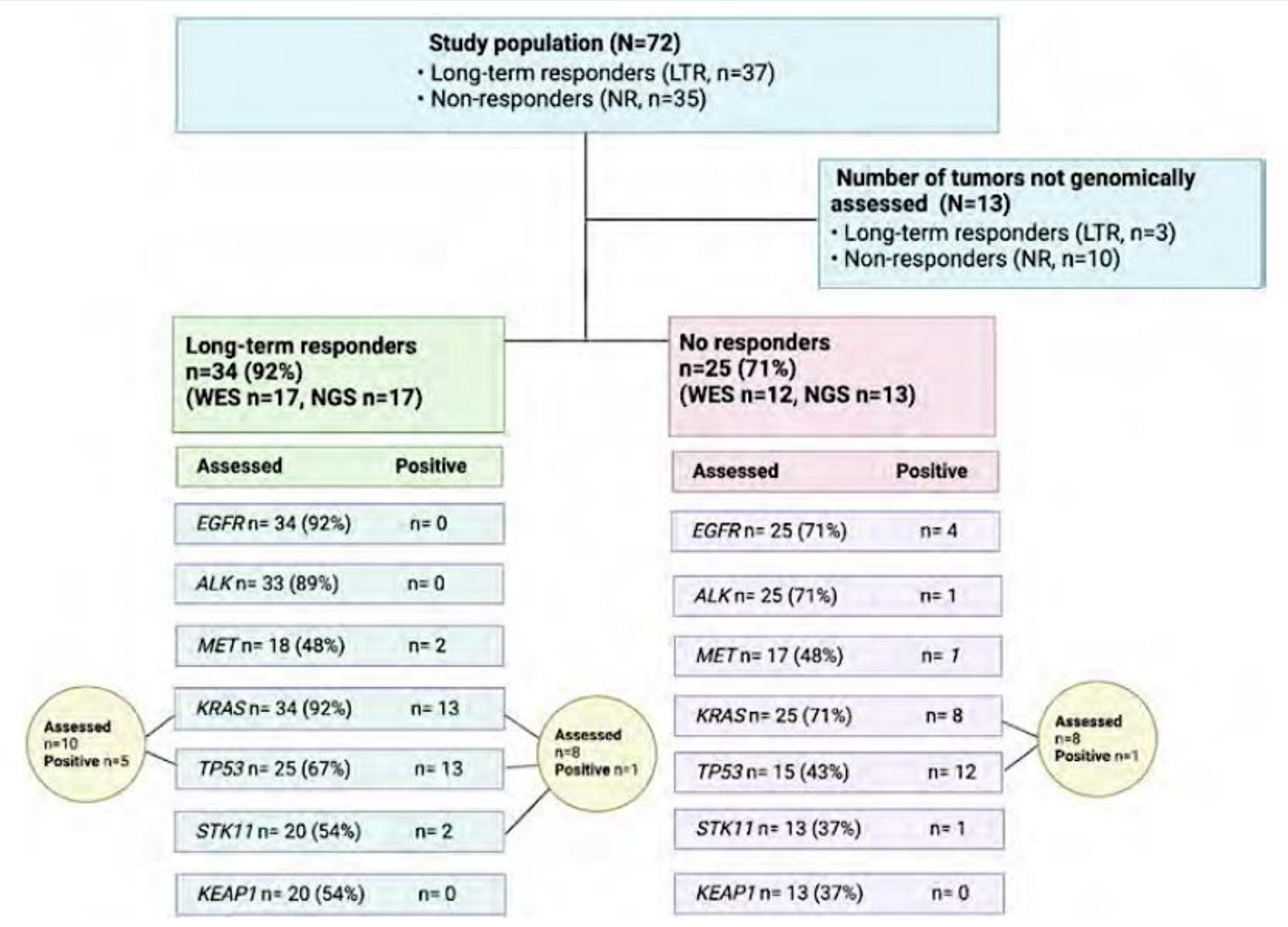
Clin Lung Cancer 2024;25(2):109-18.

Determinants of Clinical Benefit with Immune Checkpoint Blockade



Ghanem P et al. *Clin Lung Cancer* 2024;25(2):109-18.

Genomic Features by Cohort



Ghanem P et al. *Clin Lung Cancer* 2024;25(2):109-18.

QUESTIONS?

RTP Year in Review 2025

Year in Review:
Nontargeted Approaches for Lung Cancer

INTRODUCTION: The Boards

MODULE 1: Immune Checkpoint Inhibition for Localized Non-Small Cell Lung Cancer (NSCLC)

MODULE 2: Immunotherapy for Metastatic NSCLC

MODULE 3: Antibody-Drug Conjugates

MODULE 4: Novel Bispecific Antibodies

MODULE 5: Journal Club with Dr Levy

Antibody-Drug Conjugates in Advanced Lung Cancer: Is This a New Frontier?

Joshua E. Reuss, MD[1]; Samuel Rosner, MD[2]; and Benjamin P. Levy, MD[3]

[1]Georgetown Lombardi Comprehensive Cancer Center, Washington, DC

[2]University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center, Baltimore, MD

[3]Johns Hopkins Sidney Kimmel Cancer Center at Sibley Memorial Hospital, Washington, DC

Clin Adv Hematol Oncol 2024;22(5):217-26.

LUNG CANCER

Antibody-Drug Conjugates for Lung Cancer: Payloads and Progress

Samuel Rosner, MD[1]; Augusto Valdivia, MD[2]; Hui Jing Hoe, MBBS[3]; Joseph C. Murray, MD[1]; Benjamin Levy, MD[1]; Enriqueta Felip, MD[2]; and Benjamin J. Solomon, MBBS, PhD[3]

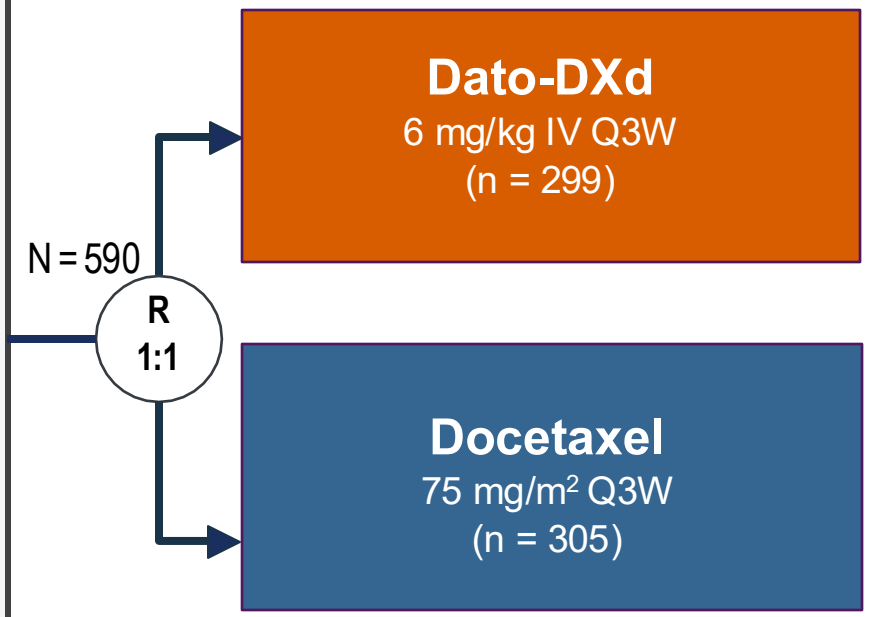
Am Soc Clin Oncol Educ Book 2023;43:e389968.

Datopotamab Deruxtecan vs Docetaxel in NSCLC

TROPION-Lung01: Study Design

Key Eligibility Criteria

- NSCLC (stage IIIB, IIIC, or IV)
- ECOG PS of 0 or 1
- No prior docetaxel
- Without actionable genomic alterations
  - 1 or 2 prior lines, including platinum CT and anti–PD-(L)1 mAb therapy
- With actionable genomic alterations
  - Positive for EGFR, ALK, NTRK, BRAF, ROS1, MET exon 14 skipping, or RET
  - 1 or 2 prior approved targeted therapies + platinum-based CT, and ≤ 1 anti–PD-(L)1 mAb



Stratification by

- *Histology (actionable genomic alteration)*
- *Anti-PD-(L)1 mAb included in most recent prior therapy, geography*

Primary Endpoints

- PFS assessed by BICR, per RECIST v1.1
- OS

Key Secondary Endpoints

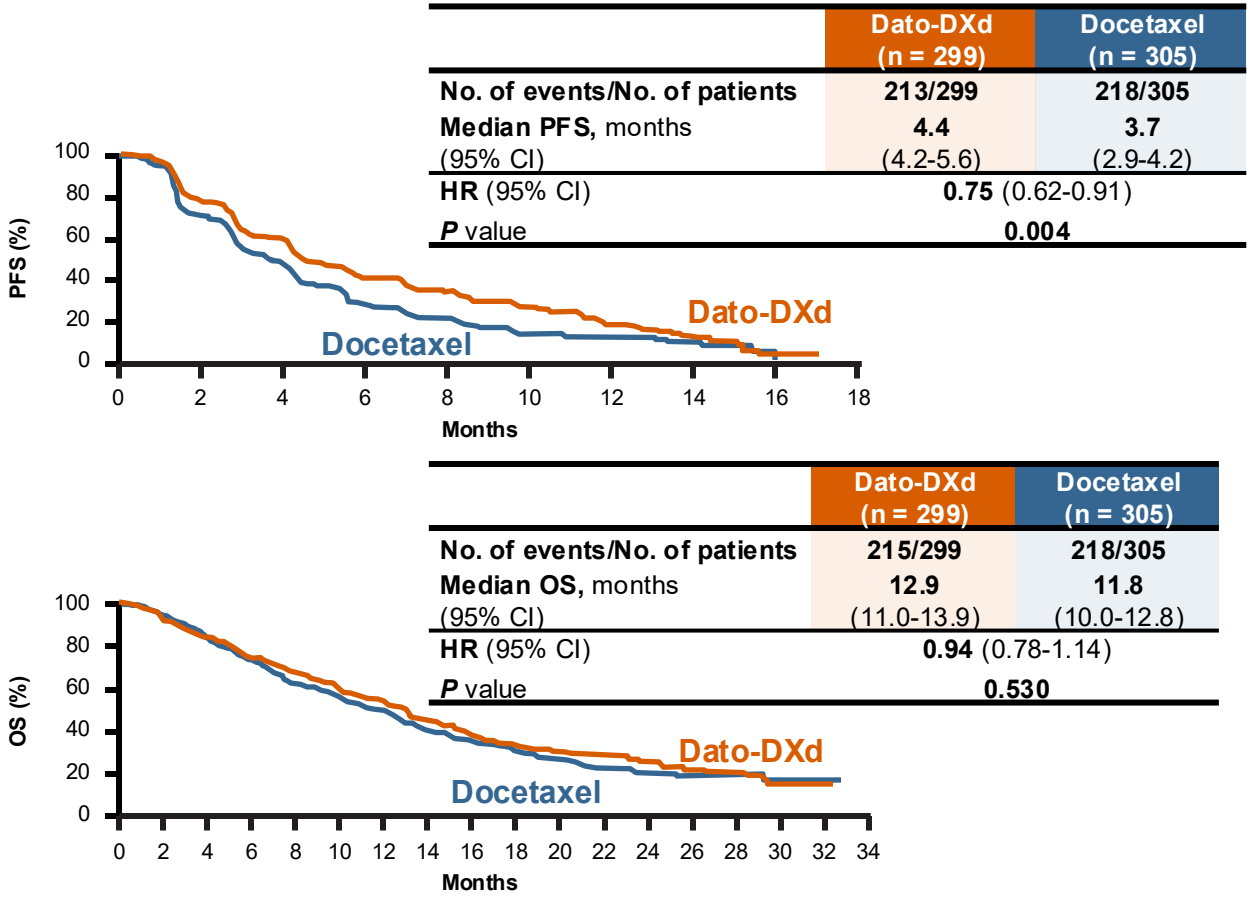
- ORR by BICR
- DOR by BICR
- Safety

Datopotamab Deruxtecan vs Docetaxel in NSCLC

TROPION-Lung01: Primary Endpoints

Dual primary endpoints: PFS endpoint met, but OS endpoint not met

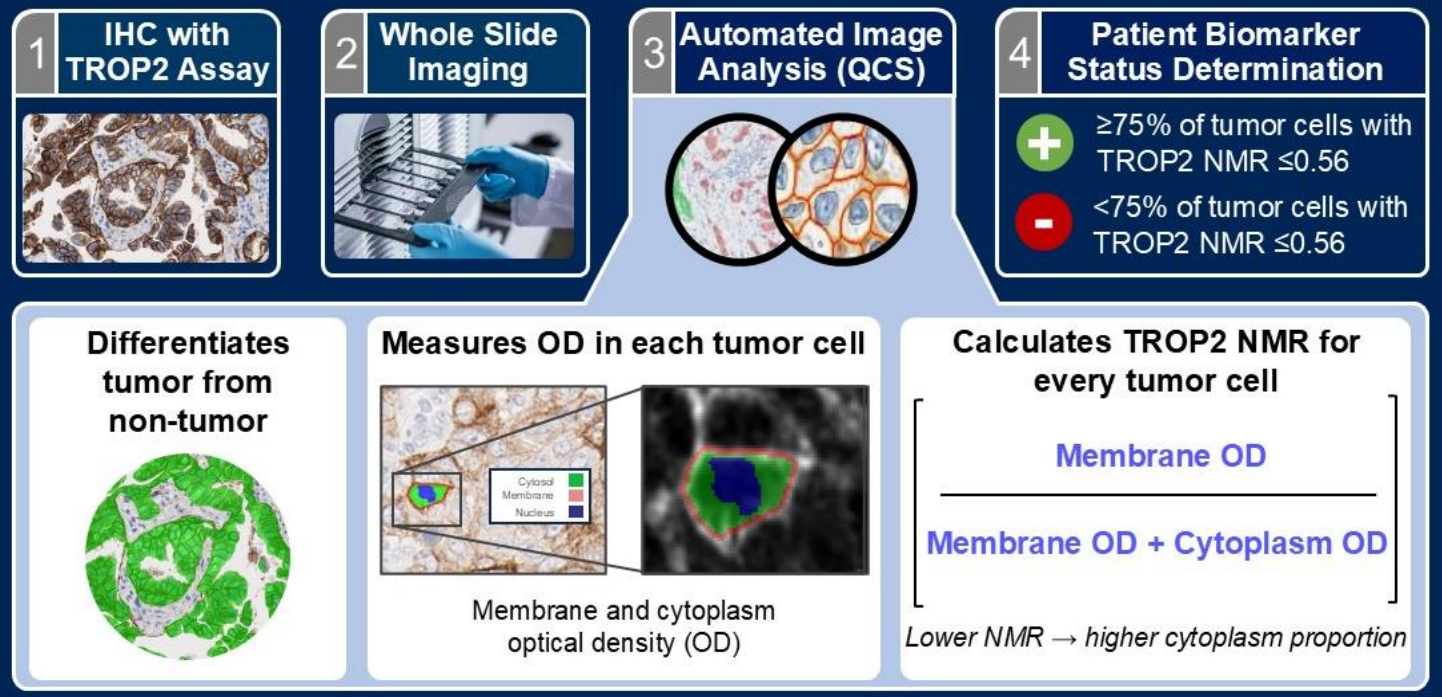
	Datopotamab deruxtecan	Docetaxel
ORR	26.4%	12.8%
mDOR	7.1 mos	5.6 mos
mPFS	4.4 mos	3.7 mos
mOS	12.9 mos	11.8 mos



TROP2 Normalized Membrane Ratio (NMR) Measured by Quantitative Continuous Scoring (QCS)

QCS is a novel, fully-supervised computational pathology approach that precisely quantifies and locates targets like TROP2

- TROP2 tumor membrane expression using conventional IHC and pathology visual scoring does not enrich for response
- TROP2 NMR as measured by QCS reflects the expression of TROP2 in the membrane relative to total TROP2 (membrane and cytoplasm)

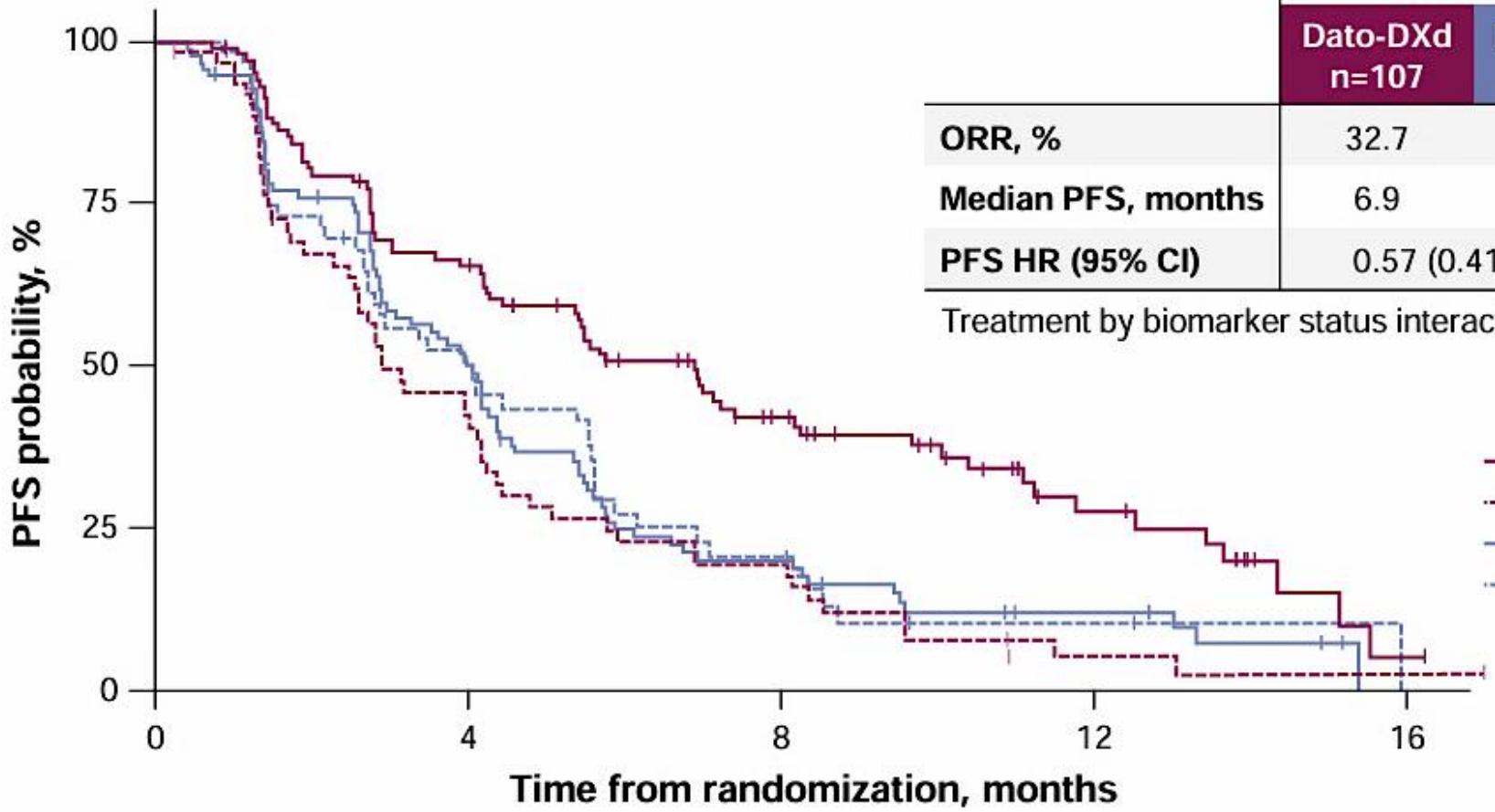


Levy ASCO 2025; Abstract 8501

Overall BEP: Efficacy by TROP2 QCS-NMR Status

TROP2 QCS-NMR positivity is predictive for longer PFS with Dato-DXd in the biomarker-evaluable population

Biomarker-evaluable population, n=352



	TROP2 QCS-NMR+		TROP2 QCS-NMR–	
	Dato-DXd n=107	Docetaxel n=107	Dato-DXd n=65	Docetaxel n=73
ORR, %	32.7	10.3	16.9	15.1
Median PFS, months	6.9	4.1	2.9	4.0
PFS HR (95% CI)	0.57 (0.41–0.79)		1.16 (0.79–1.70)	

Treatment by biomarker status interaction: p=0.0063

Dr Marina Chiara Garassino | Normalized Membrane Ratio of TROP2 by Quantitative Continuous Scoring is Predictive of Clinical Outcomes in TROPION-Lung01

Data cutoff: March 29 2023

PFS HR (95% CI) by TROP2 QCS-NMR status (+ vs -) within treatment: Dato-DXd: 0.48 [0.33-0.69]; Docetaxel:0.97 [0.68-1.39]

