

Real-world outcomes with chemoradiation and durvalumab consolidation in patients with stage III *KRAS* G12C-mutant NSCLC in the US

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Study was sponsored by Eli Lilly and Company

OBJECTIVES

- To describe definitive chemoradiation (CRT) approach, consolidation therapy, and time to treatment discontinuation (TTD) among patients with unresected stage III non-small cell lung cancer (NSCLC).
- To evaluate real-world progression-free survival (rwPFS) proxy and overall survival (OS) by *KRAS* status among patients treated with concurrent CRT (cCRT) and consolidation durvalumab.

CONCLUSIONS

- This is the largest real-world study to date evaluating outcomes in patients with stage III unresected *KRAS* G12Cm NSCLC treated with cCRT and durvalumab consolidation.
- The majority of patients in this study received cCRT followed by durvalumab consolidation.
- Among patients treated with cCRT and durvalumab consolidation, rwPFS and OS were consistent across *KRAS* subgroups, with no significant differences for Other *KRAS* or *KRAS* WT versus *KRAS* G12C in multivariable models.
- More than half of the patients experienced disease progression or death within 2 years from the initiation of consolidation with durvalumab.
- Despite comparable outcomes across *KRAS* subgroups, the high rate of disease progression or death within 2 years reflects an unmet need; these findings support the prospective evaluation of *KRAS* G12C inhibitors in combination with durvalumab following cCRT, as evaluated in SUNRAY-02 Part B (NCT06890598).



BACKGROUND

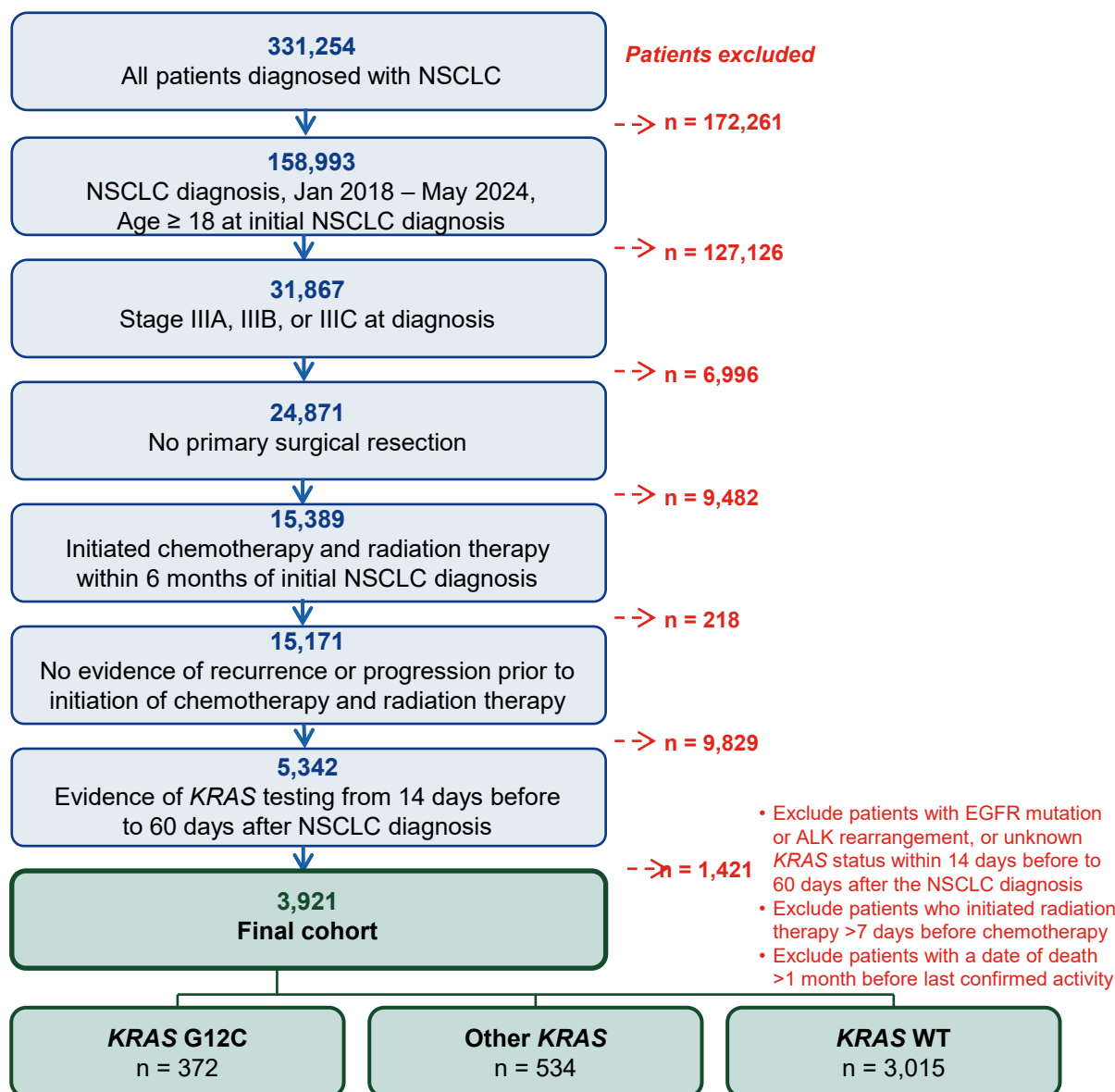
- KRAS* is among the most prevalent oncogenic mutations in non-small cell lung cancer (NSCLC), occurring in approximately 35% of non-squamous NSCLC cases.¹ *KRAS* G12C is the most common variant, representing ~10-13% of patients with non-squamous NSCLC in Western populations.²
- The PACIFIC trial demonstrated improved survival outcomes (progression-free survival [PFS] and overall survival [OS]) with consolidation durvalumab following concurrent chemoradiation (cCRT) in patients with unresectable stage III NSCLC, compared with placebo.³ However, *KRAS* mutation status was not reported in the PACIFIC trial, limiting the characterization of outcomes in patients with *KRAS*-mutant (*KRAS*m) disease.
- Emerging evidence suggests that patients with *KRAS*m stage III locally advanced-NSCLC experience inferior PFS following cCRT and consolidation durvalumab compared to patients with *KRAS* wild-type (WT) NSCLC.⁴
- There are currently no approved targeted therapies for *KRAS* G12Cm unresectable stage III NSCLC.⁵