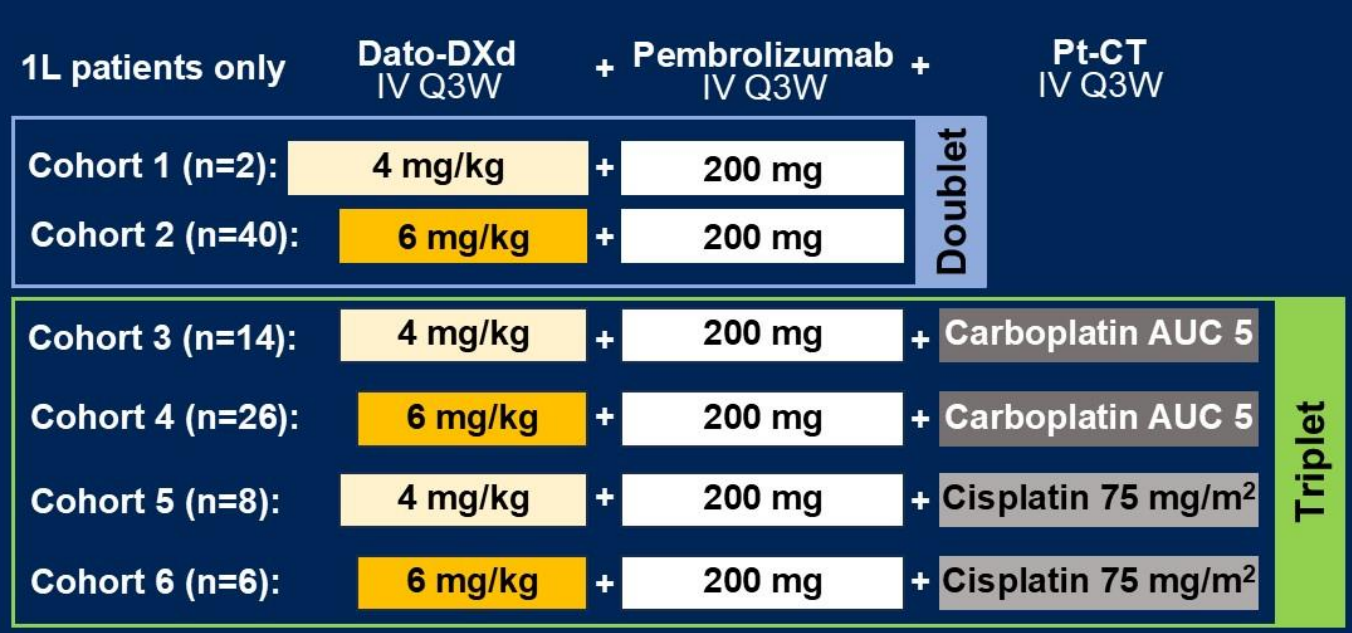
Garassino et al WCLC 2024

TROPION-Lung02

- Phase 1b study of Dato-DXd + pembrolizumab ± Pt-CT in a/mNSCLC without actionable genomic alterations[a]

Key eligibility criteria

- a/mNSCLC
- Dose escalation[b]: ≤2 lines of prior therapy[c]
- Dose expansion
  - ≤1 line of Pt-CT (cohorts 1 and 2)[c]
  - Treatment-naive (cohort 2)[c,d]
  - Treatment-naive (cohorts 3–6)[c]



Objectives

Primary: Safety and tolerability

Secondary: Efficacy

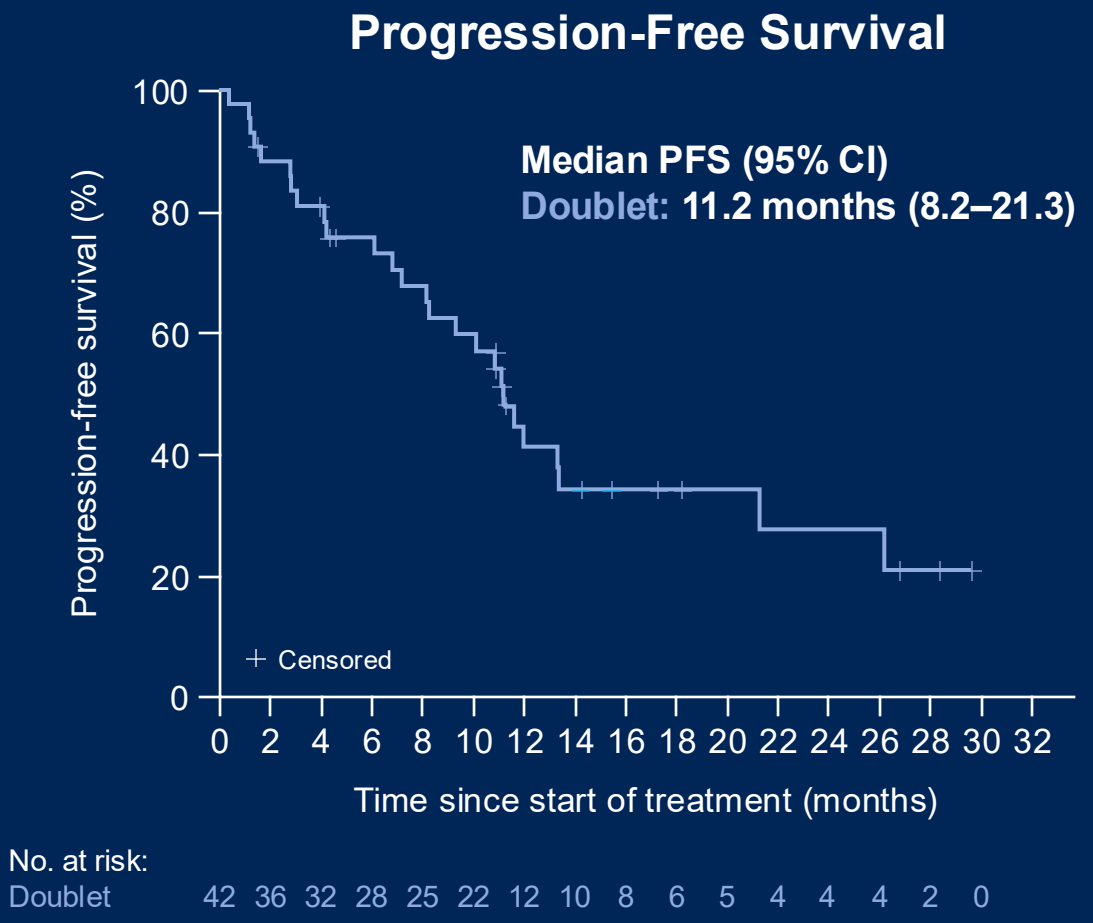
Data cutoff: April 29, 2024. Median study duration was 18.7 months (range, 11–33.8) for doublet and 24.6 months (range, 15.4–32.4) for triplet combinations.

[a]Patients with known actionable genomic alterations in *EGFR*, *ALK*, *ROS1*, *NTRK*, *BRAF*, *RET*, or *MET*, or with alterations in other actionable oncogenic driver kinases were not eligible for this study. [b]The first 3 to 6 patients in each cohort were enrolled to confirm acceptable safety/DLT rate; the remaining patients are considered part of dose expansion. [c]Prior therapy requirements are for treatment in the a/m setting. [d]Enrollment after June 30, 2022.

1L, first line; a/m, advanced or metastatic; CT, chemotherapy; DLT, dose-limiting toxicity; IV, intravenous; NSCLC, non-small cell lung cancer; Pt-CT, platinum-based chemotherapy; Q3W, every 3 weeks.

TROPION-Lung02: Efficacy, 1L Doublet

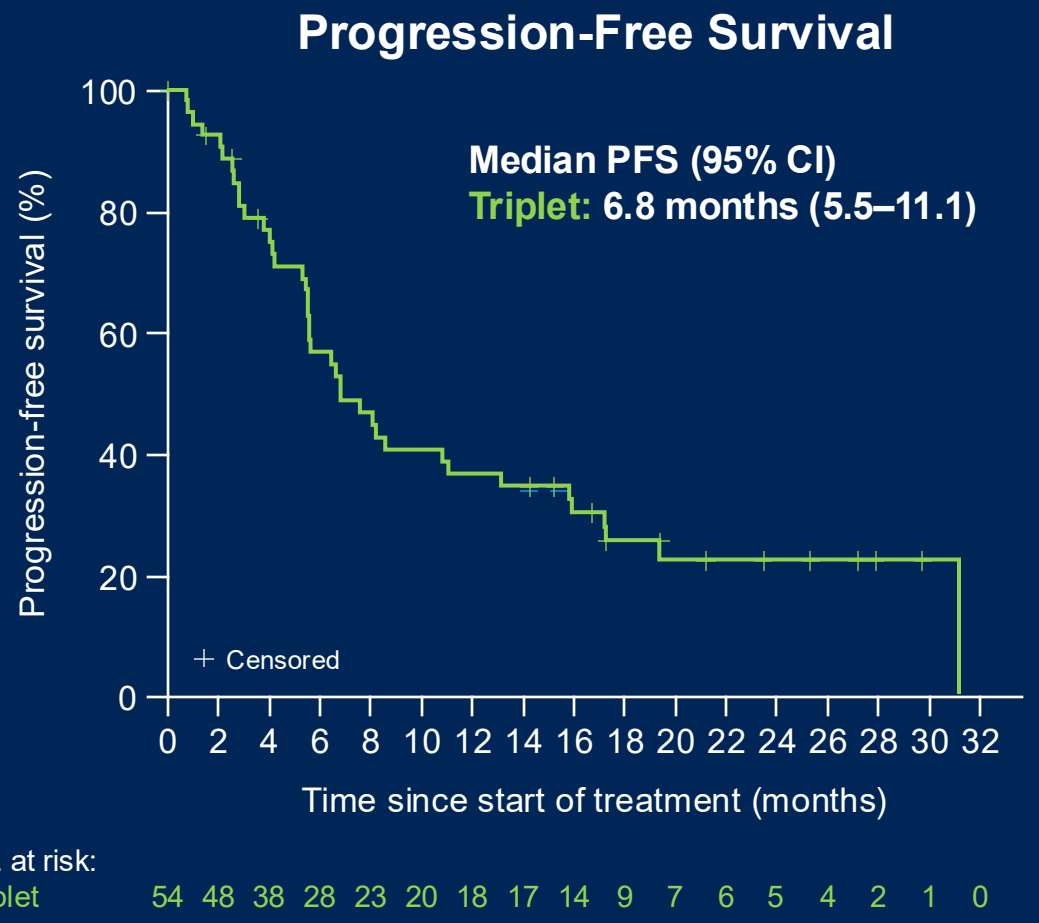
	Doublet (n=42)
Confirmed ORR*, n (%)	**23 (54.8)**
95% CI	38.7–70.2
Median DOR, months	**20.1**
95% CI	9.7–NE
DCR, n (%)	**37 (88.1)**
95% CI	74.4–96.0
Median TTR, months	**1.4**
Range	1.2–7.0
Median PFS, months	**11.2**
95% CI	8.2–21.3
Median OS, months	**NE**
95% CI	19.2–NE



Data cutoff: April 29, 2024. *1 CR, 22 PR. Pooled data including patients who received Dato-DXd 4mg/kg (5%) and Dato-DXd 6 mg/kg (doublet: 95%)
1L, first line; BOR, best overall response; CI, confidence interval; CR, complete response; DCR, disease control rate; DOR, duration of response; NE, not evaluable; ORR, objective response rate; PR, partial response; TTR, time to response.

TROPION-Lung02: Efficacy, 1L Triplet

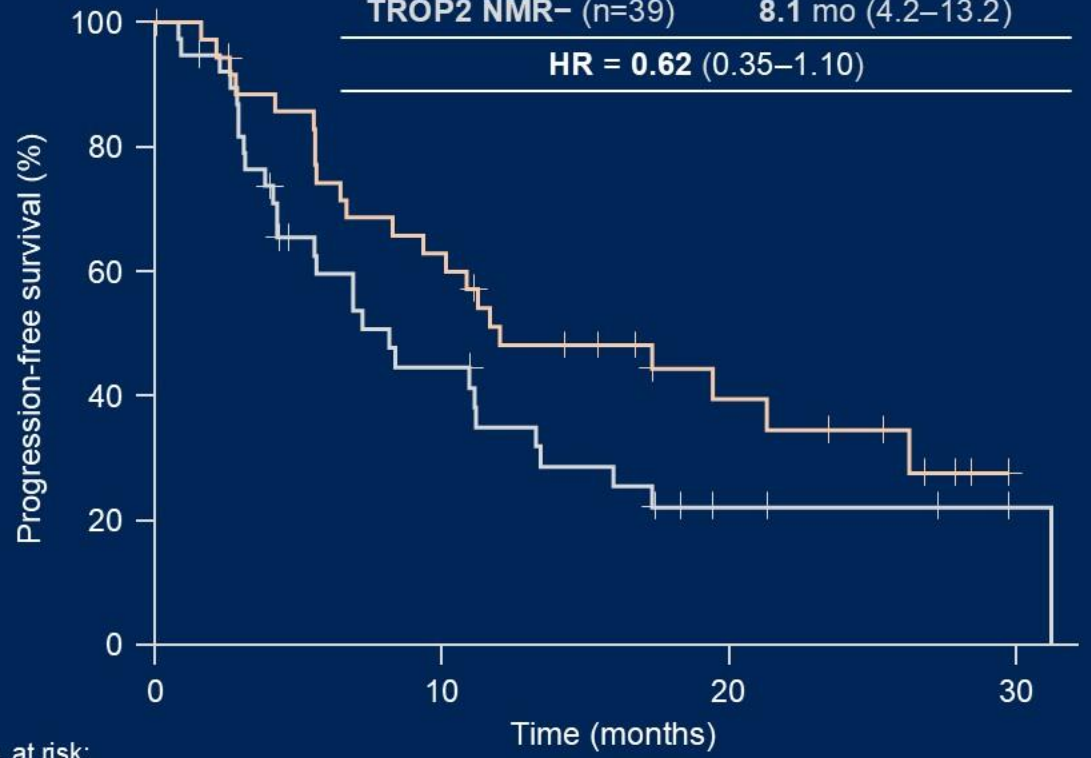
	Triplet (n=54)
Confirmed ORR*, n (%)	**30 (55.6)**
95% CI	41.4–69.1
Median DOR, months	**13.7**
95% CI	5.7–NE
DCR, n (%)	**48 (88.9)**
95% CI	77.4–95.8
Median TTR, months	**1.4**
Range	1.2–9.6
Median PFS, months	**6.8**
95% CI	5.5–11.1
Median OS, months	**17.4**
95% CI	9.1–NE



Data cutoff: April 29, 2024. *2 CR, 28 PR. Pooled data including patients who received Dato-DXd 4mg/kg (41%) and Dato-DXd 6 mg/kg (59%)
1L, first line; BOR, best overall response; CI, confidence interval; CR, complete response; DCR, disease control rate; DOR, duration of response; NE, not evaluable; ORR, objective response rate; PR, partial response; TTR, time to response.

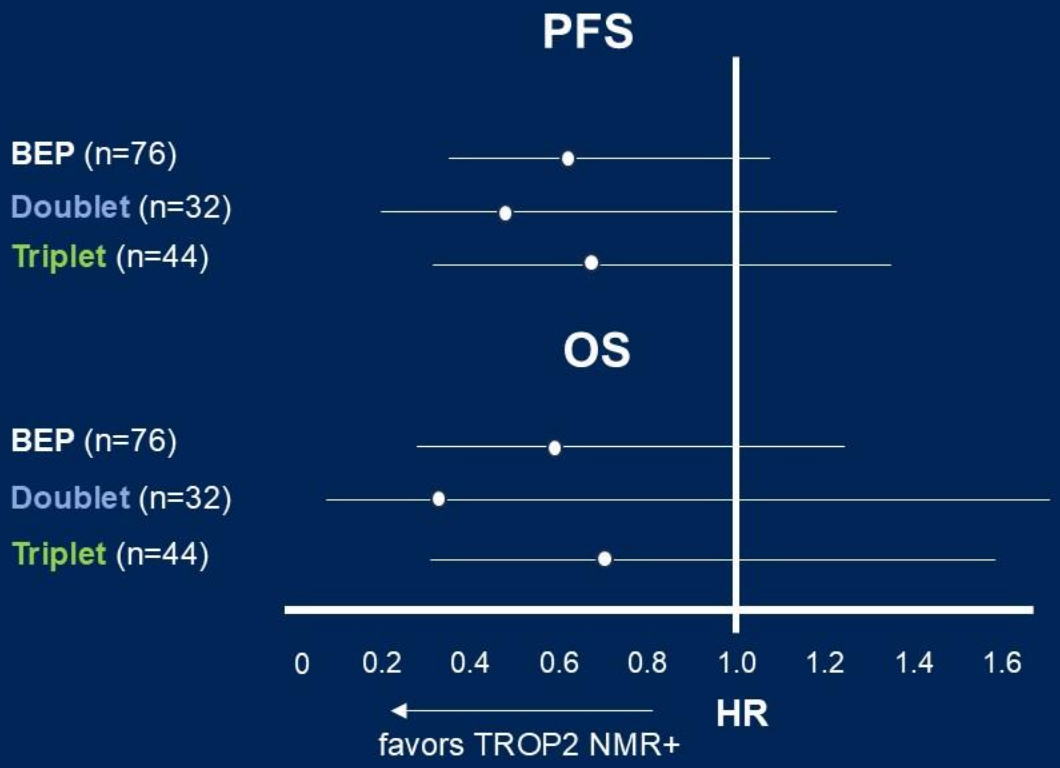
Efficacy by TROP2 NMR, 1L Biomarker Evaluable Population

	Median PFS (95% CI)
TROP2 NMR+ (n=37)	**12.0** mo (8.2–26.2)
TROP2 NMR− (n=39)	**8.1** mo (4.2–13.2)
HR = 0.62 (0.35–1.10)	



No. at risk:

TROP2 NMR+	37	22	8	0
TROP2 NMR−	39	15	4	1



Data cutoff: April 29, 2024. Pooled data including patients who received Dato-DXd 4mg/kg and 6 mg/kg

BEP, biomarker evaluable population;CI, confidence interval; HR, hazard ratio; mo, months; NE, not evaluable; OS, overall survival; PFS, progression-free survival; TROP2 NMR, TROP2 normalized membrane ratio.

QUESTIONS?

RTP Year in Review 2025

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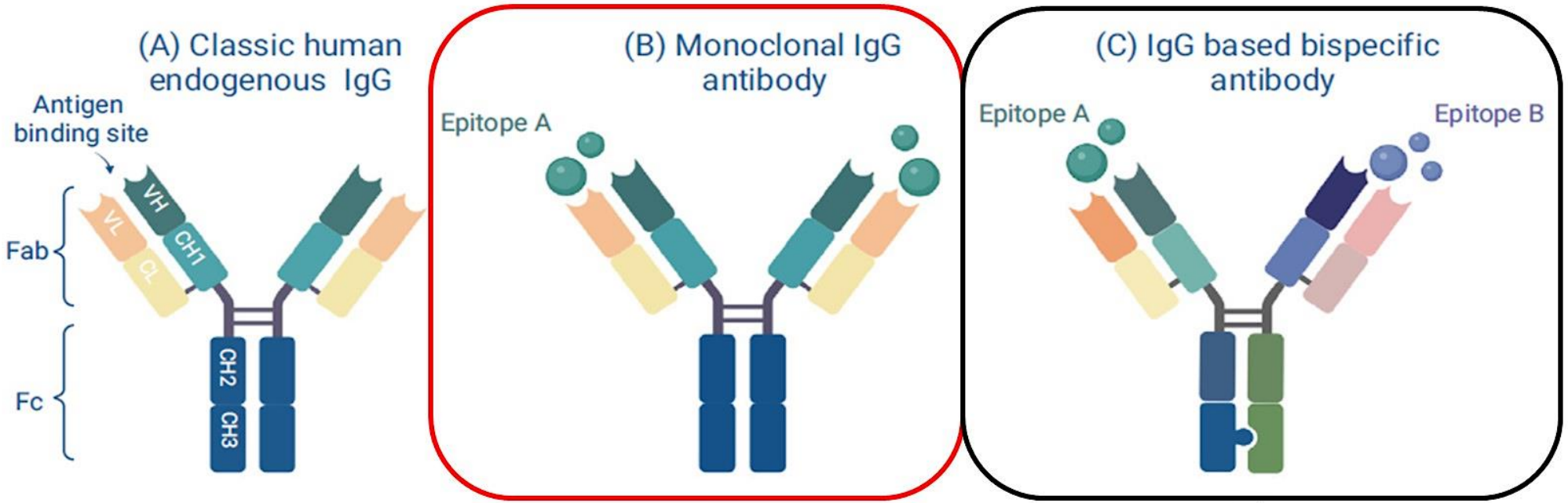
RTP Year in Review 2025

The science



Coexistence of multiple parallel signaling pathways

Resistance

Distinct antigen-binding domains designed to target two different epitopes

Herrera et al., Trends in Cancer, 2024

HARMONi-2 STUDY
Ivonescimab vs Pembrolizumab for PD-L1 positive NSCLC

HARMONi-2 (AK112-303): Study Design

Randomized, double-blind, phase 3 study conducted in China[a]

(NCT05499390)

HARMONi-2

Patient Population

- Stage IIIB/C or IV aNSCLC
- No prior systemic therapy
- No *EGFR* mutations or *ALK* rearrangements
- At least one measurable lesion by RECIST v1.1
- ECOG PS 0 or 1
- PD-L1 TPS ≥1%

R 1:1

N=398

Ivonescimab IV
20 mg/kg Q3W (n=198)

Pembrolizumab IV
200 mg Q3W (n=200)

Treatment until disease progression confirmed by IRRC, unacceptable toxicity or up to 24 months

[a] Patients were randomized from November 2022 to August 2023.
Data cut off: January 29, 2024.
Patients who received ≥1 dose of study treatment

Stratification

- Clinical stage (IIIB/C vs. IV)
- Histology (SQ vs. non-SQ)
- PD-L1 TPS (≥50% vs. 1-49%)

Endpoints

Primary:
- PFS by IRRC per RECIST v1.1

Secondary:
- OS, PFS assessed by investigator, ORR, DCR, DoR, TTR, assessed by masked IRRC per RECIST v 1.1, PK, and safety

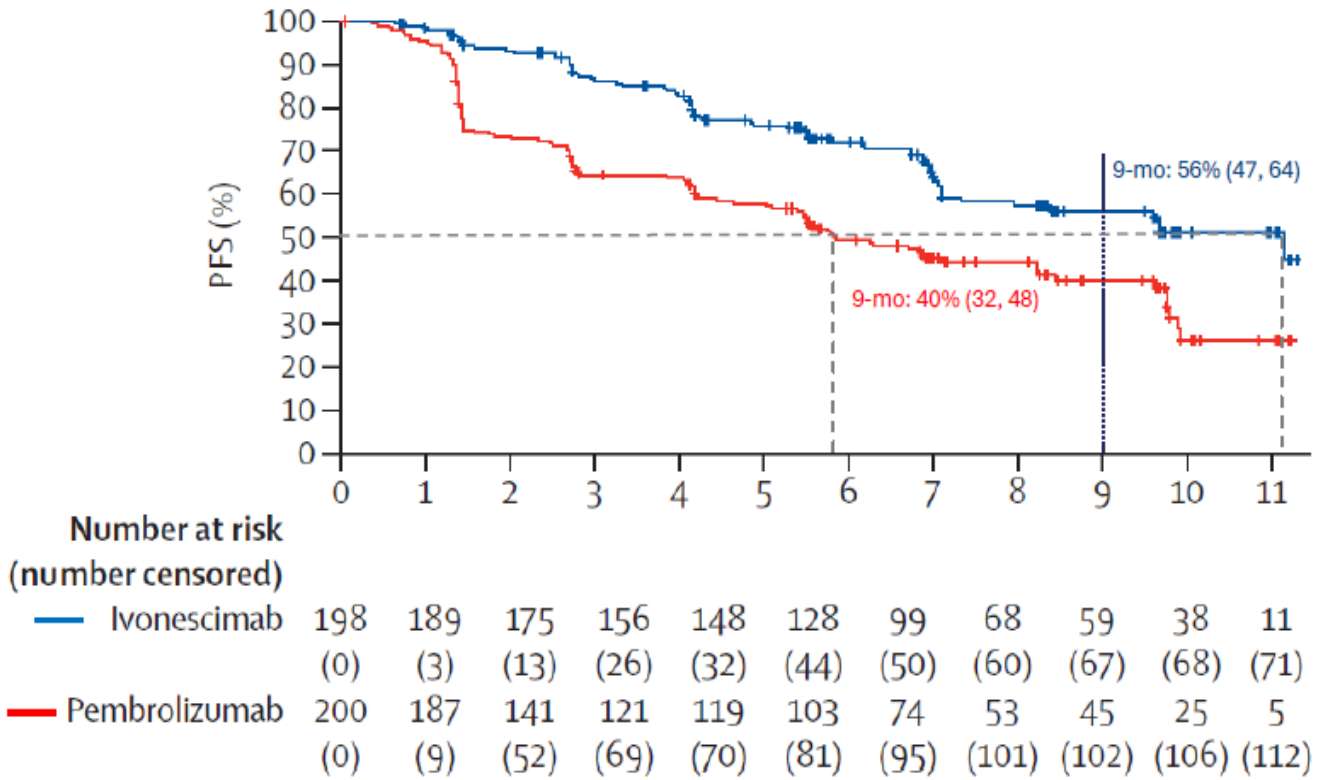
Exploratory:
- QoL

Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA)

Xiong Lancet 2025

HARMONi-2 (AK112-303): Efficacy Data

Primary Endpoint—PFS per IRRC



	Ivonescimab (n = 198)	Pembrolizumab (n = 200)
Number of Events/Patients	72/198	112/200
mPFS, mos (95% CI)	**11.1** (7.3, NE)	**5.8** (5.0, 8.2)
Stratified HR (95% CI)	**0.51** (0.38, 0.69)	
***P*-value**	**<0.0001**	

Median Duration of Follow-up: 8.7 months (IQR: 7.1, 10.3)
Data cut off: January 29, 2024.
Interim analysis for PFS was conducted after 184 IRRC-assessed PFS events were observed

Ivonescimab demonstrated a statistically significant improvement in PFS vs. pembrolizumab with HR = 0.51, and a 5.3 months improvement in mPFS

Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA)

Xiong Lancet 2025

HARMONi-2

Safety Summary

TRAEs

Safety Summary, n (%)	Ivonescimab (n = 197[a])	Pembrolizumab (n = 199[a])
TRAEs (all grades)	177 (89.8)	163 (81.9)
Grade≥3	58 (29.4)	31 (15.6)
Serious TRAEs	41 (20.8)	32 (16.1)
Leading to discontinuation	3 (1.5)	6 (3.0)
Leading to death	1 (0.5)	2 (1.0)

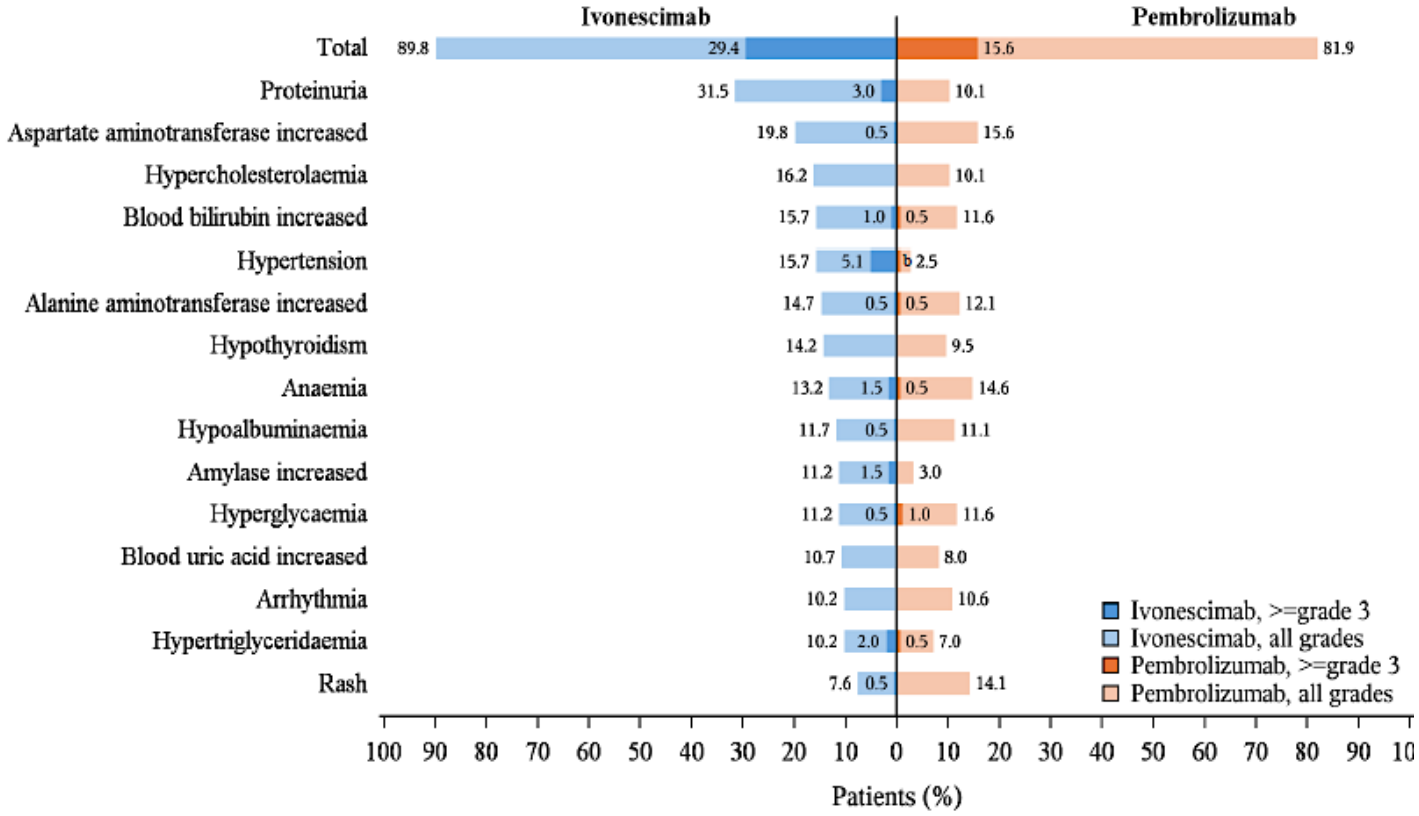
Ivonescimab showed a manageable safety profile, which was consistent with previous studies.

TRAEs in SQ Subgroup

Safety Summary, n (%)	Ivonescimab (n = 90[a])	Pembrolizumab (n = 91[a])
TRAEs (all grades)	77 (85.6)	73 (80.2)
Grade≥3	20 (22.2)	17 (18.7)
Serious TRAEs	17 (18.9)	17 (18.7)
Leading to discontinuation	2 (2.2)	3 (3.3)
Leading to death	0	1 (1.1)

Ivonescimab also demonstrated a tolerable safety profile in SQ patients.

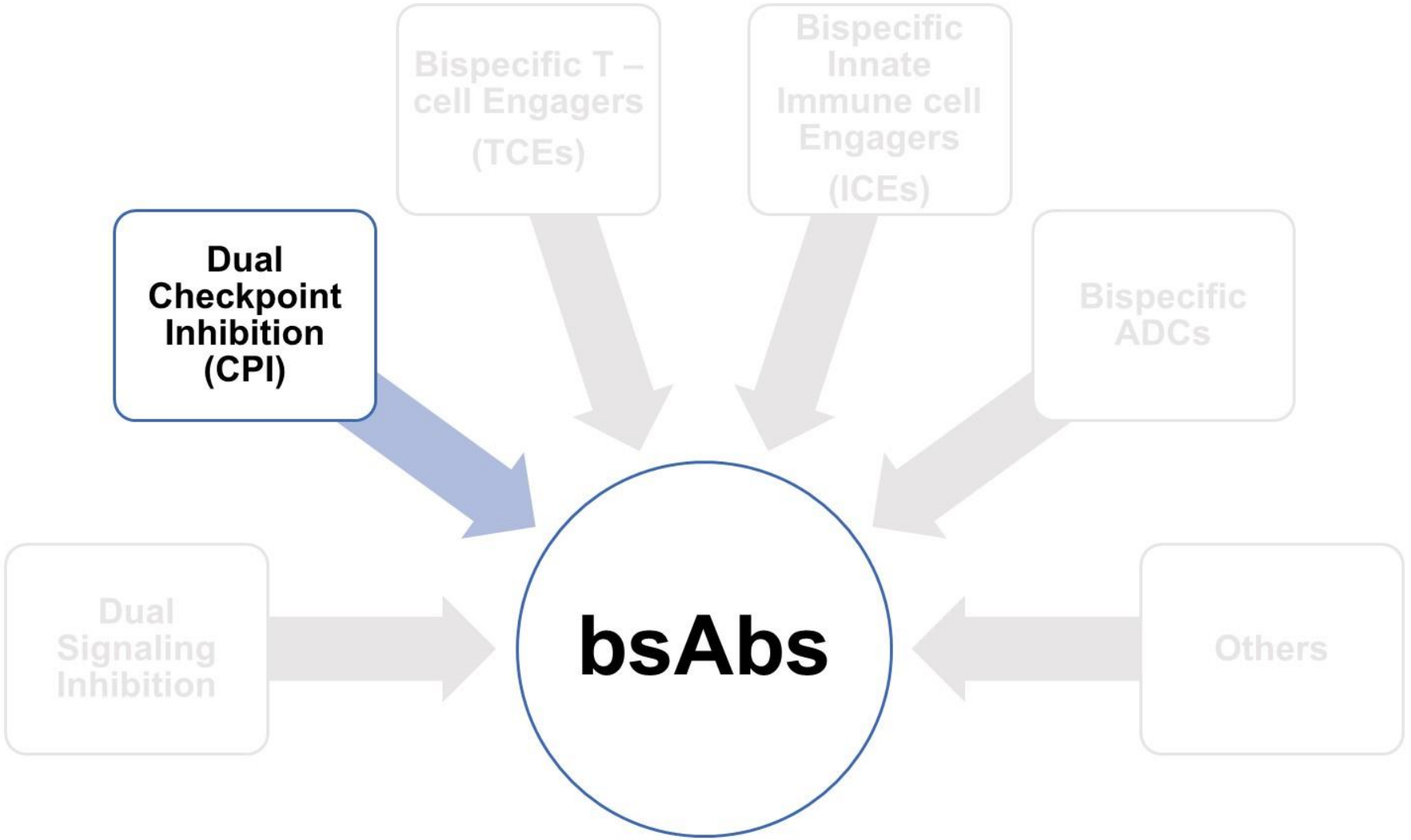
The Most Common TRAEs (incidence ≥10%)



The differences in AEs were predominantly proteinuria, hypertension, and laboratory abnormalities.

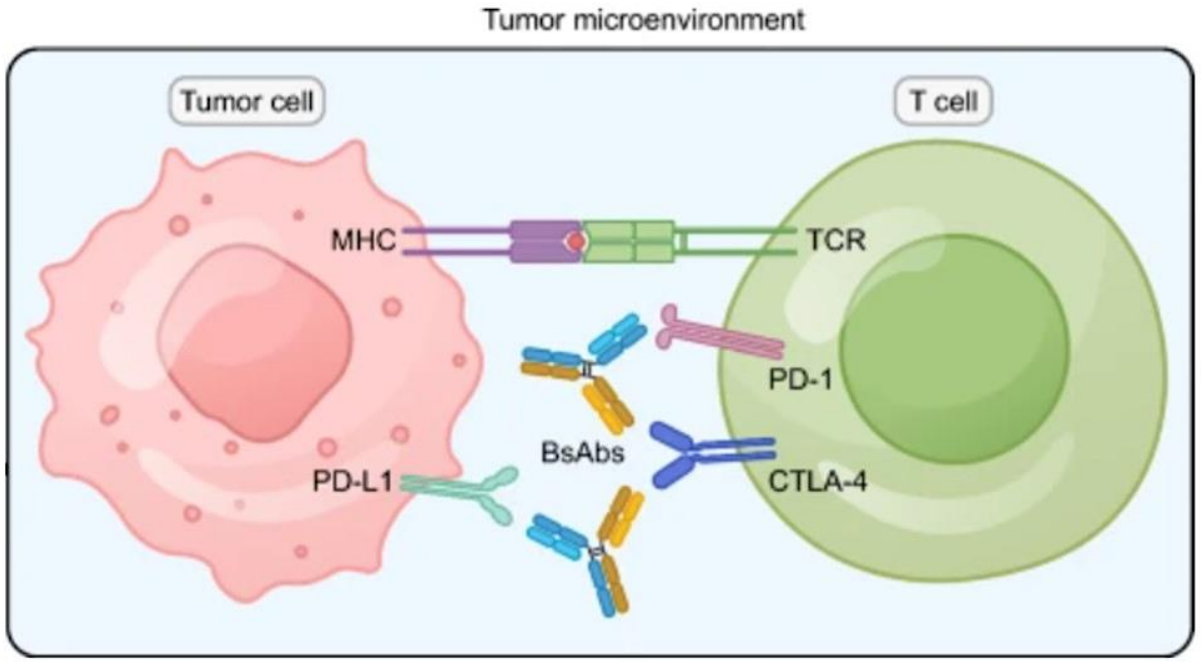
Zhou WCLC 2024; Abstract PL02.04

Mechanisms of action



Mamdani ASCO 2025; Clinical Science Symposium

Dual CPI



Cheng et al., J Hemat Oncol 2024

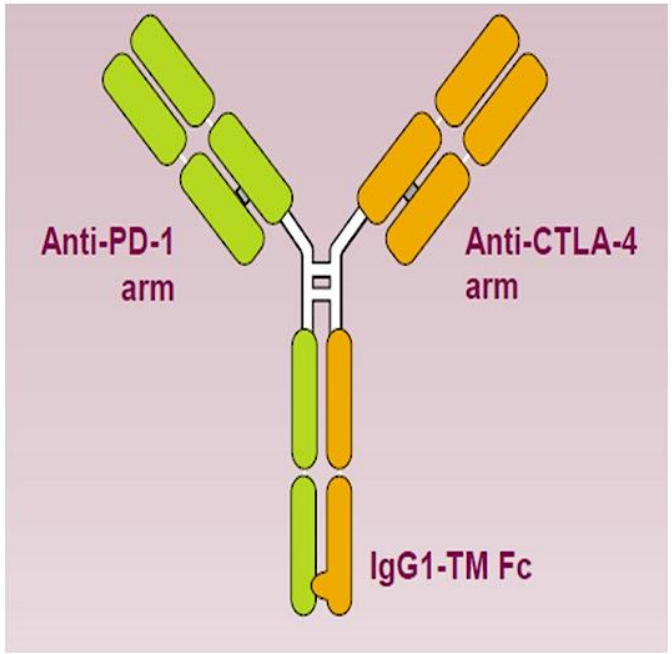
Other co-targets:

- TIGIT
- LAG3
- TIM3

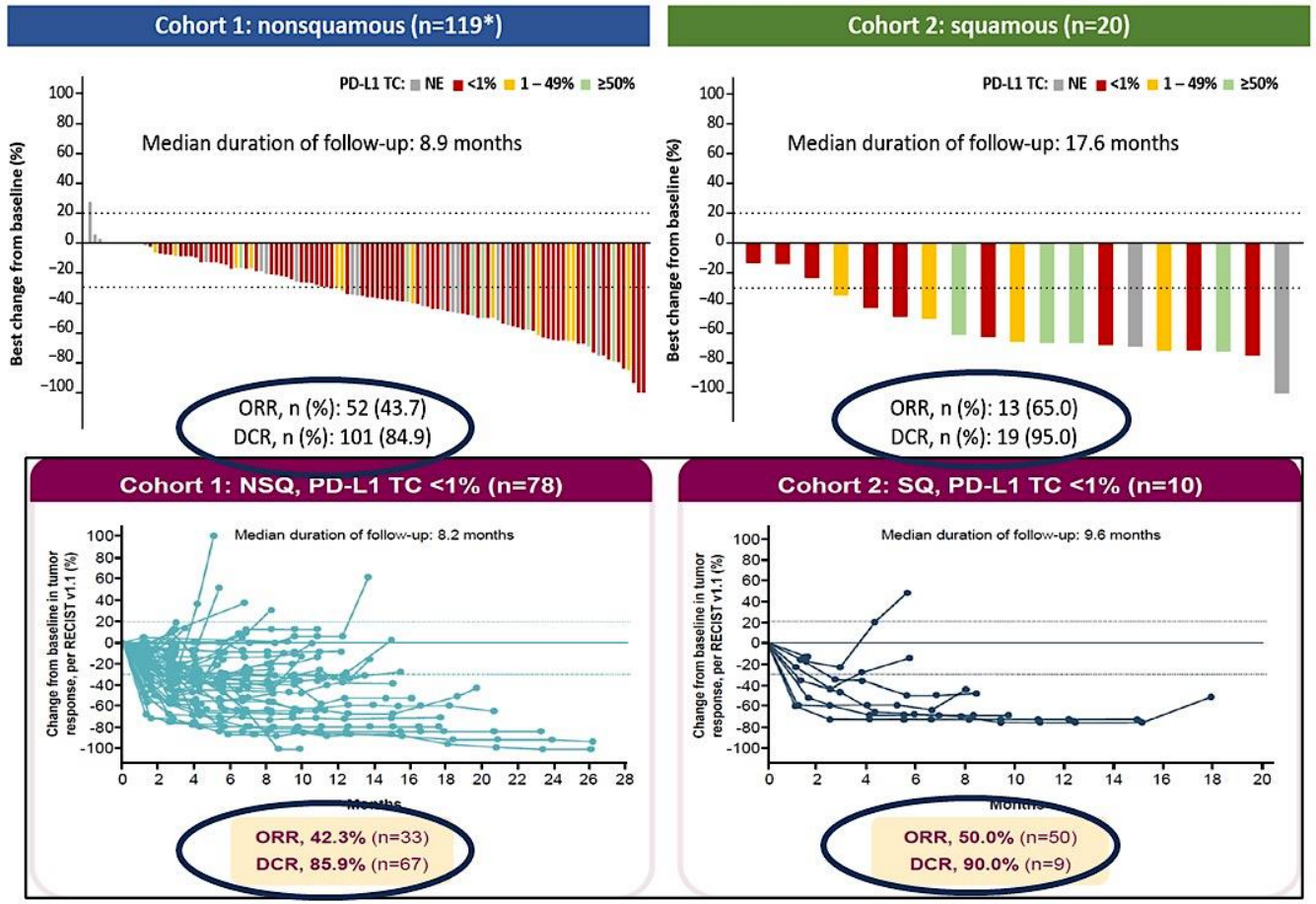
- **In Thoracic Malignancies:**

Target	Agent
PD-1 x CTLA-4	Volrustomig
	Cadonilimab
	Vudalimab
	Lorigerlimab
	Danvilostomig
	Erfonrilimab
PD-1 x TIGIT	Rilvegostomig