METHODS

Study design and data sources

- This retrospective, observational study used the US-based, electronic health record-derived (EHR) deidentified Flatiron Health Research Database.⁶ Patients were followed until death, loss to follow-up, or end of the database (August 31, 2025).

Study attrition diagram



Outcomes assessed and analysis

- Demographics, clinical characteristics, and treatment patterns were summarized descriptively. Continuous variables were compared using Kruskal-Wallis tests; categorical variables using chi-square or Fisher's exact tests.
- TTD among durvalumab-treated patients was estimated using the Kaplan-Meier (KM) method.
- A rwPFS proxy (time to locoregional recurrence, advanced or metastatic diagnosis, or death) and OS were estimated and reported by *KRAS* status from initiation of durvalumab using the KM method and weighted multivariable Cox regression models, which estimate a weighted average hazard ratio that is robust to violations of the proportional hazards assumption.⁷
- Outcomes were evaluated by *KRAS* status in patients treated with cCRT and durvalumab consolidation therapy. Analyses were also performed among patients with non-squamous histology disease.
- Analyses were conducted using R software, version 4.1.3 or a more recent version.

ABBREVIATIONS

AHR, average hazard ratio; CRT, chemoradiotherapy; cCRT, concurrent chemoradiation; CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group Performance Status; EHR, electronic health record-driven; HR, hazard ratio; IQR, inter-quartile range; KM, Kaplan-Meier; *KRAS*m, *KRAS* mutant; *KRAS* WT, *KRAS* wild-type; N, no. of patients; n, no. of patients in subgroup; NA, not applicable; NOS, not otherwise specified; NSCLC, non-small cell lung cancer; OS, overall survival; rwPFS, real-world progression-free survival; Q, quartile; TTD, time to treatment discontinuation.

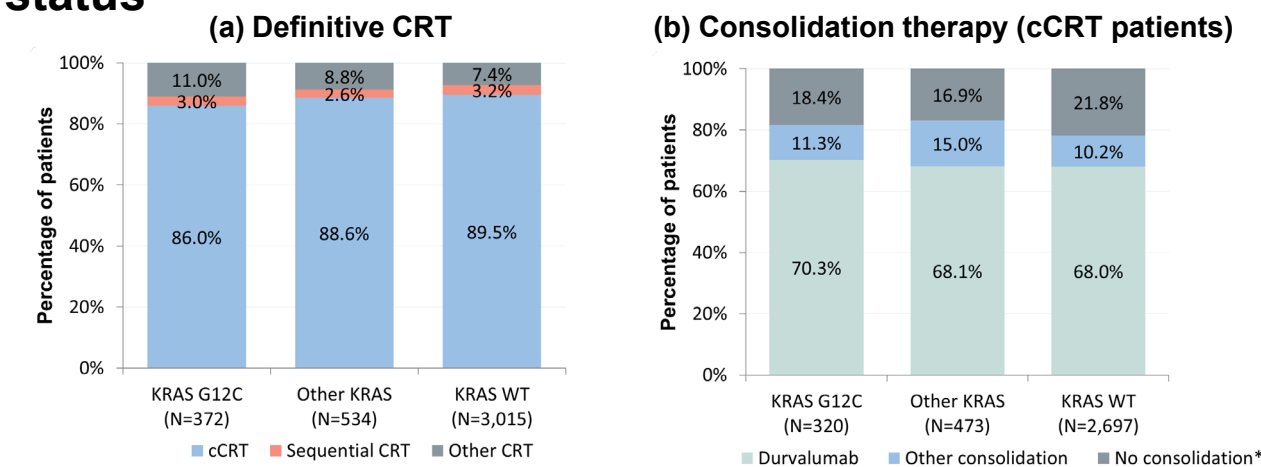
Study demographic, clinical, and tumor characteristics