Volrustomig



Volrustomig + chemotherapy as 1L treatment of mNSCLC (Phase Ib)



Spigel et al., WCLC 2024

Volrustomig: Toxicity

Volrustomig + chemotherapy as 1L treatment of mNSCLC (Phase Ib)

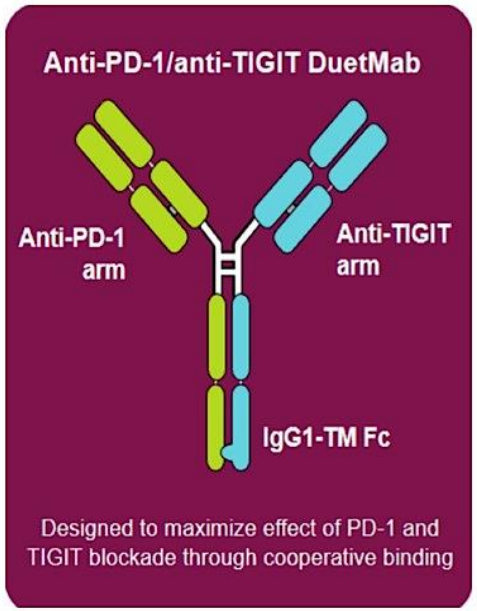
	All (N=140)		NSQ Cohort 1A (n=66)		NSQ Cohort 1B (n=54)		SQ Cohort 2 (n=20)	
Median volrustomig exposure (range), months	4.8 (0.3–28.3)		4.8 (0.3–28.3)		4.4 (0.3–18.6)		6.8 (0.7–18.6)	
Any TEAE, n (%)	139 (99.3)		66 (100.0)		53 (98.1)		20 (100.0)	
Any TRAE, n (%)	136 (97.1)		65 (98.5)		51 (94.4)		20 (100.0)	
Grade 3/4 TRAE	106 (75.7)		50 (75.8)		38 (70.4)		18 (90.0)	
TRAE leading to volrustomig discontinuation	42 (30.0)		19 (28.8)		16 (29.6)		7 (35.0)	
TRAE leading to death*	7 (5.0)		6 (9.1)		0		1 (5.0)	
Select TRAEs (preferred term), n (%)	**Any grade**	**Grade 3/4**	**Any grade**	**Grade 3/4**	**Any grade**	**Grade 3/4**	**Any grade**	**Grade 3/4**
Rash	38 (27.1)	4 (2.9)	21 (31.8)	2 (3.0)	10 (18.5)	0	7 (35.0)	2 (10.0)
ALT increased	33 (23.6)	9 (6.4)	13 (19.7)	4 (6.1)	18 (33.3)	5 (9.3)	2 (10.0)	0
AST increased	32 (22.9)	6 (4.3)	13 (19.7)	2 (3.0)	17 (31.5)	4 (7.4)	2 (10.0)	0
Hyperthyroidism	18 (12.9)	0	10 (15.2)	0	6 (11.1)	0	2 (10.0)	0
Pneumonitis	10 (7.1)	4 (2.9)	2 (3.0)	0	4 (7.4)	3 (5.6)	4 (20.0)	1 (5.0)
Diarrhea	15 (10.7)	2 (1.4)	8 (12.1)	1 (1.5)	3 (5.6)	1 (1.9)	4 (20.0)	0

Spigel et al., WCLC 2024

Volrustomig: Ongoing Trials

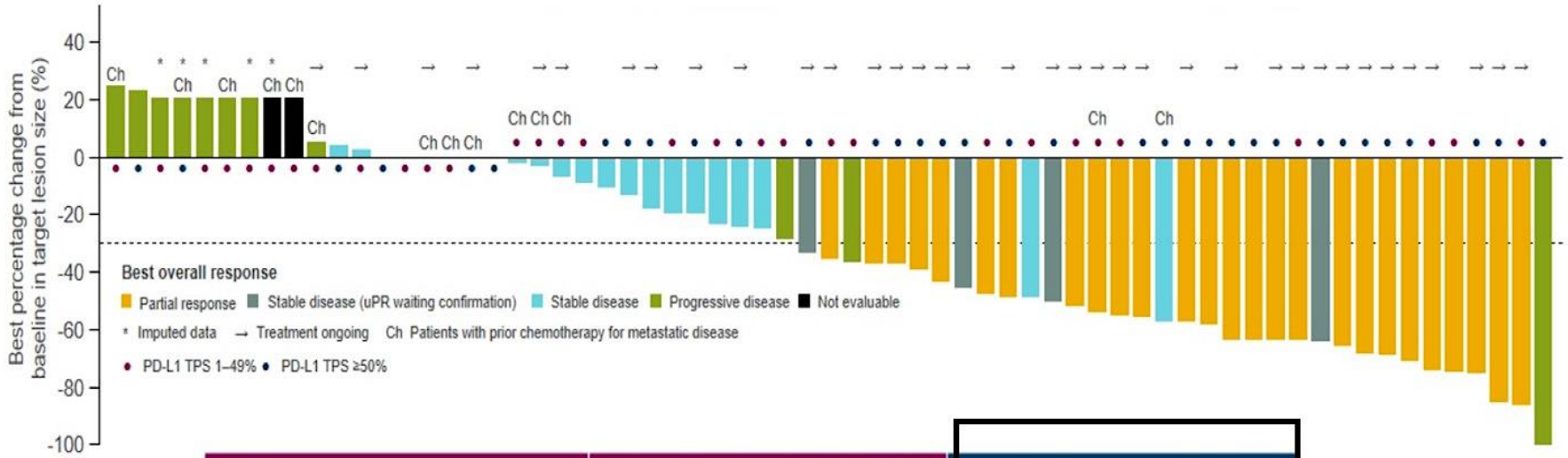
Trial	Phase	Treatment Line	Regimen
eVOLVE-LUNG02	III	1L	Volrustomig + chemo vs pembrolizumab + chemo; PD-L1 <50%
eVOLVE-MESO	III	1L	Volrustomig + chemo vs investigator's choice SOC (nivo/ipi or chemo)

Rilvegostomig



ARTEMIDE-01

Rilvegostomig in advanced NSCLC with PD-L1 ≥1%; CPI naïve (Phase II)

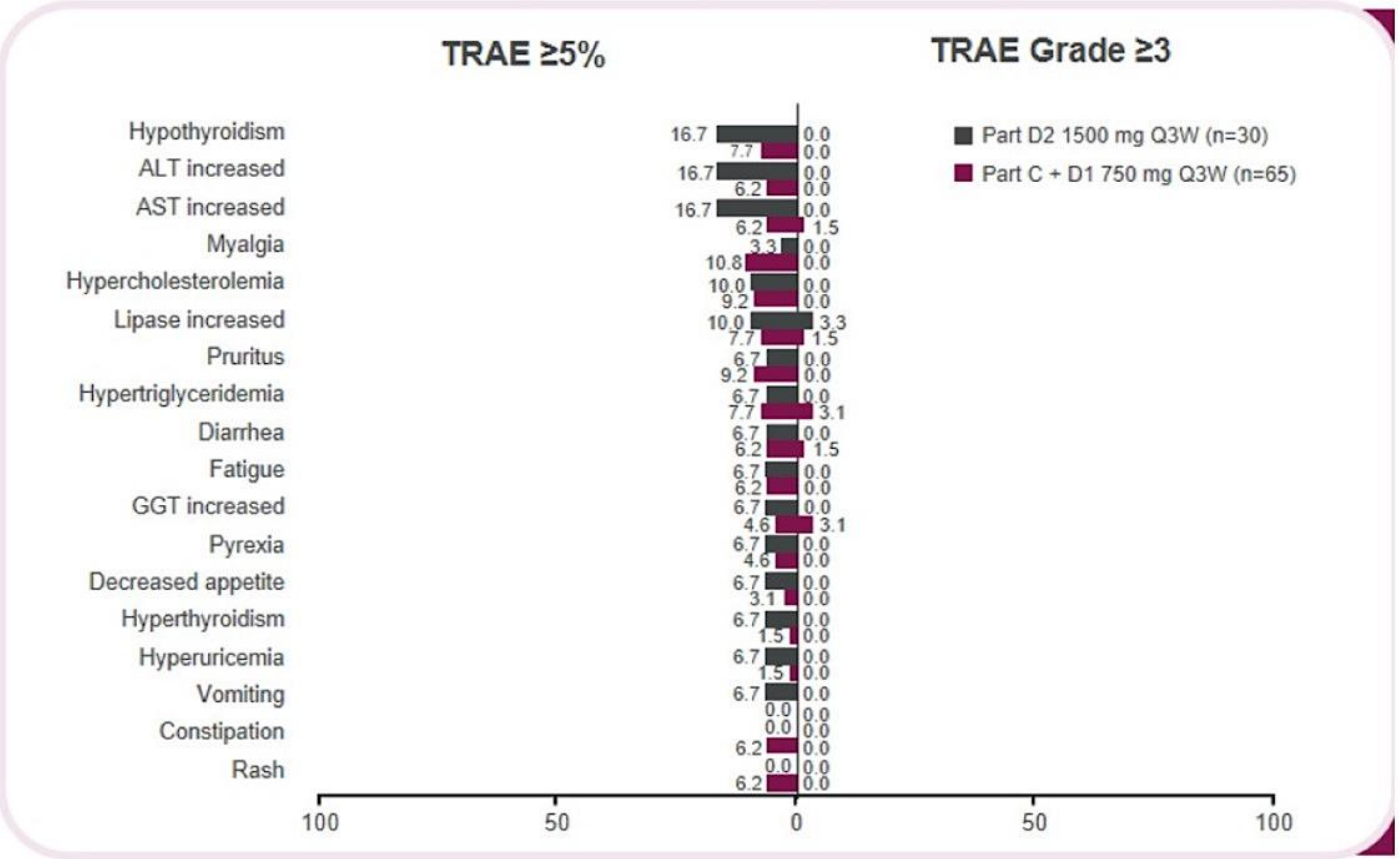


n (%)	PD-L1 1–49% TPS (n=31)	PD-L1 ≥50% TPS (n=34)
ORR, confirmed + pending [95% CI]	**9 (29.0)** [14.2–48.0]	**21 (61.8)** [43.6–77.8]
Continuing treatment	12 (38.7)	24 (70.6)

4 patients with PD-L1 ≥50% pending confirmation.

Hiltermann et al., WCLC 2024

Rilvegostomig: Toxicity



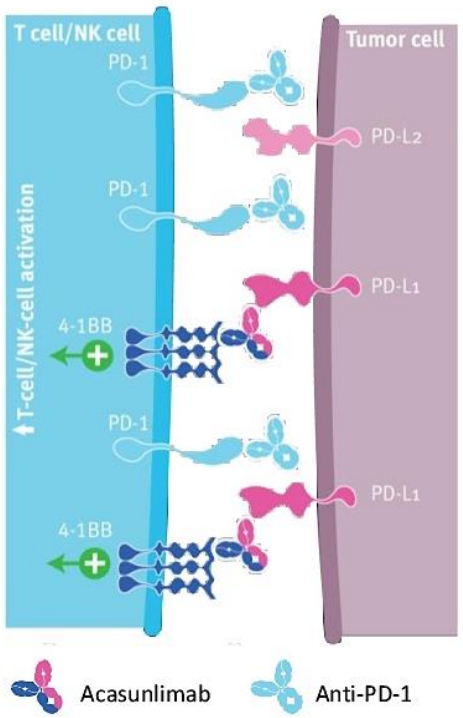
- No clear difference in safety profile between 750mg and 1500mg
- Very few grade 3 toxicities
- No grade 4 or 5 TRAEs reported
- Low rate of treatment discontinuation due to toxicity (4.2%)

Hiltermann et al., WCLC 2024

Rilvegostomig: Ongoing Trials

Trial	Phase	Treatment Line	Regimen
ARTEMIDE-Lung02	III	1L	Rilvegostomig vs Pembrolizumab plus Chemotherapy for mNSCLC (squamous)
ARTEMIDE-Lung03	III	1L	Rilvegostomig vs Pembrolizumab plus Chemotherapy for mNSCLC (non-squamous)
ARTEMIDE-Lung 04	III	1L	Rilvegostomig vs Pembrolizumab monotherapy for PD-L1-high mNSCLC
TROPION-Lung 12	III	Adjuvant, Stage I	Dato-DXd + Rilvegostomig or Rilvegostomig monotherapy vs standard of care, following R0 resection in stage I adenocarcinoma of the lung (ctDNA-positive or high-risk pathologic features)
TROPION-Lung 10	III	1L	Dato-DXd + Rilvegostomig or Rilvegostomig monotherapy vs pembrolizumab for mNSCLC (non-squamous) with high PD-L1 expression

Phase II Study of Acasunlimab with or without Pembrolizumab for Previously Treated Metastatic NSCLC



GCT1046-04 PLANNED STUDY DESIGN

Phase 2, multicenter, randomized, open-label trial evaluating acasunlimab as monotherapy and in combination with pembro in patients with relapsed/refractory metastatic NSCLC after treatment with standard-of-care therapy with a CPI

Key inclusion criteria

- Age ≥18 years
- mNSCLC with disease progression after ≥1 prior anti-PD-(L)1 treatment
- Confirmed PD-L1 expression[a]
- ECOG PS 0–1
- Adequate hematologic and renal/hepatic function

Target N=126[b]

RANDOMIZED[c]

- **Acasunlimab 100 mg IV Q3W cycles 1–2, then 500 mg IV Q6W**
- **Acasunlimab 100 mg IV + pembro 200 mg IV Q3W**
- **Acasunlimab 100 mg IV + pembro 400 mg IV Q6W**

Treatment continued until

- Progressive disease, unacceptable toxicity, or other reason for discontinuation; or
- ≤35 doses (Q3W) or ≤18 doses (Q6W) of pembro

Primary endpoint: ORR by RECIST v1.1 per investigator

Key secondary endpoints: DOR, PFS, OS, AEs, laboratory abnormalities

Selected exploratory endpoints: PK, biomarkers

NCT05117242.
Enrollment was discontinued in the acasunlimab monotherapy group in October 2023 and in the acasunlimab + pembro Q3W group in February 2024; enrollment is ongoing in acasunlimab + pembro Q6W group. [a]Prior to cycle 1 day 1 with PD-L1 expression in ≥1% of tumor cells by a sponsor-designated central laboratory using the Dako PD-L1 IHC 22C3 pharmDx assay or by local assessment. [b]Including safety run-in for combination regimen cohorts, up to 40 centrally confirmed PD-L1+ patients per arm. [c]Randomization stratified by PD-L1 expression (1–49% vs ≥50% PD-L1+ tumor cells) and histology (squamous vs nonsquamous).

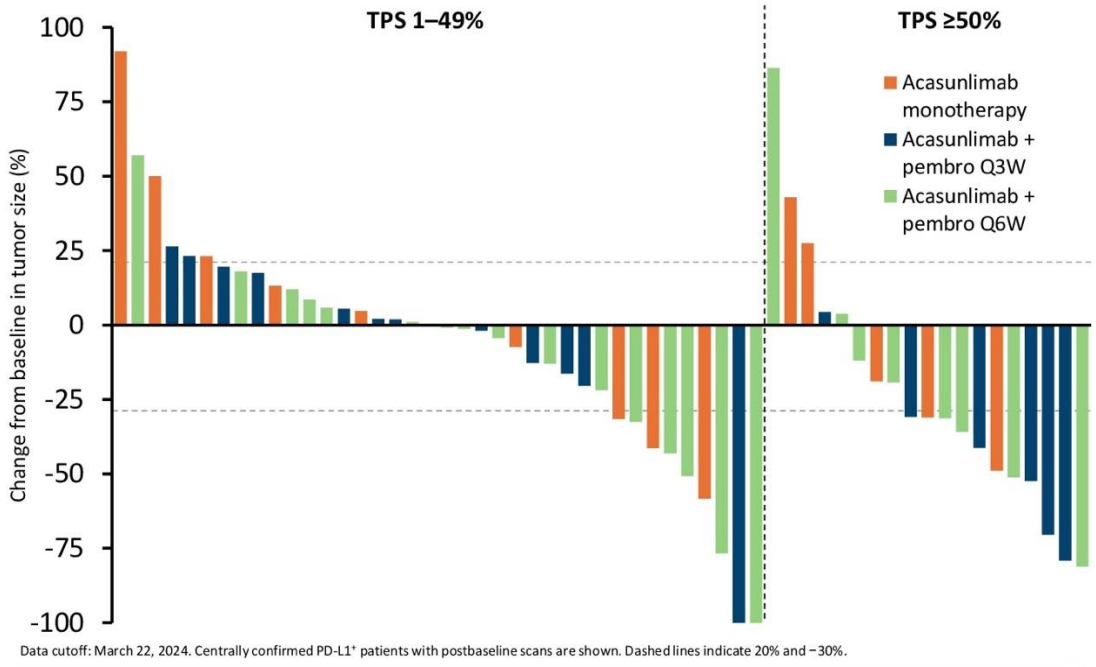
Aerts J et al. ASCO 2024;Abstract 2533.

Acasunlimab with or without Pembrolizumab: Efficacy by PD-L1 Status

	Acasunlimab Monotherapy (n=16)	Acasunlimab + Pembro Q3W (n=22)[a]	Acasunlimab + Pembro Q6W (n=24)[b]
Unconfirmed ORR, % (95% CI)	31.3 (11.0–58.7)	20.8 (7.1–42.2)	29.6 (13.8–50.2)
Confirmed ORR, % (95% CI)	12.5 (1.6–38.3)	18.2 (5.2–40.3)	16.7 (4.7–37.4)
Confirmed DCR, % (95% CI)	50.0 (24.7–75.3)	59.1 (36.4–79.3)	75.0 (53.3–90.2)
Median DOR, mo (95% CI)	2.0 (1.6–NR)	5.2 (3.5–NR)	NR (NR–NR)
6-month PFS rate, % (95% CI)	0 (NA)	14 (3–31)	34 (13–56)
12-month OS rate, % (95% CI)	30 (9–54)	26 (6–52)	69 (43–85)

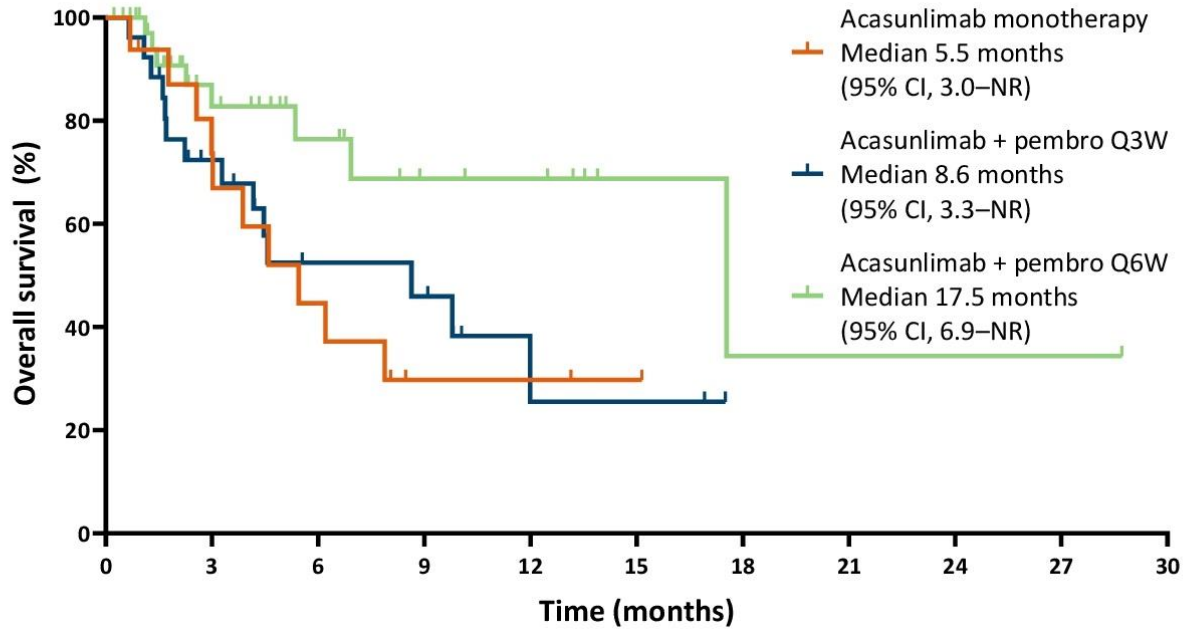
Data cutoff: March 22, 2024. Centrally confirmed PD-L1⁺ patients are shown.
[a]n=24 for unconfirmed ORR. [b]n=27 for unconfirmed ORR.

Anti-Tumor Activity by Treatment Group and Best Overall Response



Data cutoff: March 22, 2024. Centrally confirmed PD-L1⁺ patients with postbaseline scans are shown. Dashed lines indicate 20% and −30%.

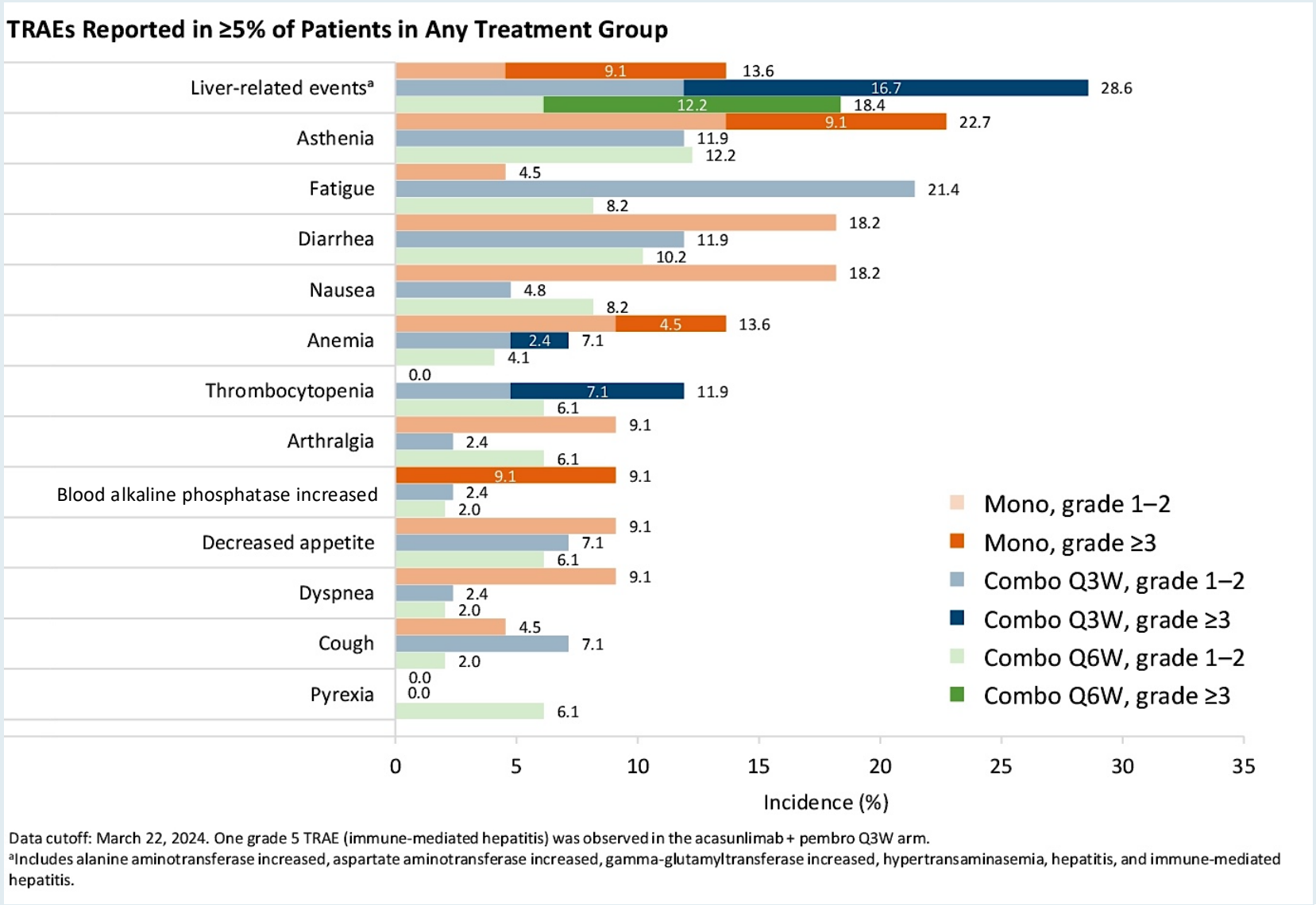
Kaplan–Meier Plot of OS in Patients With PD-L1⁺ mNSCLC



ORR = objective response rate; DCR = disease control rate; DOR = duration of response; PFS = progression-free survival; OS = overall survival; TPS = tumor proportion score

Aerts J et al. ASCO 2024;Abstract 2533.

Acasunlimab with or without Pembrolizumab: Safety



Data cutoff: March 22, 2024. One grade 5 TRAE (immune-mediated hepatitis) was observed in the acasunlimab + pembro Q3W arm.

[a]Includes alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyltransferase increased, hypertransaminasemia, hepatitis, and immune-mediated hepatitis.

TRAEs = treatment-related adverse events

Aerts J et al. ASCO 2024;Abstract 2533.

Ongoing Phase III ABBIL1TY NSCLC-06 Trial Schema

ABBIL1TY

Screening
Up to 28 days

Randomized 1:1
(N=702)

Stratification factors:
Tumor PD-(L)1 expression level, tumor histology, ECOG PS, sequence of prior line of therapy in the metastatic setting

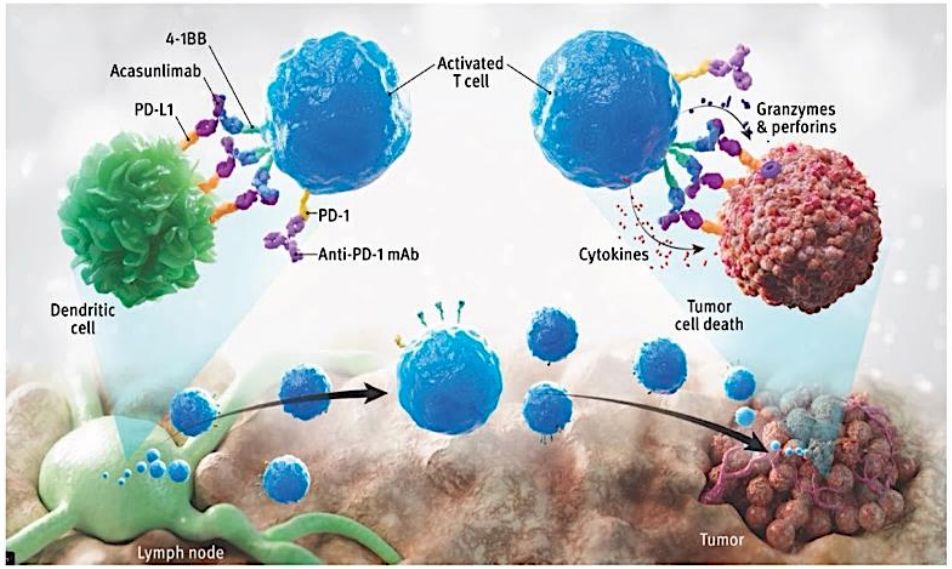
Arm A[a]
Acasunlimab (100 mg) Q6W
+
Pembro (400 mg) Q6W

Arm B[b]
Docetaxel
(75 mg/m^2) Q3W

Trial Endpoints

Primary Endpoint	• Overall survival
Secondary Endpoints	• Progression-free survival per RECIST v1.1 as assessed by the investigator • Confirmed objective response rate per RECIST v1.1 as assessed by the investigator • Duration of response • Occurrence of AEs • Time to treatment discontinuation due to an AE • Pharmacokinetic assessments and anti-drug antibodies associated with acasunlimab • Patient perspective on symptom burden and treatment impact per FACIT-GP5 and PRO-CTCAE
Exploratory Endpoints	• Time to deterioration and change from baseline in global health status • Biomarkers

Proposed Mechanism of Action of Acasunlimab in Combination With Anti–PD-1 Immunotherapy



Trial Objective

Evaluate acasunlimab in combination with pembro vs docetaxel in patients with PD-L1+ mNSCLC after progression on PD-(L)1-inhibitor and platinum-based chemotherapy

Trial Overview

- Randomized Phase 3
- Patients: Stage 4 mNSCLC
- Primary Endpoint: OS
- Treatment: Acasunlimab + Pembro vs Docetaxel
- Enrolling Globally in 13 Countries

Paz-Ares L et al. ELCC 2025;Abstract 128TiP.

QUESTIONS?

RTP Year in Review 2025

Year in Review:
Nontargeted Approaches for Lung Cancer

INTRODUCTION: The Boards

MODULE 1: Immune Checkpoint Inhibition for Localized Non-Small Cell Lung Cancer (NSCLC)

MODULE 2: Immunotherapy for Metastatic NSCLC

MODULE 3: Antibody-Drug Conjugates

MODULE 4: Novel Bispecific Antibodies

MODULE 5: Journal Club with Dr Levy

RTP Year in Review 2025

nature medicine

Article

https://doi.org/10.1038/s41591-023-02598-9

ctDNA response after pembrolizumab in non-small cell lung cancer: phase 2 adaptive trial results

Received: 14 March 2023

Accepted: 19 September 2023

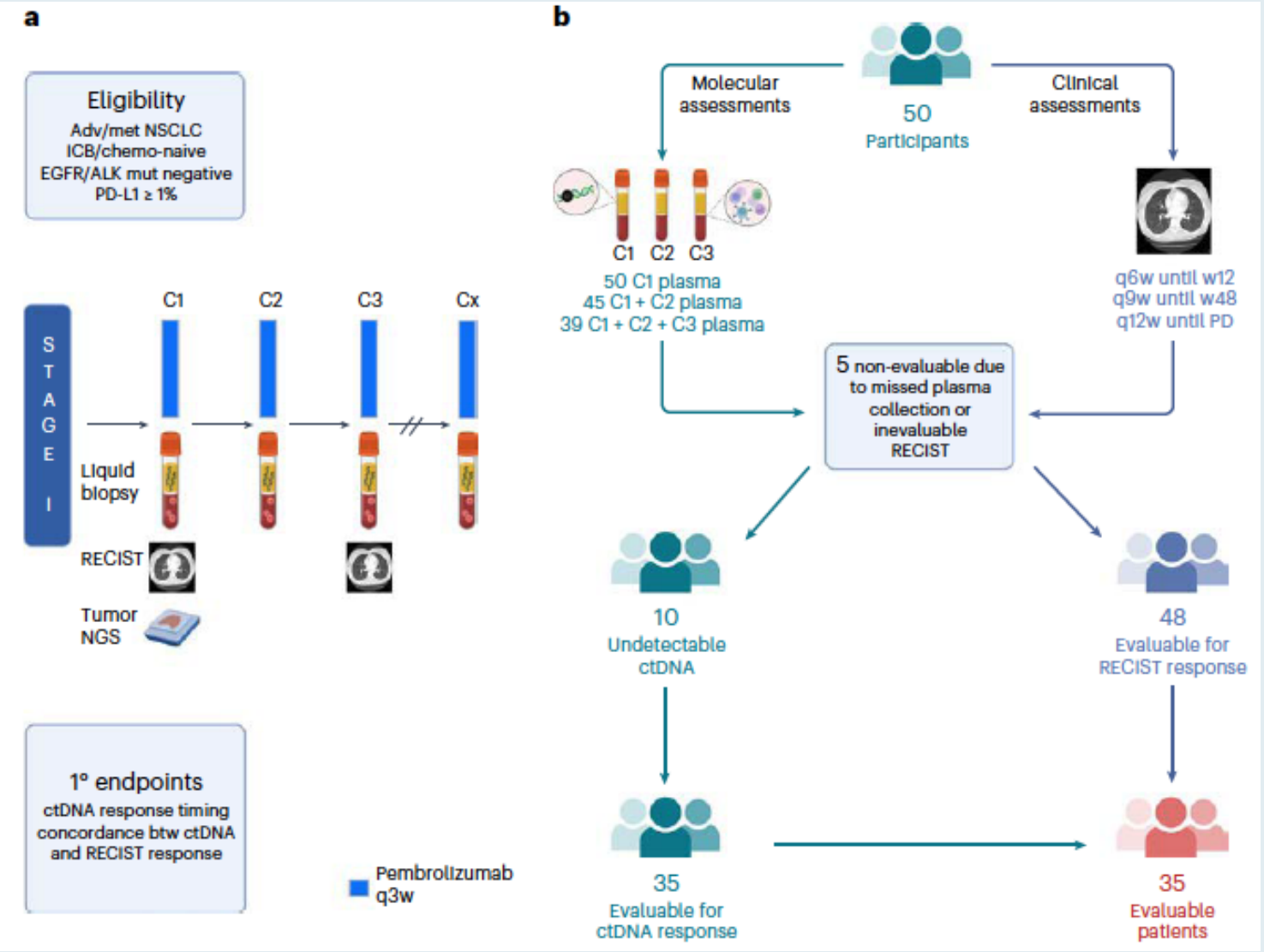
Published online: 9 October 2023

Valsamo Anagnostou[1,2], Cheryl Ho[3], Garth Nicholas[4], Rosalyn Anne Juergens[5], Adrian Sacher[6], Andrea S. Fung[7], Paul Wheatley-Price[4], Scott A. Laurie[4], Benjamin Levy[1], Julie R. Brahmer[1,2], Archana Balan[1], Noushin Niknafs[1], Egor Avrutin[8], Liting Zhu[8], Mark Sausen[9], Penelope A. Bradbury[6], Jill O'Donnell-Tormey[10], Pierre Olivier Gaudreau[8], Keyue Ding[8] & Janet Dancey[8]

2023;29(10):2559-69.

BR36 Trial Schema

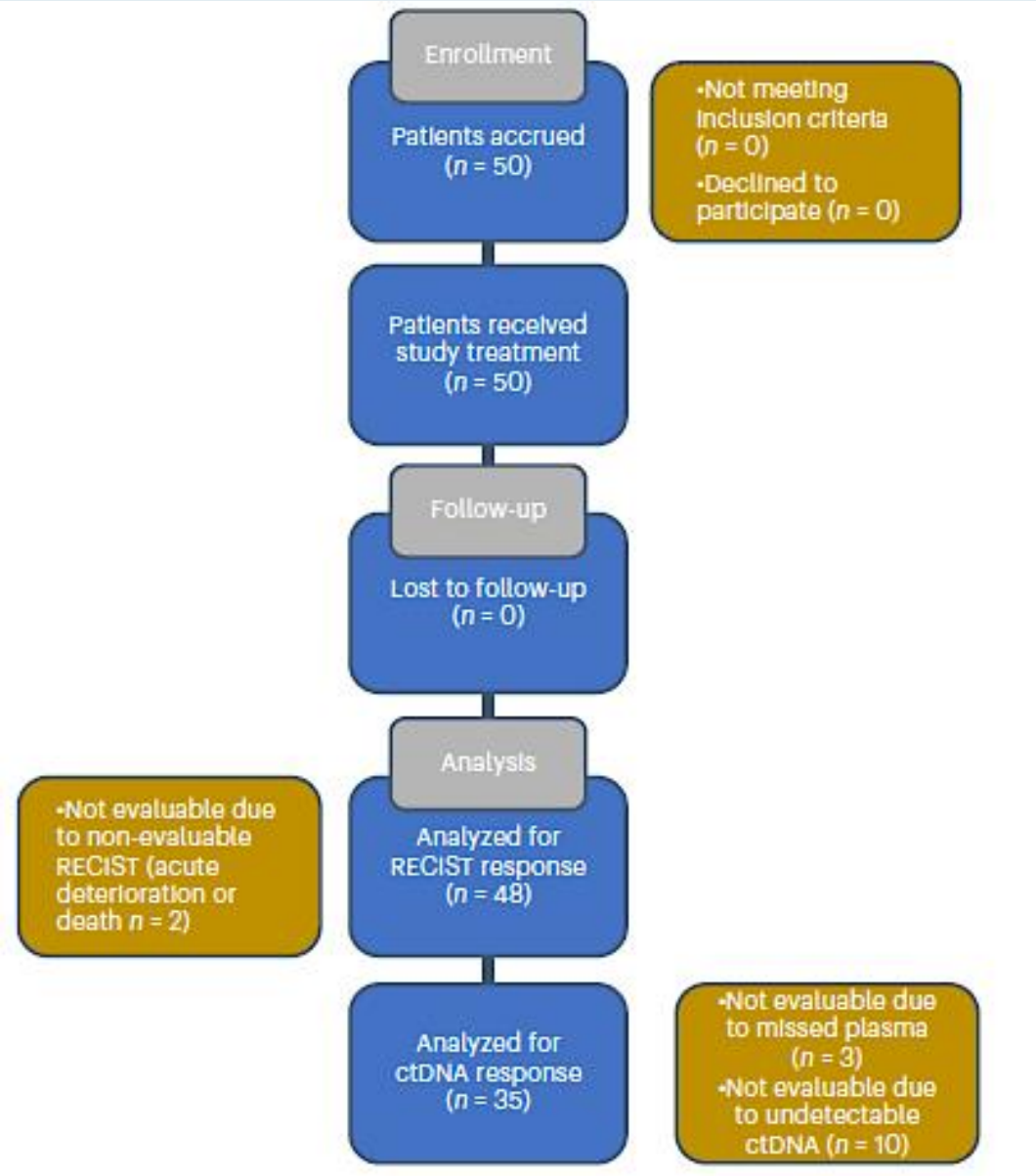
First stage



Target enrollment of 50 patients reached

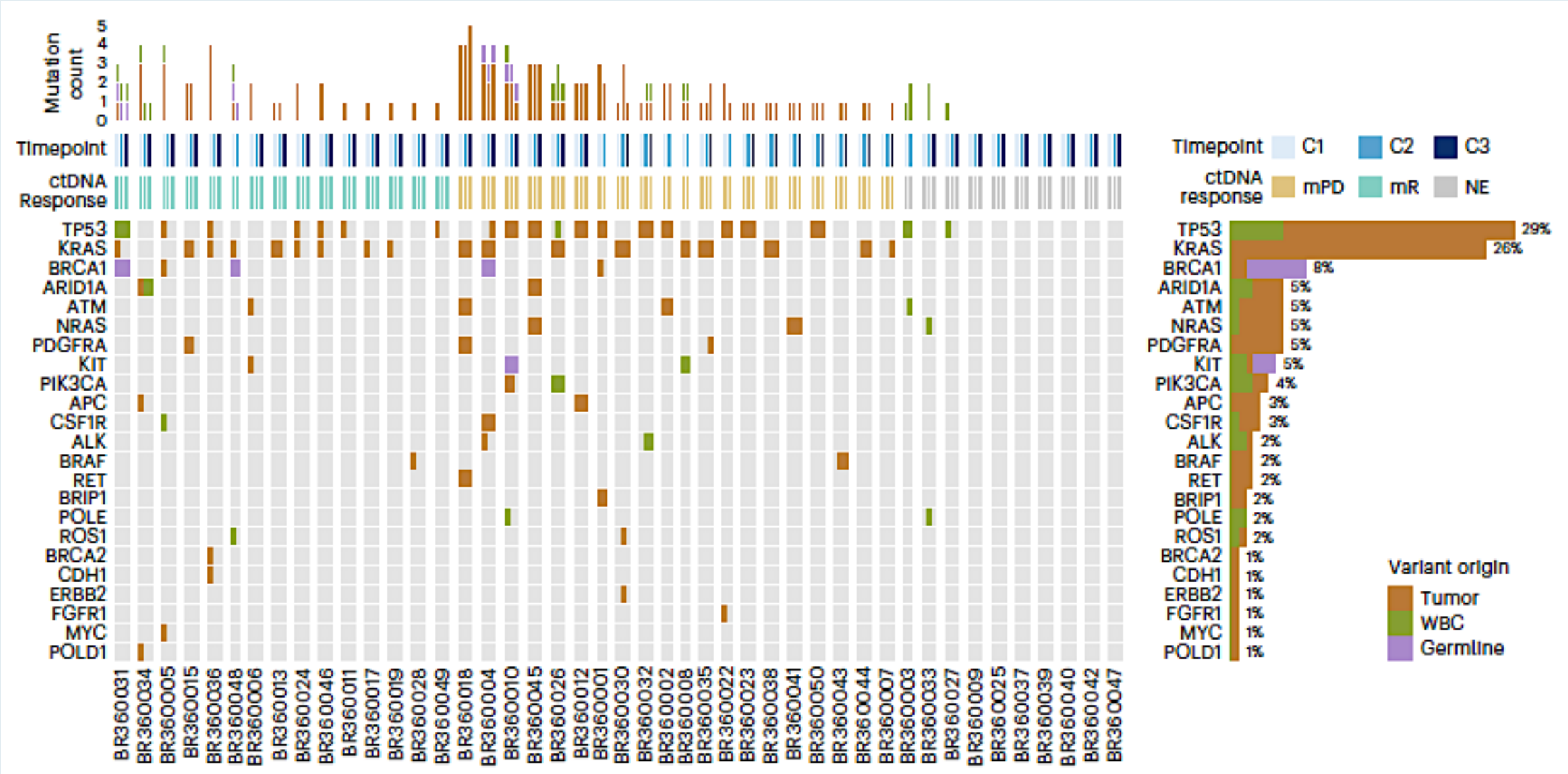
Anagnostou V et al. *Nat Med* 2023;29(10):2559-69.

BR36 Consort Flow Diagram



Anagnostou V et al. *Nat Med* 2023;29(10):2559-69.