Characteristics	<i>KRAS</i> G12C (N = 372)	Other <i>KRAS</i> (N = 534)	<i>KRAS</i> WT (N = 3,015)	P-value ^a
Median age (Q1, Q3) at index, years	68.0 (61.0, 75.3)	69.0 (63.0, 76.0)	70.0 (64.0, 76.0)	0.045
Female, n (%)	235 (63.2%)	331 (62.0%)	1,297 (43.0%)	<0.001
History of smoking, n (%)	371 (99.7%)	516 (96.6%)	2,841 (94.2%)	<0.001
ECOG PS, n (%)				0.109
0-1	298 (80.1%)	441 (82.6%)	2,348 (77.9%)	
≥ 2	34 (9.1%)	41 (7.7%)	331 (11.0%)	
Unknown	40 (10.8%)	52 (9.7%)	336 (11.1%)	
Histology, n (%)				<0.001
Non-squamous	342 (91.9%)	459 (86.0%)	1,341 (44.5%)	
Squamous	17 (4.6%)	54 (10.1%)	1,543 (51.2%)	
NSCLC histology NOS	13 (3.5%)	21 (3.9%)	131 (4.3%)	
Stage at diagnosis, n (%)				0.406
Stage IIIA	165 (44.4%)	241 (45.1%)	1,459 (48.4%)	
Stage IIIB	165 (44.4%)	236 (44.2%)	1,230 (40.8%)	
Stage IIIC	42 (11.3%)	57 (10.7%)	326 (10.8%)	
PD-L1 expression ^{b,c} , n (%)				<0.001
≥50%	135 (43.7%)	170 (41.2%)	636 (28.5%)	
1-49%	86 (27.8%)	126 (30.5%)	813 (36.5%)	
<1%	66 (21.4%)	96 (23.2%)	661 (29.6%)	
Inconclusive	22 (7.1%)	21 (5.1%)	120 (5.4%)	
Not tested within specified time window	63	121	785	
STK11 ^{b,c} , n (%)				<0.001
Positive	43 (18.3%)	58 (16.0%)	153 (8.1%)	
Negative	191 (81.3%)	304 (83.7%)	1,699 (90.1%)	
Inconclusive	1 (0.4%)	1 (0.3%)	33 (1.8%)	
Not tested within specified time window	137	171	1,130	
Progression during CRT or within 6 weeks after end of CRT, n (%)	17 (4.6%)	44 (8.2%)	101 (3.3%)	<0.001

- Most patients with *KRAS* G12Cm NSCLC were female (63.2%), had a history of smoking (99.7%), non-squamous carcinoma histology (91.9%) and ECOG PS score of 0-1 (80.1%).
- Patients with *KRAS*m NSCLC, including *KRAS* G12C, had higher percentage of non-squamous carcinoma histology, higher PD-L1 expression, and higher frequency of STK11 mutation compared to patients with *KRAS* WT disease.

^aContinuous variables were compared using Kruskal-Wallis tests; categorical variables using chi-square or Fisher's exact tests; ^bBiomarker test results are from 14 days prior to and 60 days after the index date; ^cPercentages are based on patients with known biomarker status.

Definitive CRT and consolidation therapy by *KRAS* status



Among patients with *KRAS* G12Cm NSCLC, 86.0% received cCRT, 3.0% sequential CRT and 11.0% other CRT

Among patients with *KRAS* G12Cm NSCLC treated with cCRT, 70.3% received durvalumab consolidation, 11.3% other consolidation, and 18.4% no consolidation

^ai.e., no regimen ≤ 90 days after end date of CRT

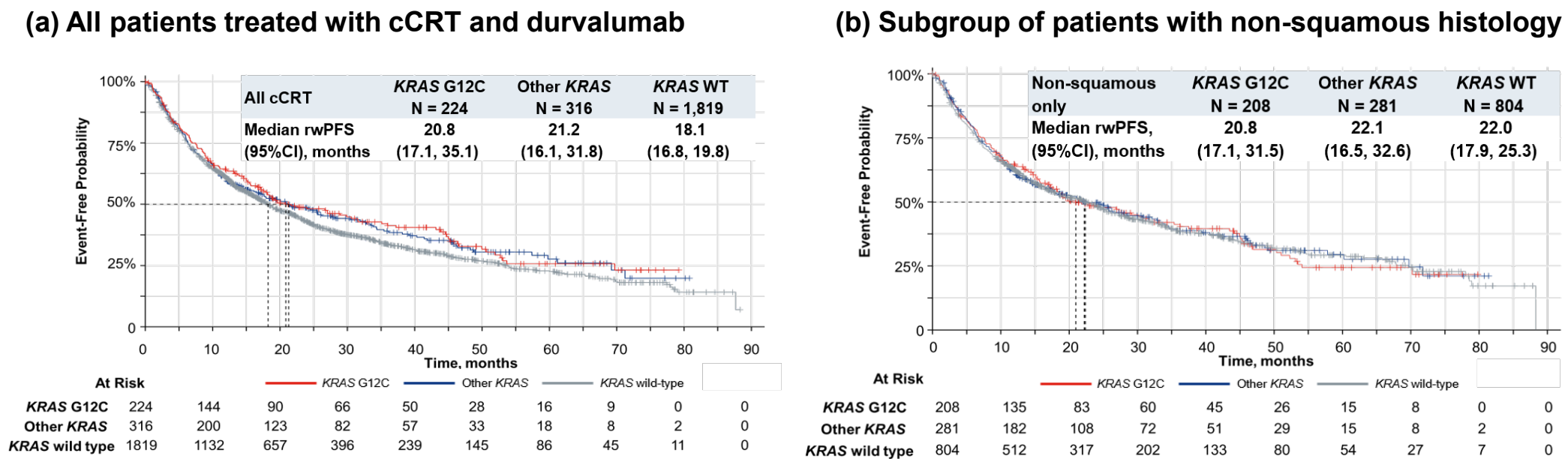
- Median time (Q1, Q3) from end of cCRT to initiation of durvalumab was 1.12 (0.76, 1.41), 1.15 (0.76, 1.61), and 1.15 (0.79, 1.61) months for *KRAS* G12C (N=225), other *KRAS* (N=322), and *KRAS* WT (N=1,833), respectively.
- Median TTD (95% CI) from first drug episode of consolidation durvalumab following cCRT was 10.1 (7.4–10.8), 9.7 (7.9–10.3), and 8.5 (7.8–9.2) months for *KRAS* G12C (N=225), other *KRAS* (N=322), and *KRAS* WT (N=1,833), respectively.

LIMITATIONS

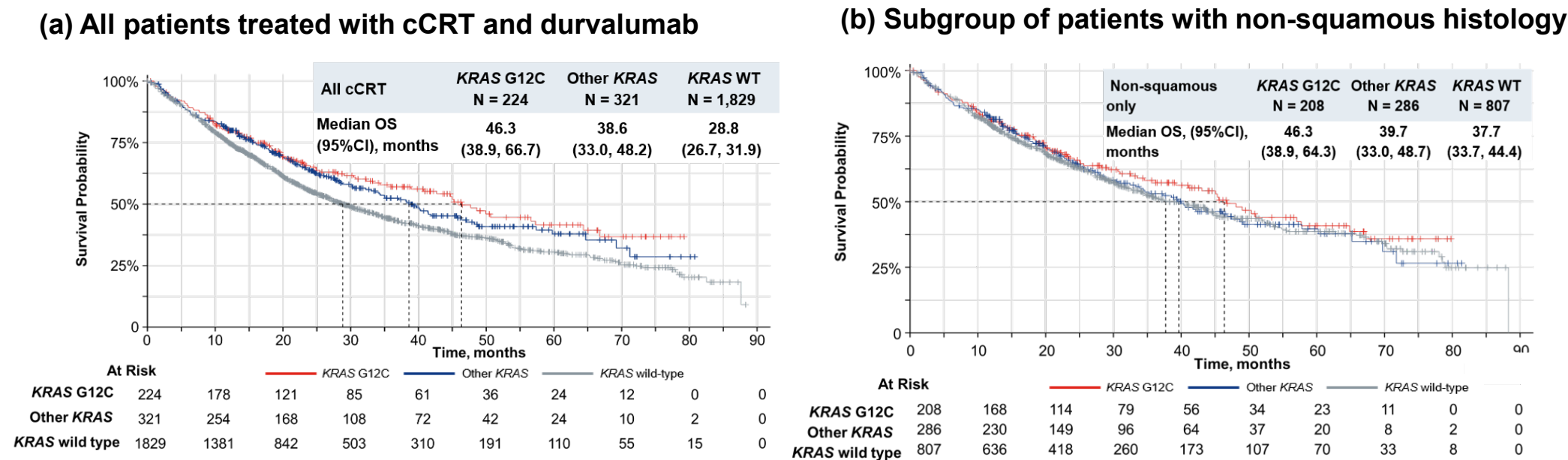
- This study was not designed for formal comparative inference; between-group differences in outcomes should be interpreted with caution
- The study used a proxy for rwPFS based on dates of diagnosis of locoregional recurrence, advanced or metastatic diagnosis, rather than clinician-assessed disease progression.

RESULTS

rwPFS from start of durvalumab among cCRT patients by *KRAS* status



OS from start of durvalumab among cCRT patients by *KRAS* status



Weighted multivariable Cox models for association with rwPFS and OS^a

Among patients treated with durvalumab following cCRT, rwPFS and OS did not differ significantly across *KRAS* G12C, other *KRAS*, and *KRAS* WT groups in multivariable weighted Cox regression models