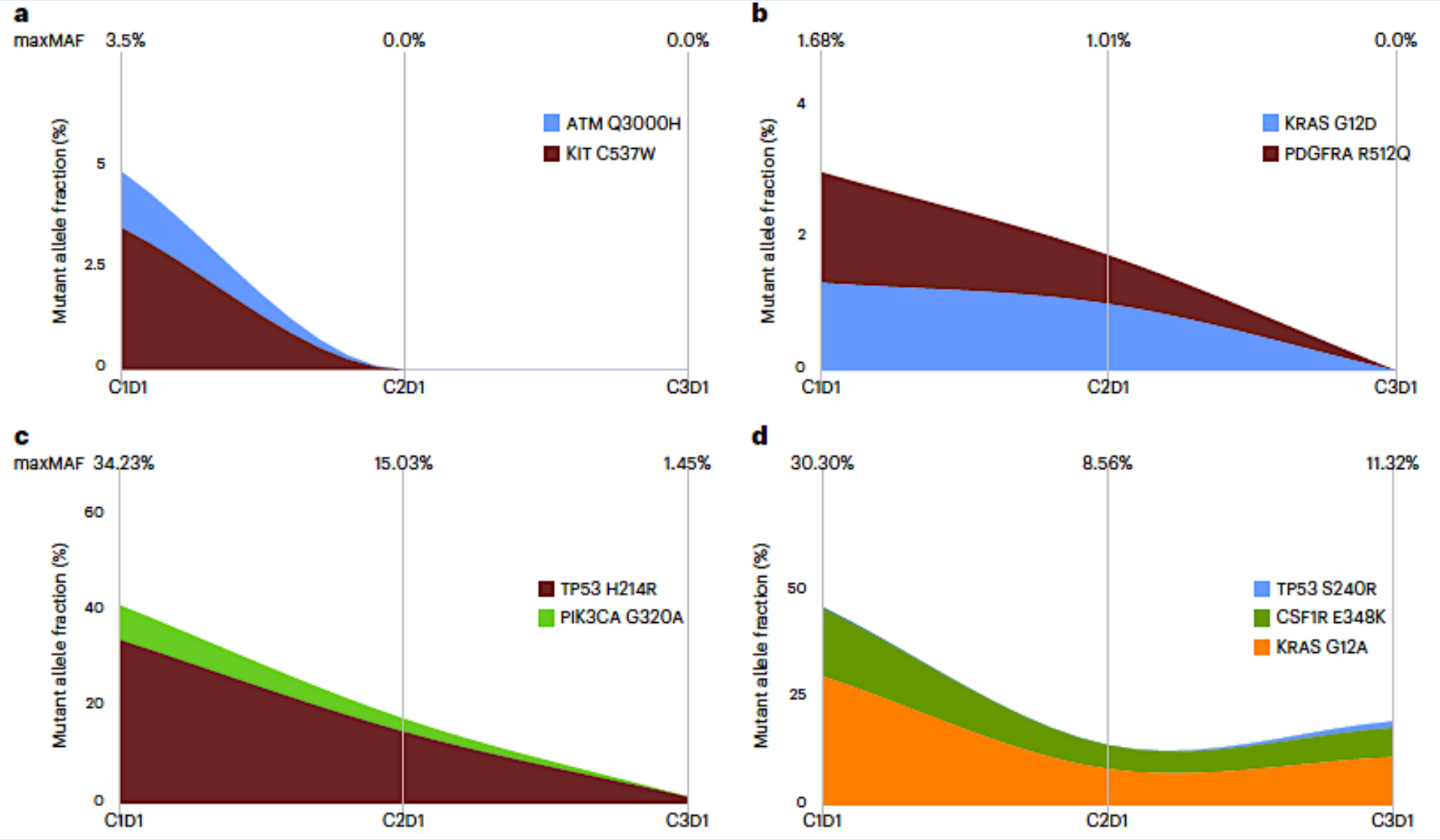
Overview of Plasma Variants Detected by Next-Generation Sequencing



ctDNA = circulating tumor DNA

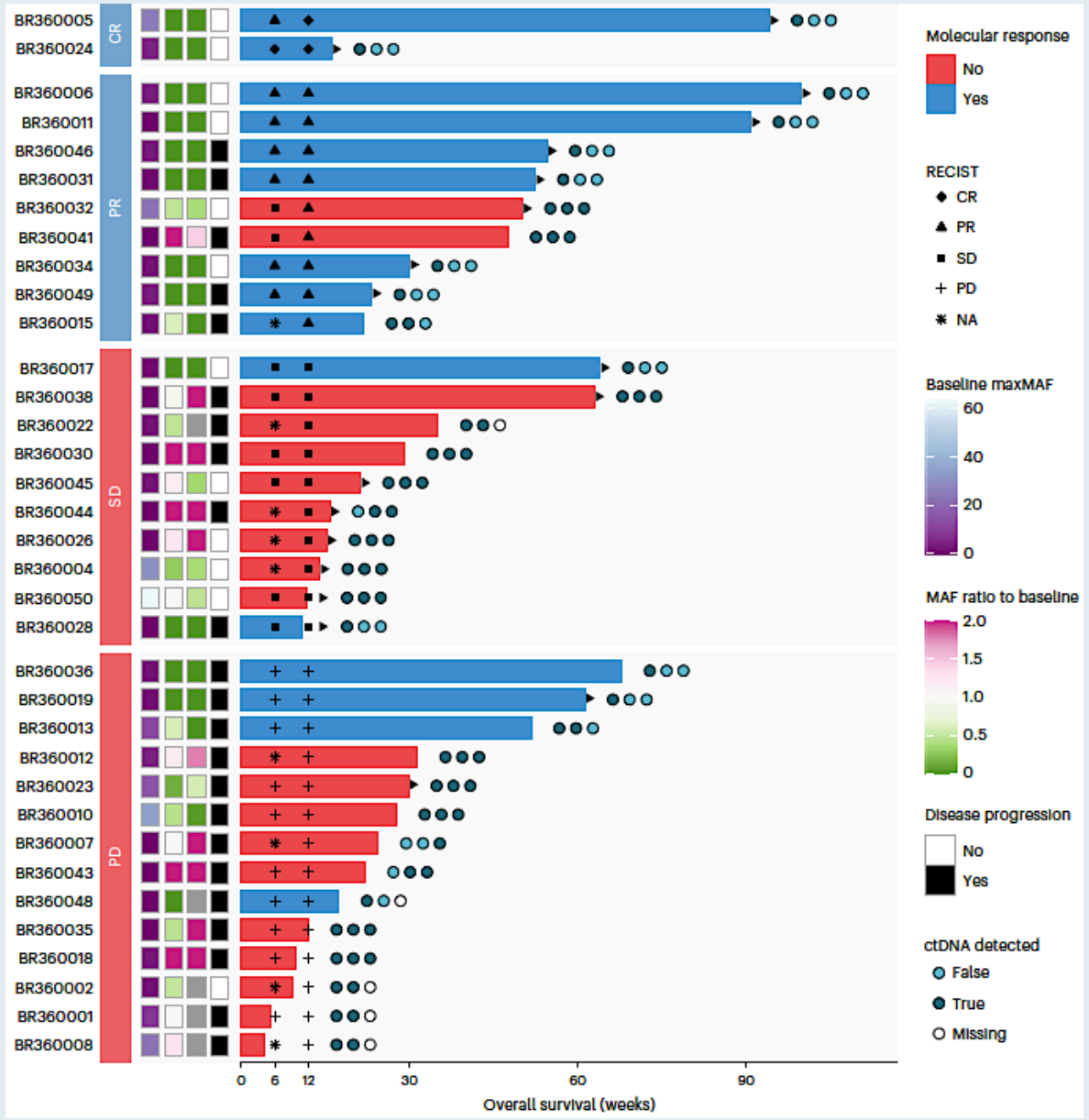
Anagnostou V et al. *Nat Med* 2023;29(10):2559-69.

Representative ctDNA Kinetics Patterns



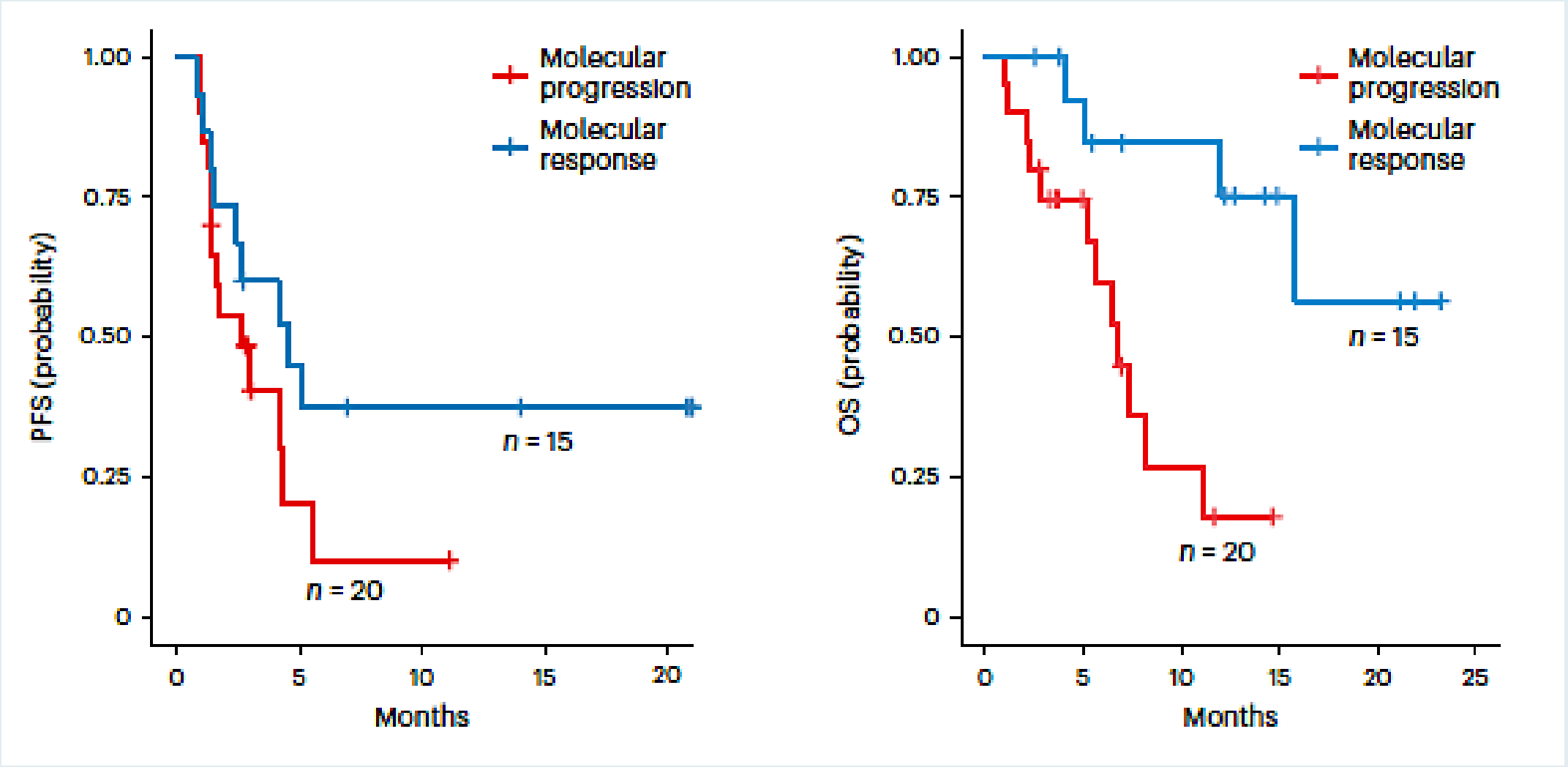
Anagnostou V et al. *Nat Med* 2023;29(10):2559-69.

Radiographic Response Assessment, Molecular Response and OS



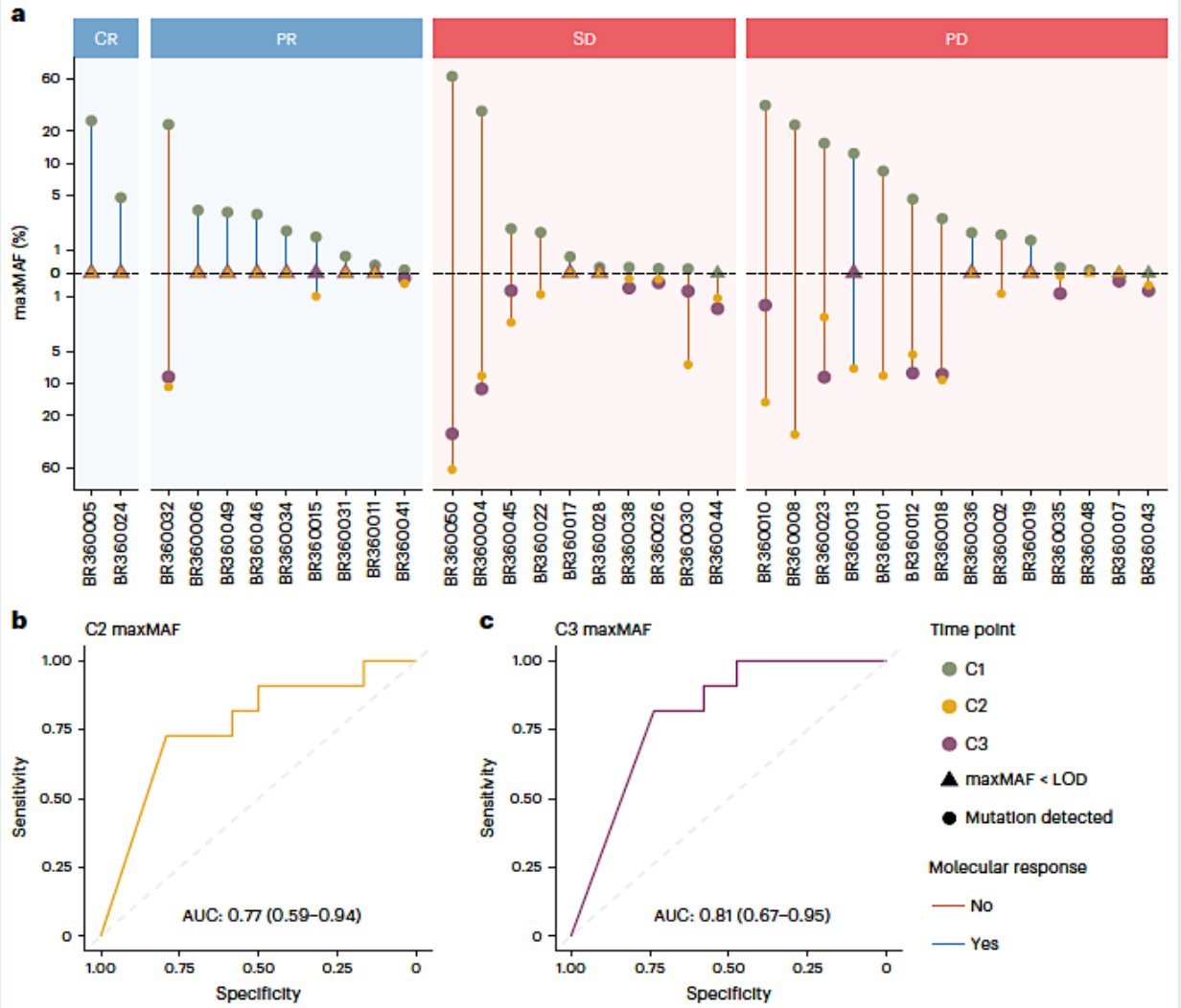
Anagnostou V et al. *Nat Med* 2023;29(10):2559-69.

PFS and OS for Patients with ctDNA Molecular Responses



Anagnostou V et al. *Nat Med* 2023;29(10):2559-69.

Depth of ctDNA Response in Association with RECIST Radiographic Response



maxMAF = maximal mutant allele fraction; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease

Anagnostou V et al. *Nat Med* 2023;29(10):2559-69.

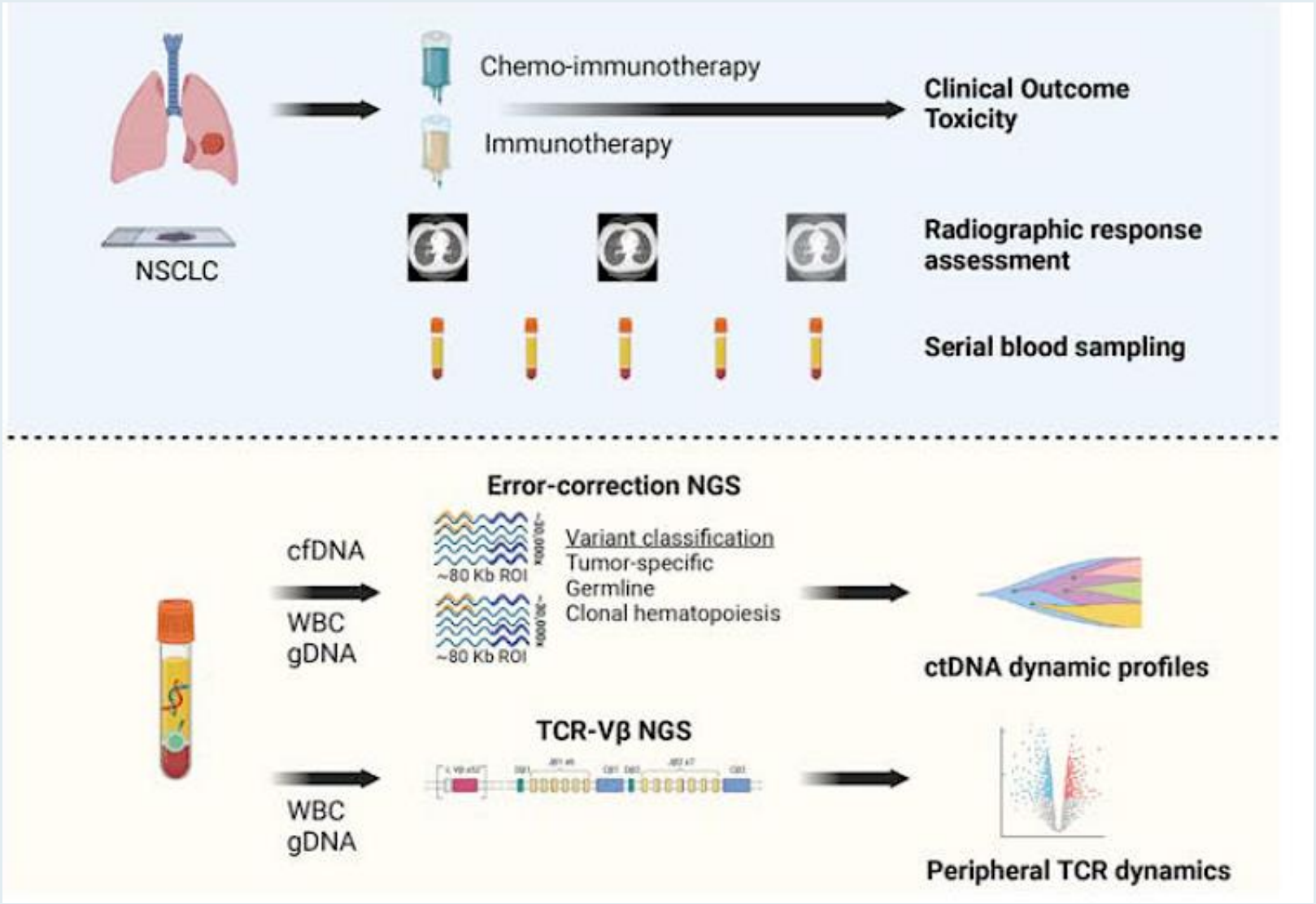
CLINICAL CANCER RESEARCH | PRECISION MEDICINE AND IMAGING

Elucidating the Heterogeneity of Immunotherapy Response and Immune-Related Toxicities by Longitudinal ctDNA and Immune Cell Compartment Tracking in Lung Cancer

Joseph C. Murray[1,2,3], Lavanya Sivapalan[1], Karlijn Hummelink[4], Archana Balan[1], James R. White[1], Noushin Niknafs[1], Lamia Rhymee[1], Gavin Pereira[1], Nisha Rao[1], Benny Weksler[5], Nathan Bahary[5], Jillian Phallen[1], Alessandro Leal[1], David L. Bartlett[5], Kristen A. Marrone[1,3], Jarushka Naidoo[1,6], Akul Goel[7], Benjamin Levy[1], Samuel Rosner[1], Christine L. Hann[1], Susan C. Scott[1], Josephine Feliciano[1], Vincent K. Lam[1], David S. Ettinger[1], Qing Kay Li[1,8], Peter B. Illei[1,8], Kim Monkhorst[4], Robert B. Scharpf[1], Julie R. Brahmer[1,2,3], Victor E. Velculescu[1], Ali H. Zaidi[5], Patrick M. Forde[1,2], and Valsamo Anagnostou[1,2,3]

2024;30(2):389-403.