	(a) rwPFS				(b) OS			
	Average Hazard Ratio (95% CI)	N	HR (95% CI)	P Value	Average Hazard Ratio (95% CI)	N	HR (95% CI)	P Value
<i>KRAS</i> status (Ref= <i>KRAS</i> G12C)		222				222		
Other <i>KRAS</i>	1.02 (0.81, 1.29)	316	1.02 (0.81, 1.29)	0.9	1.08 (0.82, 1.42)	321	1.08 (0.82, 1.42)	0.6
<i>KRAS</i> wild-type	1.02 (0.84, 1.25)	1,813	1.02 (0.84, 1.25)	0.8	1.14 (0.90, 1.45)	1,824	1.14 (0.90, 1.45)	0.3
Age at index (continuous), years	1.01 (1.01, 1.02)	2,351	1.01 (1.01, 1.02)	<0.001	1.03 (1.02, 1.04)	2,367	1.03 (1.02, 1.04)	<0.001
Sex (Ref=Female)		1,143				1,150		
Male	1.16 (1.04, 1.29)	1,208	1.16 (1.04, 1.29)	0.010	1.29 (1.05, 1.36)	1,217	1.29 (1.05, 1.36)	0.006
Race (Ref=White)		1,596				1,608		
Other Race	1.01 (0.86, 1.18)	415	1.01 (0.86, 1.18)	>0.9	1.01 (0.83, 1.24)	417	1.01 (0.83, 1.24)	0.9
Unknown	1.07 (0.92, 1.26)	340	1.07 (0.92, 1.26)	0.4	1.09 (0.92, 1.30)	342	1.09 (0.92, 1.30)	0.3
Practice Type (Ref=Community)		2,031				2,044		
Academic	0.84 (0.68, 1.05)	210	0.84 (0.68, 1.05)	0.13	0.73 (0.56, 0.94)	212	0.73 (0.56, 0.94)	0.015
Both	1.23 (0.99, 1.55)	110	1.23 (0.99, 1.55)	0.067	0.96 (0.73, 1.26)	111	0.96 (0.73, 1.26)	0.8
Smoking status (Ref=History of smoking)		2,237				2,252		
No history / Unknown / Not Documented	1.13 (0.86, 1.49)	114	1.13 (0.86, 1.49)	0.4	0.90 (0.65, 1.25)	115	0.90 (0.65, 1.25)	0.5
ECOG at index date (Ref=0-1)		1,877				1,889		
Unknown / Not tested	1.10 (0.85, 1.43)	220	1.10 (0.85, 1.43)	0.5	1.00 (0.68, 1.47)	222	1.00 (0.68, 1.47)	>0.9
Unknown	1.04 (0.86, 1.25)	254	1.04 (0.86, 1.25)	0.7	1.08 (0.88, 1.32)	256	1.08 (0.88, 1.32)	0.5
Histology (Ref=Non-squamous)		1,289				1,298		
NSCLC histology NOS	1.02 (0.77, 1.34)	97	1.02 (0.77, 1.34)	>0.9	1.29 (0.96, 1.73)	98	1.29 (0.96, 1.73)	0.091
Squamous cell carcinoma	1.07 (0.92, 1.24)	965	1.07 (0.92, 1.24)	0.4	1.22 (1.01, 1.47)	971	1.22 (1.01, 1.47)	0.042
Group stage at NSCLC diagnosis (Ref=Stage IIIA)		1,162				1,166		
Stage IIIB	1.07 (0.96, 1.20)	959	1.07 (0.96, 1.20)	0.2	1.15 (1.01, 1.31)	966	1.15 (1.01, 1.31)	0.040
Stage IIIC	1.28 (1.07, 1.54)	230	1.28 (1.07, 1.54)	0.007	1.44 (1.17, 1.76)	235	1.44 (1.17, 1.76)	<0.001
PD-L1 test result (Ref=≥50%)		564				570		
<1%	1.49 (1.27, 1.75)	621	1.49 (1.27, 1.75)	<0.001	1.45 (1.20, 1.76)	626	1.45 (1.20, 1.76)	<0.001
1-49%	1.59 (1.34, 1.89)	488	1.59 (1.34, 1.89)	<0.001	1.58 (1.29, 1.93)	489	1.58 (1.29, 1.93)	<0.001
Unknown / Not tested	1.27 (1.09, 1.49)	676	1.27 (1.09, 1.49)	0.003	1.31 (1.07, 1.60)	682	1.31 (1.07, 1.60)	0.008
STK 11 test result (Ref= Negative)		1,288				1,300		
Positive	1.42 (1.12, 1.80)	144	1.42 (1.12, 1.80)	0.004	1.43 (1.10, 1.85)	145	1.43 (1.10, 1.85)	0.007
Unknown / Not tested	1.10 (0.93, 1.29)	919	1.10 (0.93, 1.29)	0.3	1.02 (0.84, 1.24)	922	1.02 (0.84, 1.24)	0.8
KEAP1 test result (Ref= Negative)		1,024				1,032		
Positive	1.11 (0.84, 1.47)	92	1.11 (0.84, 1.47)	0.5	1.29 (0.97, 1.73)	93	1.29 (0.97, 1.73)	0.085
Unknown / Not tested	0.95 (0.83, 1.09)	1,235	0.95 (0.83, 1.09)	0.5	0.99 (0.85, 1.16)	1,242	0.99 (0.85, 1.16)	>0.9
TP53 test result (Ref= Negative)		587				584		
Positive	1.08 (0.94, 1.25)	1,180	1.08 (0.94, 1.25)	0.3	1.15 (0.97, 1.36)	1,187	1.15 (0.97, 1.36)	0.10
Unknown / Not tested	1.01 (0.82, 1.24)	584	1.01 (0.82, 1.24)	>0.9	1.13 (0.86, 1.45)	586	1.13 (0.86, 1.45)	0.3

^aMultivariable weighted Cox models controlled for age, sex, race, practice type, smoking status, ECOG performance status, histology (all cCRT models only), stage, PD-L1 status, STK11, KEAP1, and TP53. Index date is start of consolidation durvalumab. Biomarker test results are from 14 days prior to and 60 days after the initial diagnosis date.

Variables associated with significantly shorter rwPFS included age, male sex, Stage IIIC, PD-L1 expression of <1% and 1-49%, and STK11 mutation. Results were consistent in the non-squamous subgroup, except for male sex, no history of smoking, and Stage IIIC (data not shown).

Variables associated with significantly shorter OS included age, male sex, squamous cell carcinoma, Stage IIIB, Stage IIIC, PD-L1 expression of <1% and 1-49%, and STK11 mutation. Results were consistent in the non-squamous subgroup except male sex and Stage IIIB (data not shown).

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Objectives

- To describe definitive chemoradiation (CRT) approach, consolidation therapy, and time to treatment discontinuation (TTD) among patients with unresected stage III non-small cell lung cancer (NSCLC).
- To evaluate real-world progression-free survival (rwPFS) proxy and overall survival (OS) by *KRAS* status among patients treated with concurrent CRT (cCRT) and consolidation durvalumab.

Background

- *KRAS* is among the most prevalent oncogenic mutations in NSCLC, occurring in approximately 35% of non-squamous NSCLC cases.¹ *KRAS* G12C is the most common variant, representing ~10-13% of patients with non-squamous NSCLC in Western populations.²
- The PACIFIC trial demonstrated improved survival outcomes (PFS and OS) with consolidation durvalumab following cCRT in patients with unresectable stage III NSCLC, compared with placebo.³ However, *KRAS* mutation status was not reported in the PACIFIC trial, limiting the characterization of outcomes in patients with *KRAS*-mutant (*KRAS*Sm) disease.
- Emerging evidence suggests that patients with *KRAS*Sm stage III locally advanced-NSCLC experience inferior PFS following cCRT and consolidation durvalumab compared to patients with *KRAS* wild-type (WT) NSCLC.⁴
- There are currently no approved targeted therapies for *KRAS* G12Cm unresectable stage III NSCLC.⁵

1. Lee JK et al. *Precis. Onc.* 2022;6:91.

2. Lim TKH et al. *Lung Cancer.* 2023;184:107293.

3. Spigel DR et al. *J Clin Oncol.* 2022;40(12):1301-1311.

4. Mankuzhy NP et al. *J Thorac Oncol.* 2026;21:103565.

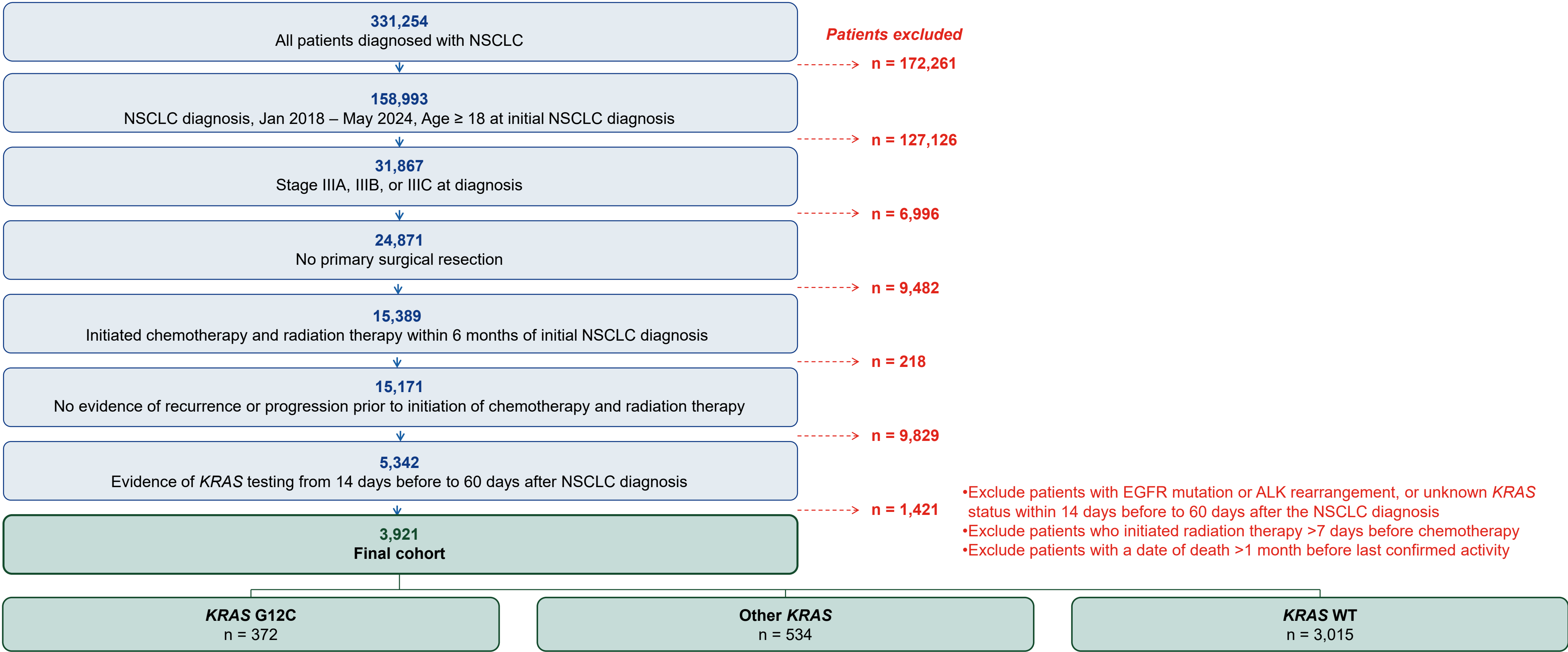
5. Yuan JX et al. *Transl Lung Cancer Res.* 2025;14(7):2799-2820.