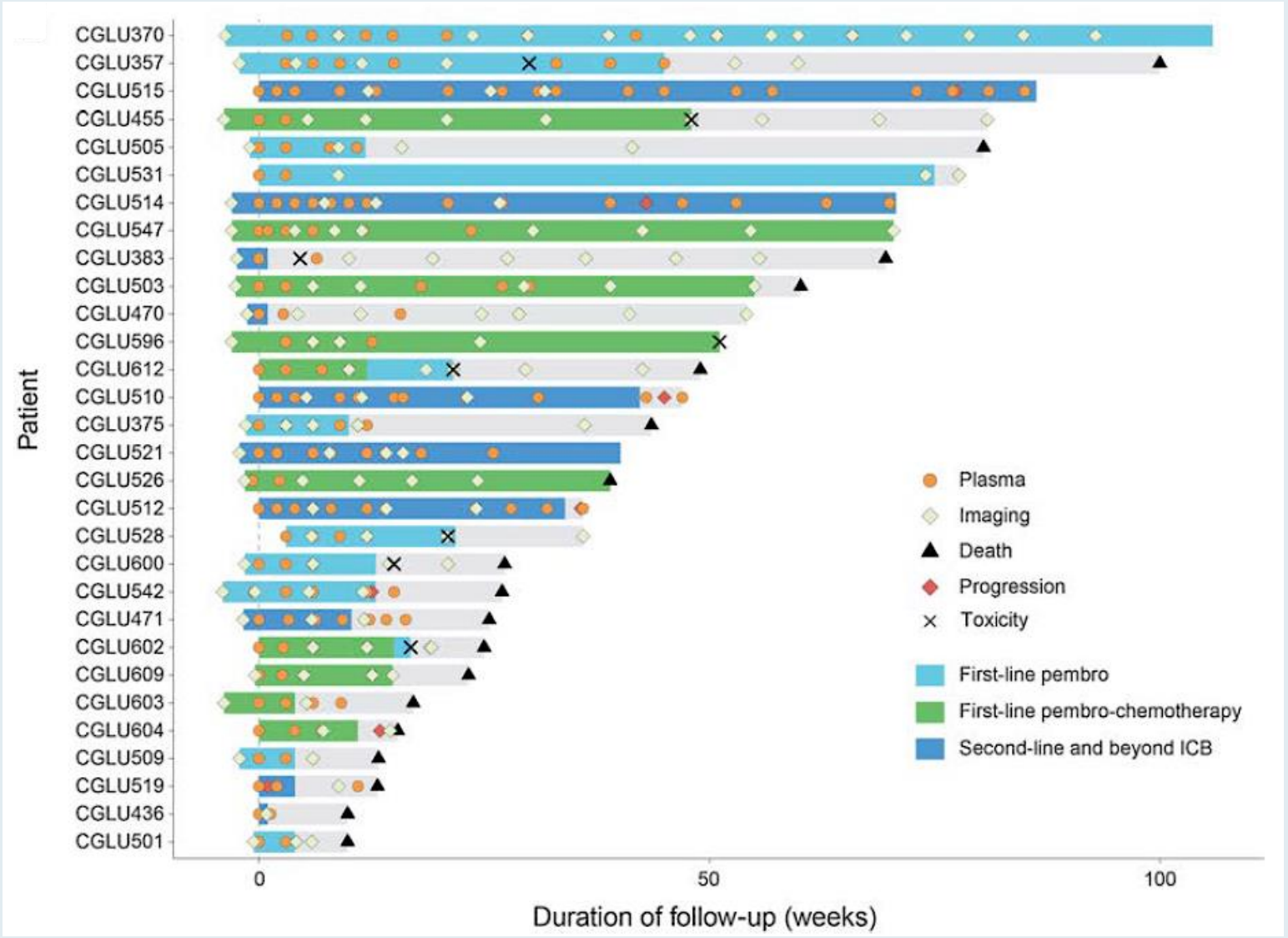
Overview of Study Methodology



NGS = next-generation sequencing

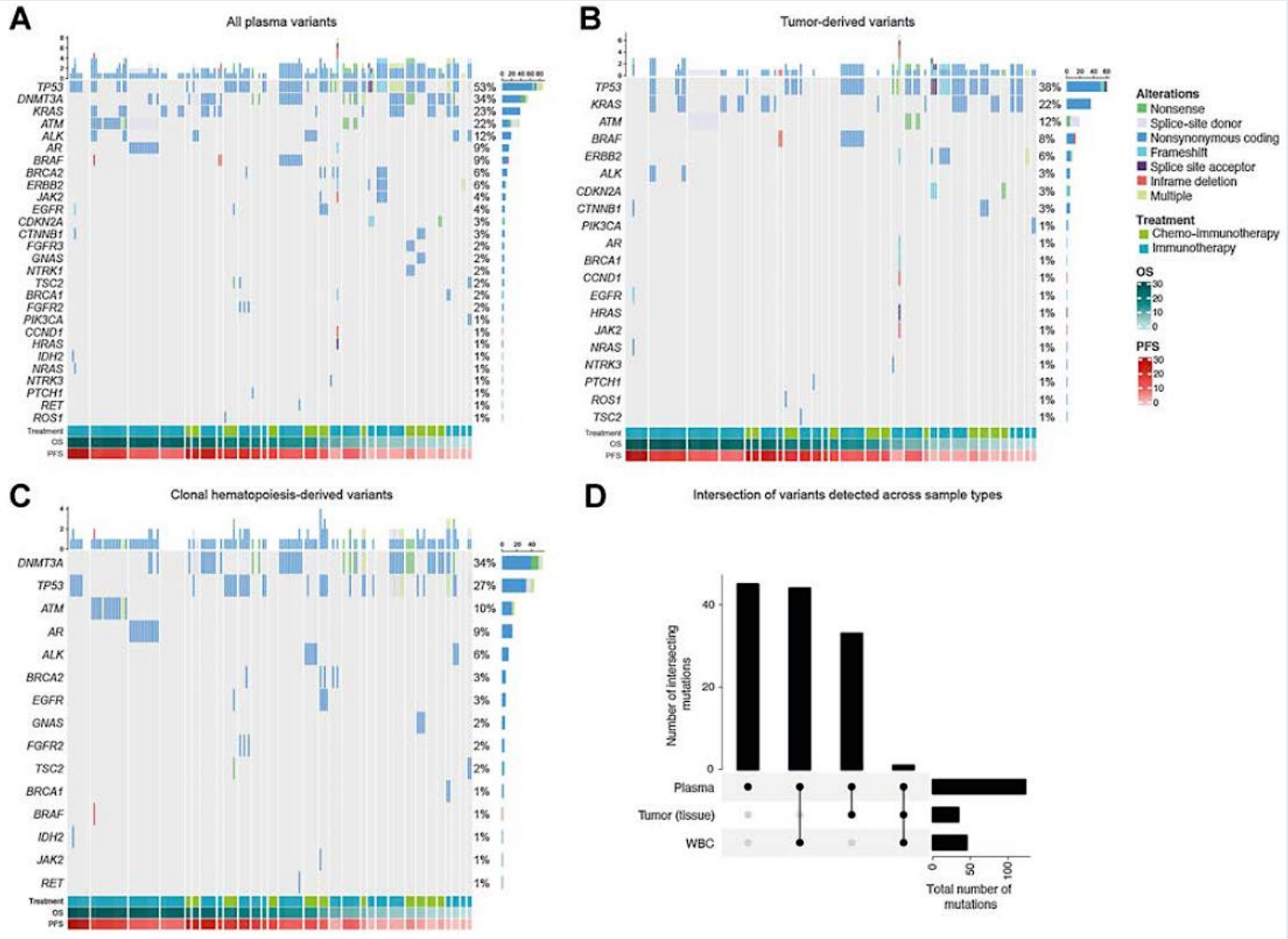
Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

Course of Disease for Each Patient



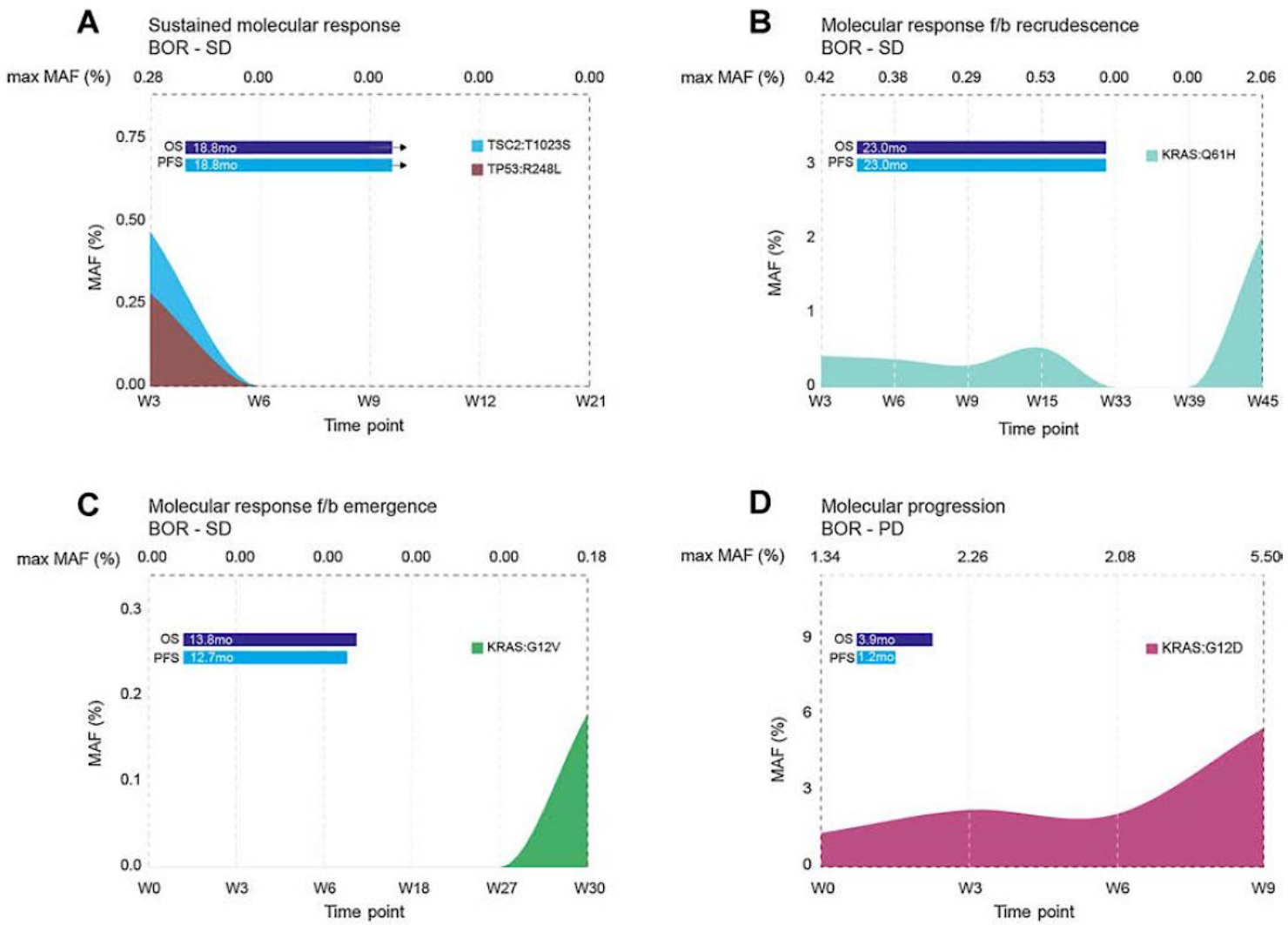
Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

Landscape of Variants Detected in Plasma



Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

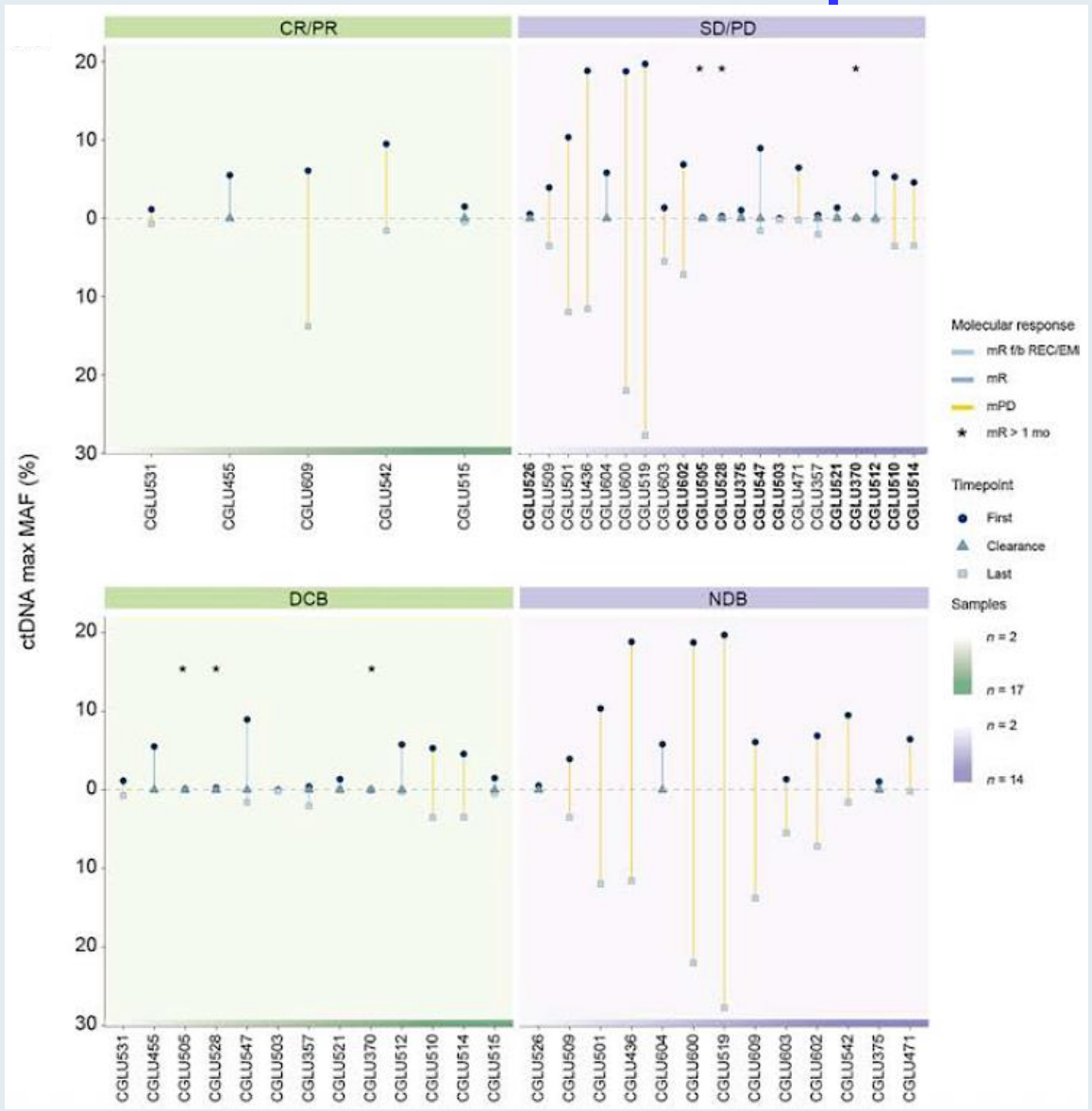
Longitudinal Cell-Free Tumor Load Dynamics and Molecular Response Classifications



BOR = best overall radiographic response

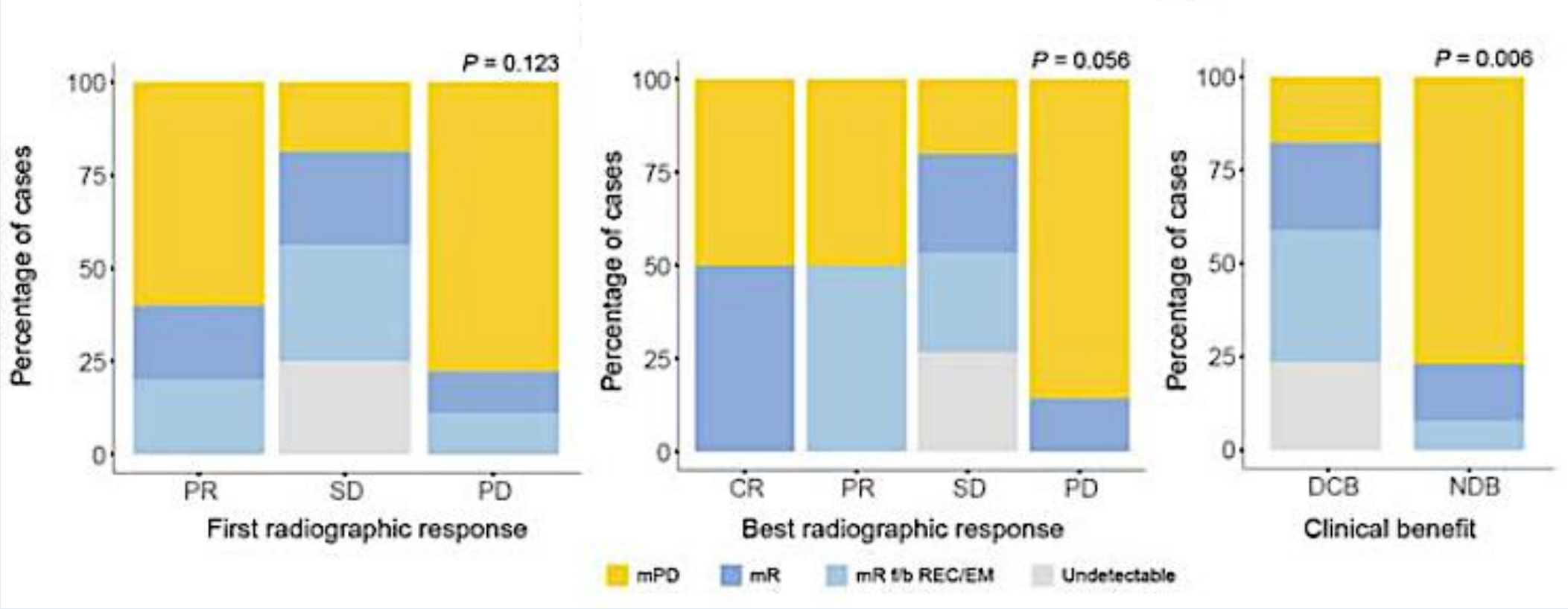
Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

Association Between ctDNA Maximum Mutant Allele Fraction (max MAF) Dynamics and Molecular Response



Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

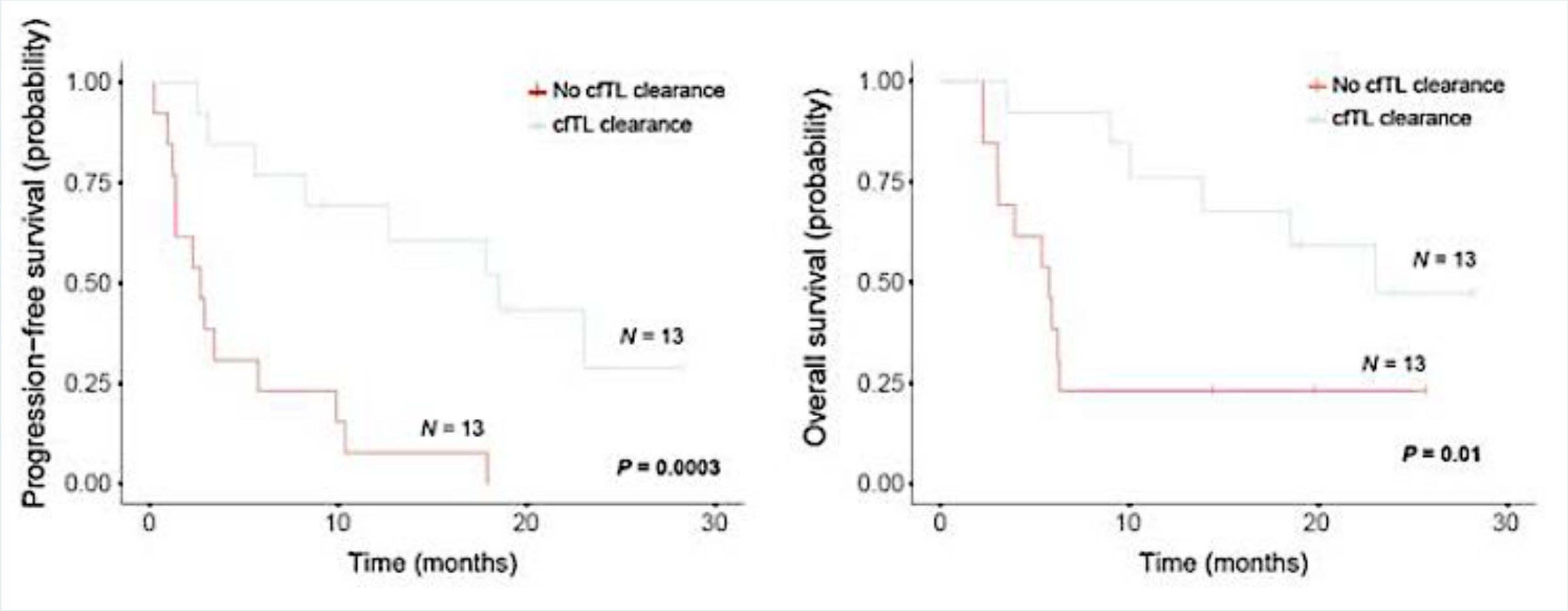
Association Between ctDNA Molecular Responses and Radiographic Response Assessments



DCB = durable clinical benefit; NDB = nondurable clinical benefit; mPD = molecular progressive disease; mR = molecular response; mR f/b REC/EM = mR followed by recrudescence/emergence