Methods (1/2)

Study design and data sources

- This retrospective, observational study used the US-based, electronic health record-derived (EHR) deidentified Flatiron Health Research Database.¹ Patients were followed until death, loss to follow-up, or end of the database (August 31, 2025)

Study attrition diagram



1. Flatiron Health. [Database Characterization Guide](#). Flatiron.com. Published March 18, 2025. Accessed May 15, 2026.

EHR, electronic health record-driven; *KRAS* WT, *KRAS* wild-type; NSCLC, non-small cell lung cancer.

Methods (2/2)

Outcomes assessed and analysis

- Demographics, clinical characteristics, and treatment patterns were summarized descriptively. Continuous variables were compared using Kruskal–Wallis tests; categorical variables using chi-square or Fisher’s exact tests.
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1. Dunkler D et al. *J Stat Softw*. 2018;84(2).

Study demographic, clinical, and tumor characteristics

Characteristics	<i>KRAS</i> G12C (N = 372)	Other <i>KRAS</i> (N = 534)	<i>KRAS</i> WT (N = 3,015)	P-value ^a
Median age (Q1, Q3) at index, years	68.0 (61.0, 75.3)	69.0 (63.0, 76.0)	70.0 (64.0, 76.0)	0.045
Female, n (%)	235 (63.2%)	331 (62.0%)	1,297 (43.0%)	<0.001
History of smoking, n (%)	371 (99.7%)	516 (96.6%)	2,841 (94.2%)	<0.001
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Inconclusive	22 (7.1%)	21 (5.1%)	120 (5.4%)	
Not tested within specified time window	63	121	785	
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Inconclusive	1 (0.4%)	1 (0.3%)	33 (1.8%)	
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Progression during CRT or within 6 weeks after end of CRT, n (%)	17 (4.6%)	44 (8.2%)	101 (3.3%)	<0.001

- Most patients with *KRAS* G12Cm NSCLC were female (63.2%), had a history of smoking (99.7%), non-squamous carcinoma histology (91.9%) and ECOG PS score of 0-1 (80.1%).
- Patients with *KRAS*Sm NSCLC, including *KRAS* G12C, had higher percentage of non-squamous carcinoma histology, higher PD-L1 expression, and higher frequency of STK11 mutation compared to patients with *KRAS* WT disease.