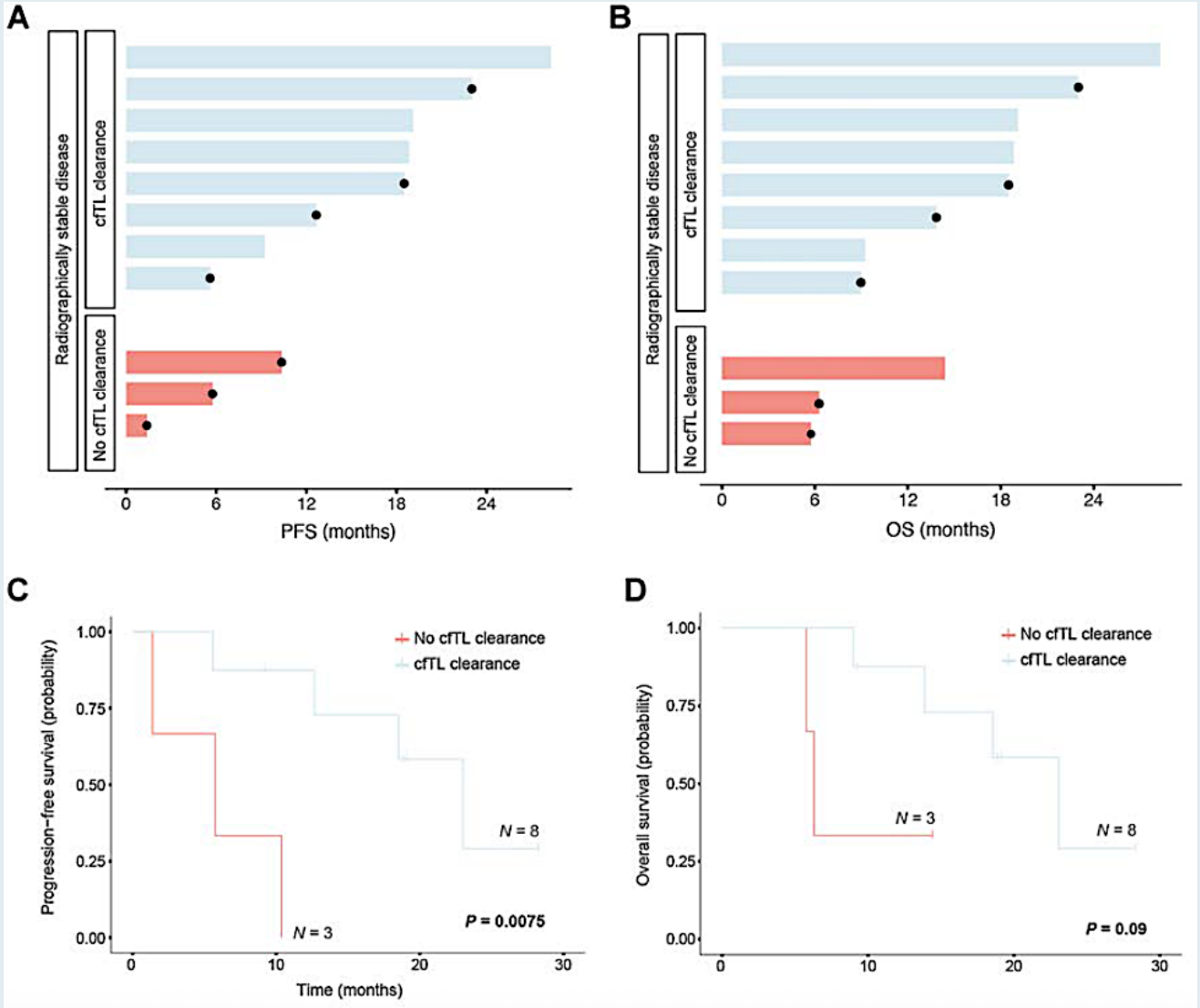
Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

Association Between Cell-Free Tumor Load (cfTL) Clearance and PFS and OS



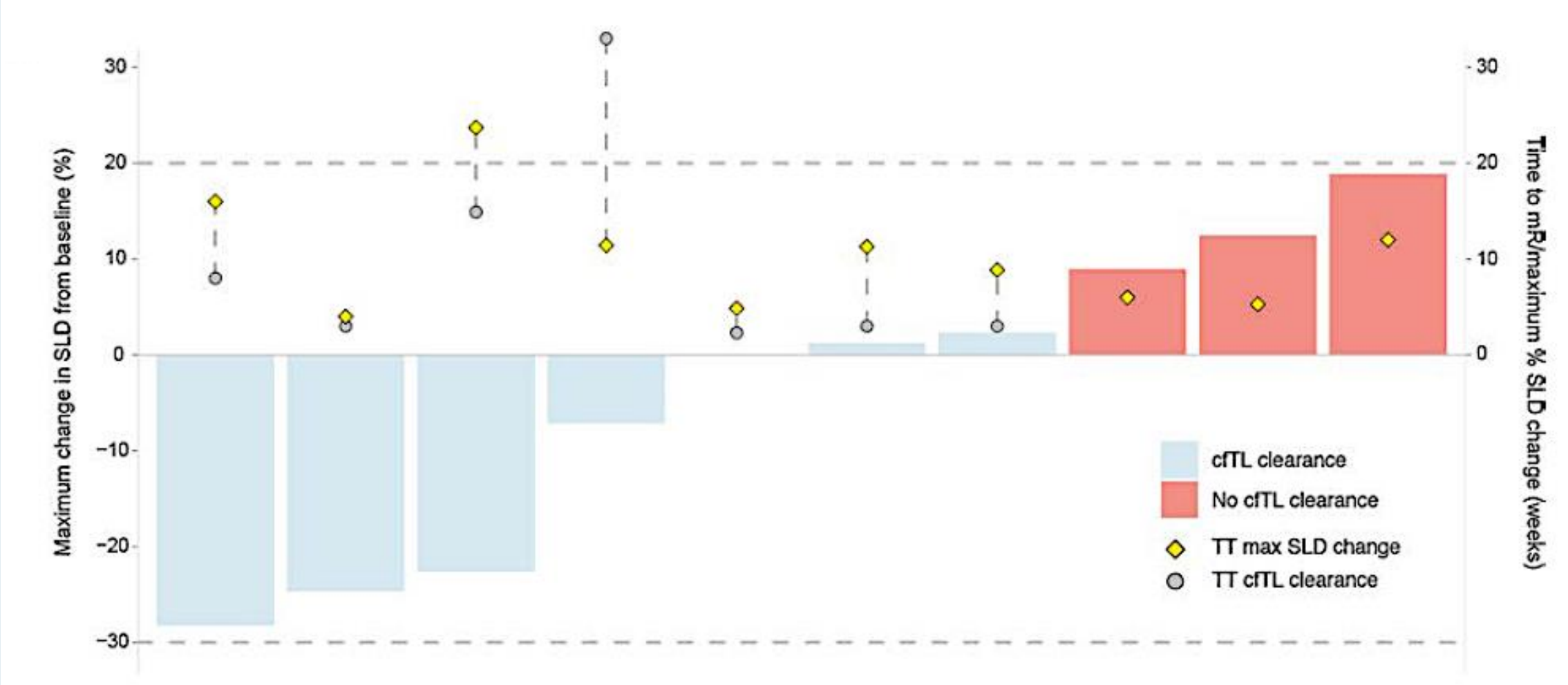
Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

Survival Outcomes in the Cohort of Patients with Radiographically Stable Disease



Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

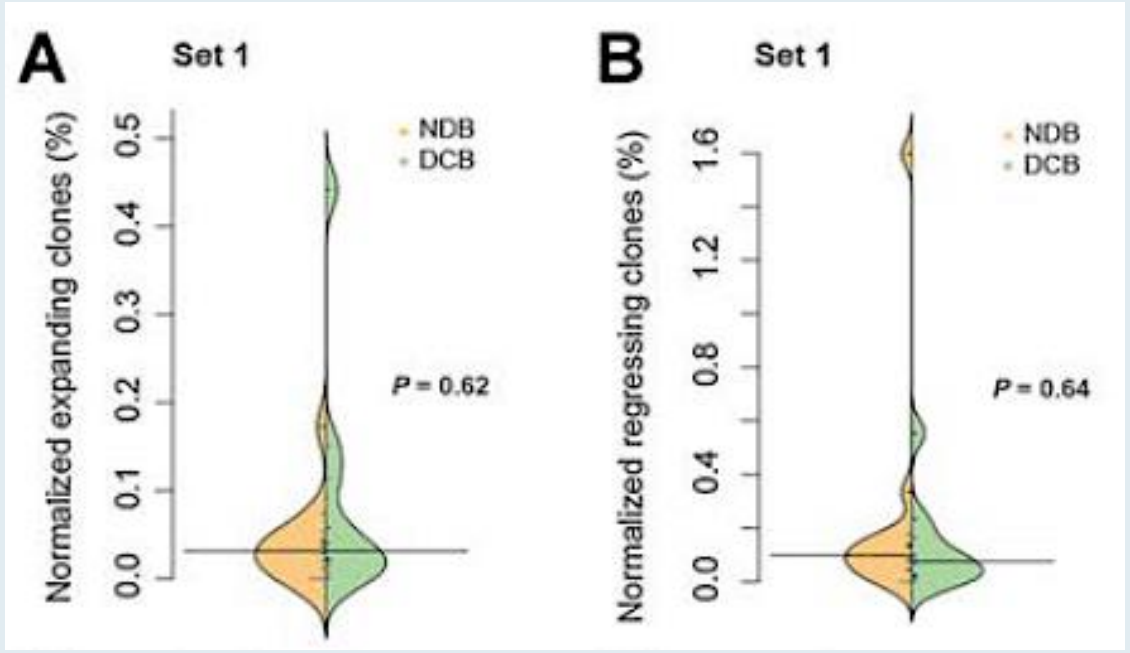
cfTL Clearance and Tumor Responses

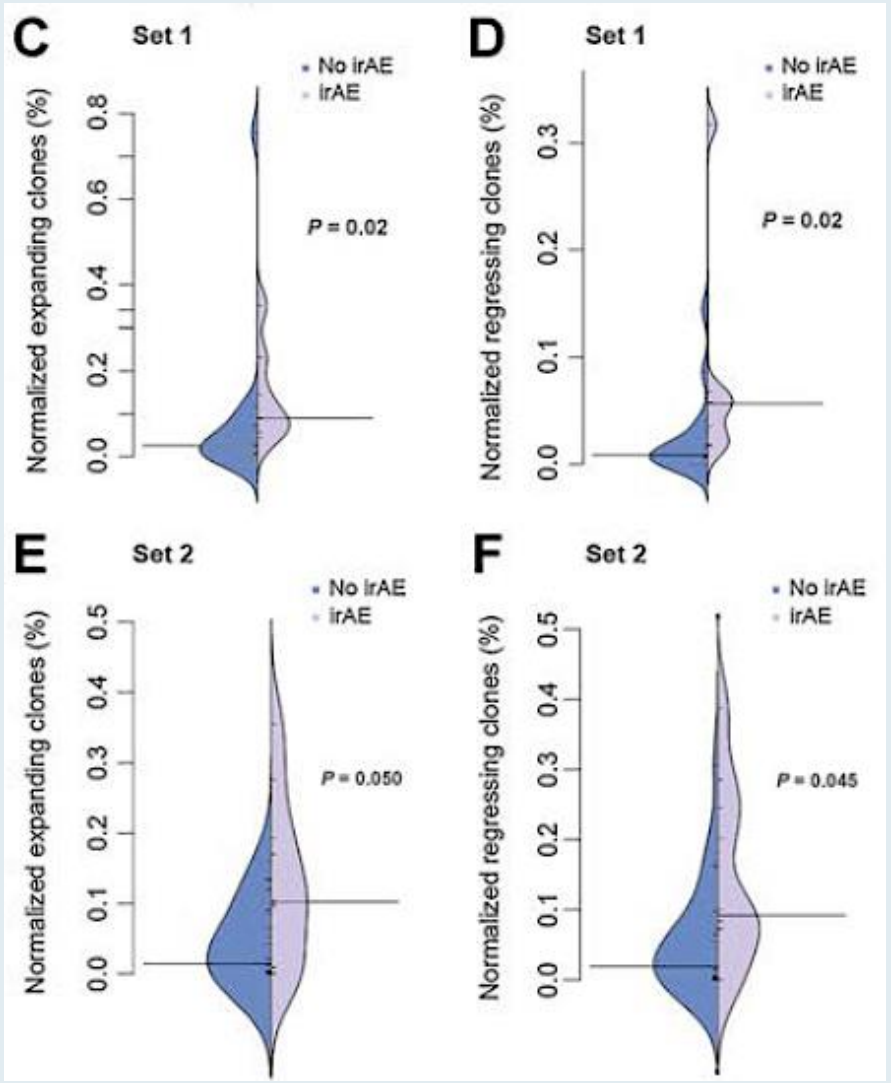


SLD = sum of tumor longest diameter; TT = time to

Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

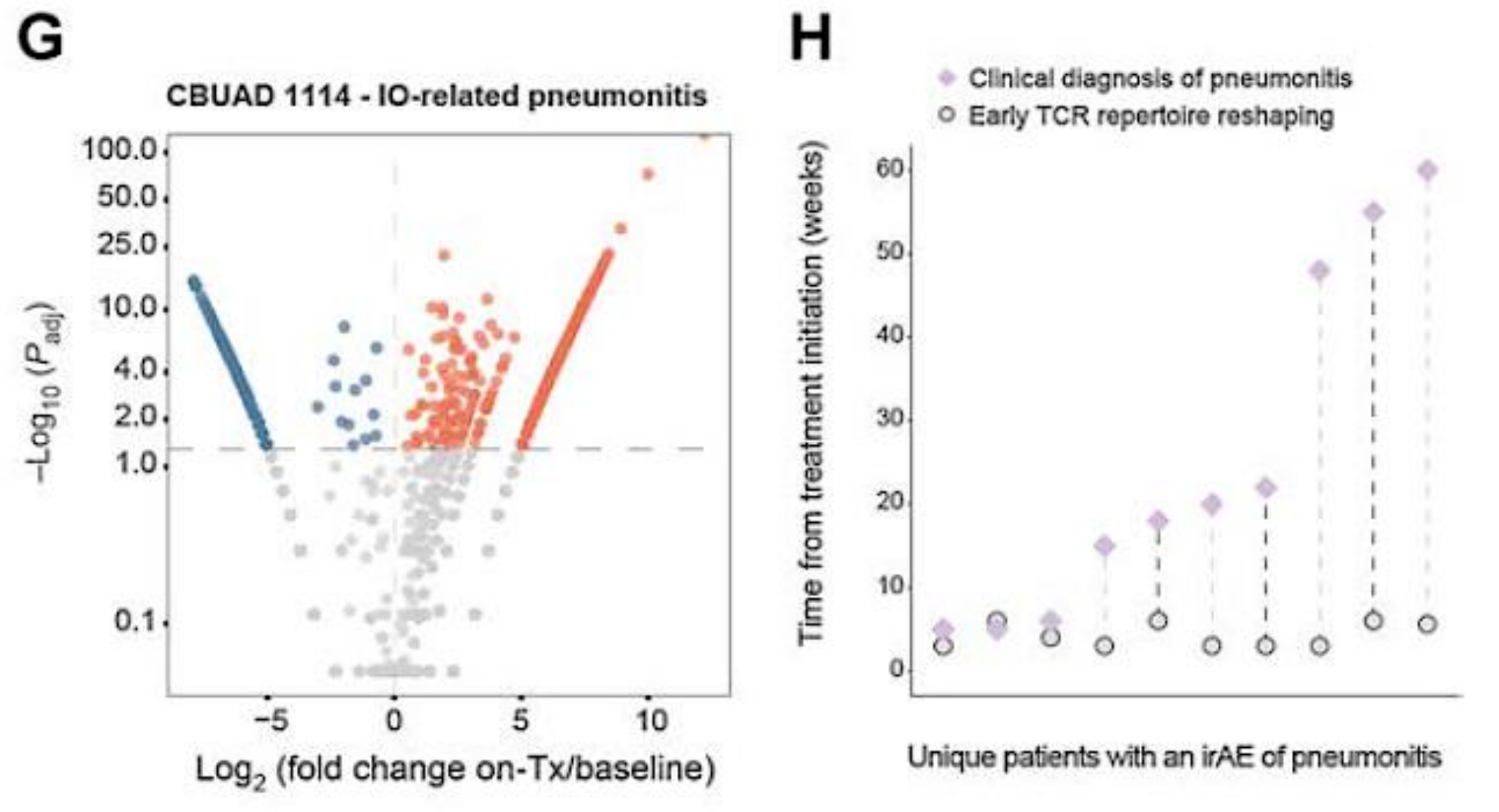
T-Cell Receptor Clonal Dynamics and Clinical Benefit and Development of Immune-Related Adverse Events (irAEs)





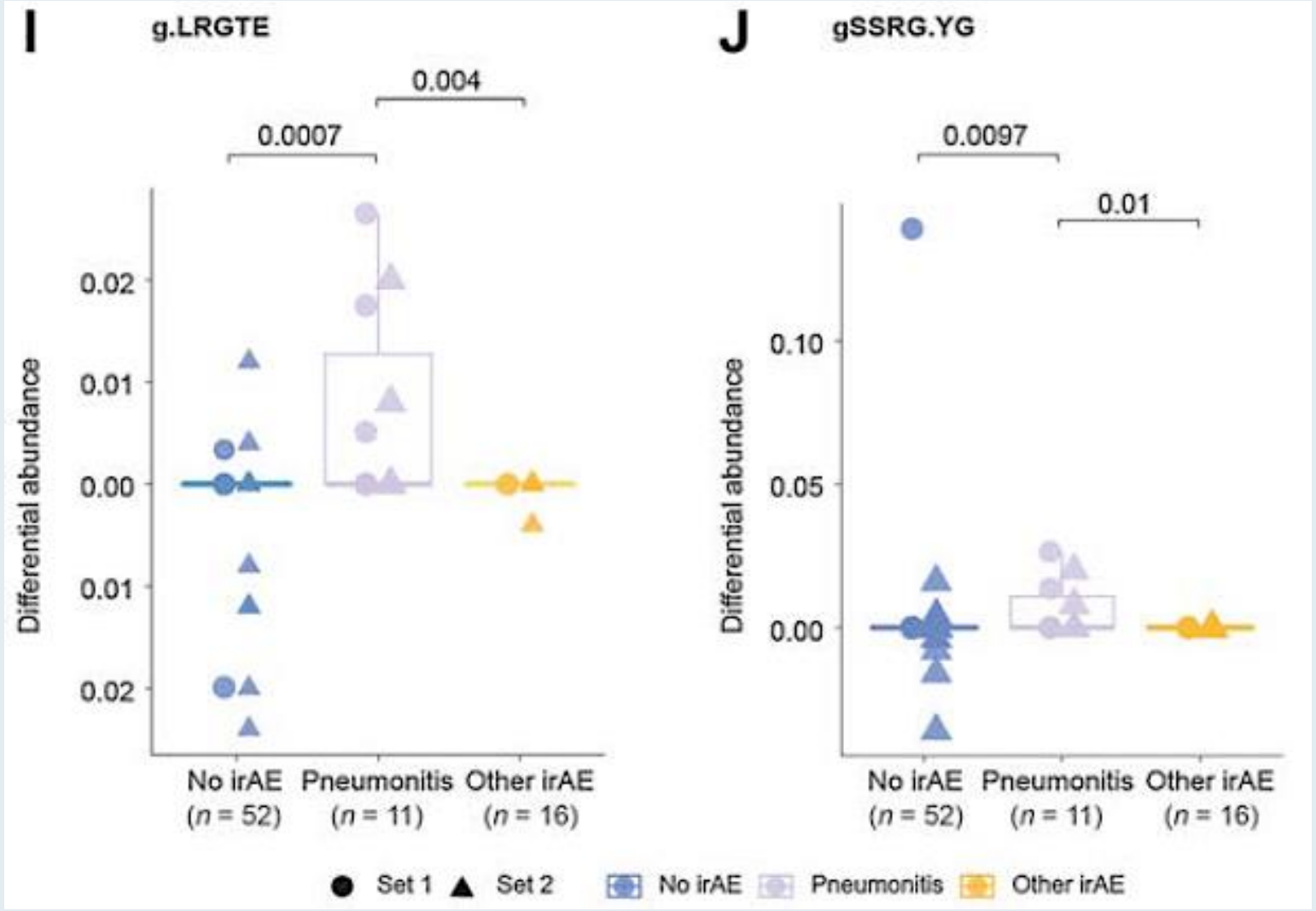
Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

T-Cell Receptor (TCR) Clonal Dynamics and Immunotherapy-Related Pneumonitis



Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

Examples of TCR Cluster Dynamics in Patients with Immune-Related Adverse Events



Murray JC et al. *Clin Cancer Res* 2024;30(2):389-403.

Optimizing the Selection of First-Line Therapy for Patients with Multiple Myeloma

A CME/MOC-Accredited Live Webinar

Tuesday, July 1, 2025
5:00 PM – 6:00 PM ET

Faculty

Xavier Leleu, MD, PhD
Peter Voorhees, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open for 5 minutes after the meeting ends.

Information on how to obtain CME, ABIM MOC and ABS credit is provided in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.

RTP Year in Review 2025