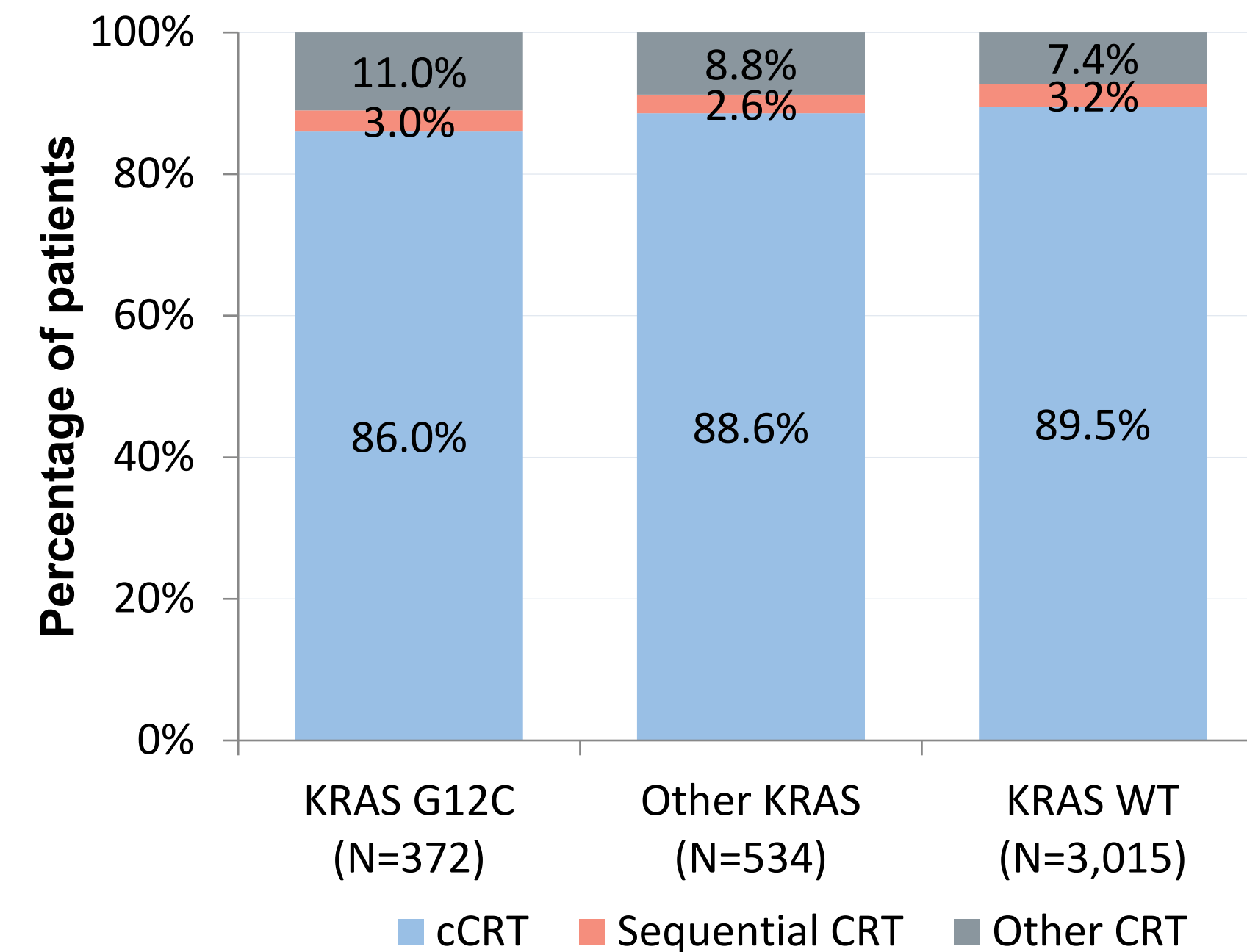
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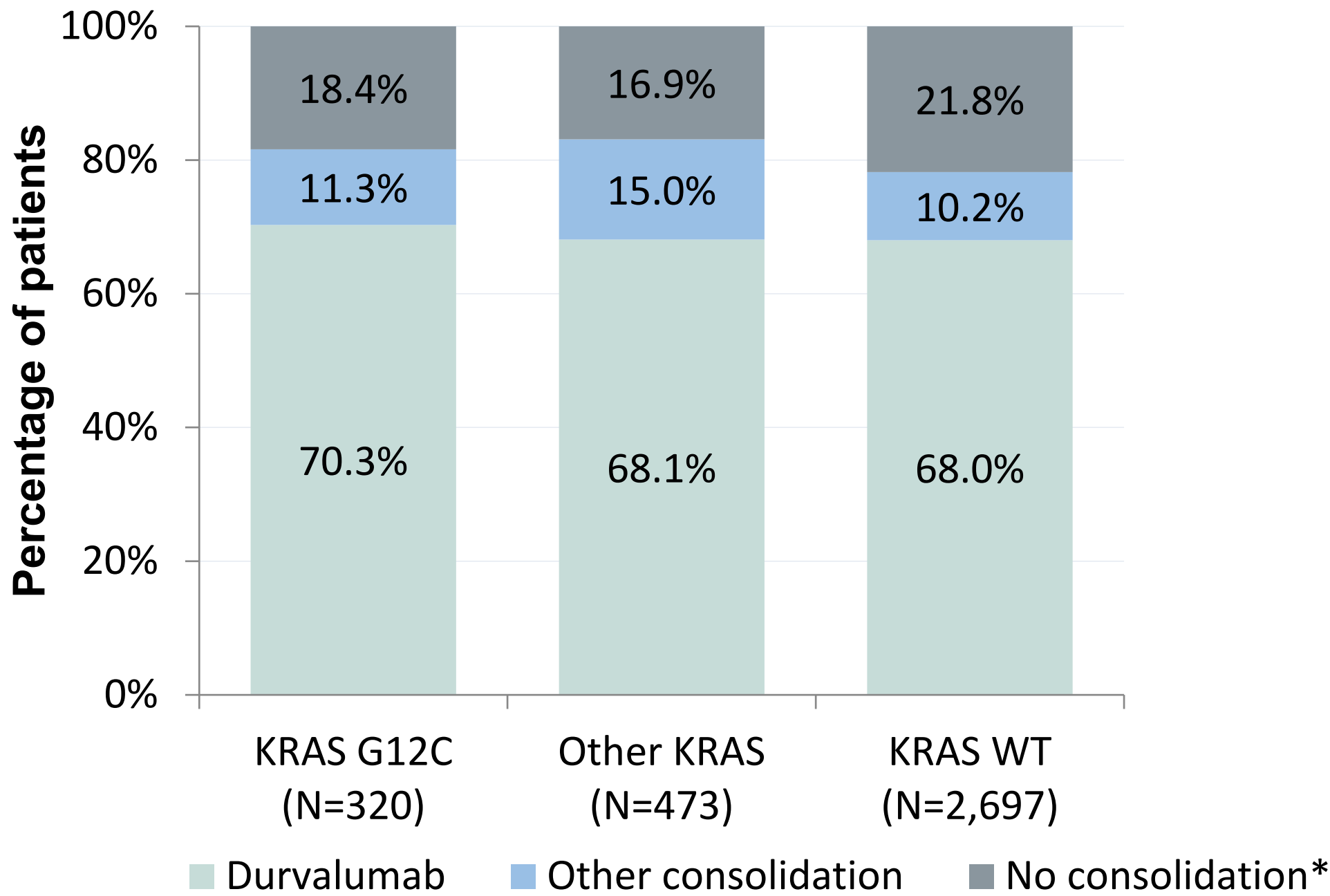
Definitive CRT and consolidation therapy by *KRAS* status

(a) Definitive CRT type



Among patients with *KRAS* G12Cm NSCLC, 86.0% received cCRT, 3.0% sequential CRT and 11.0% other CRT

(b) Consolidation therapy (cCRT patients)



Among patients with *KRAS* G12Cm NSCLC treated with cCRT, 70.3% received durvalumab consolidation, 11.3% other consolidation, and 18.4% no consolidation

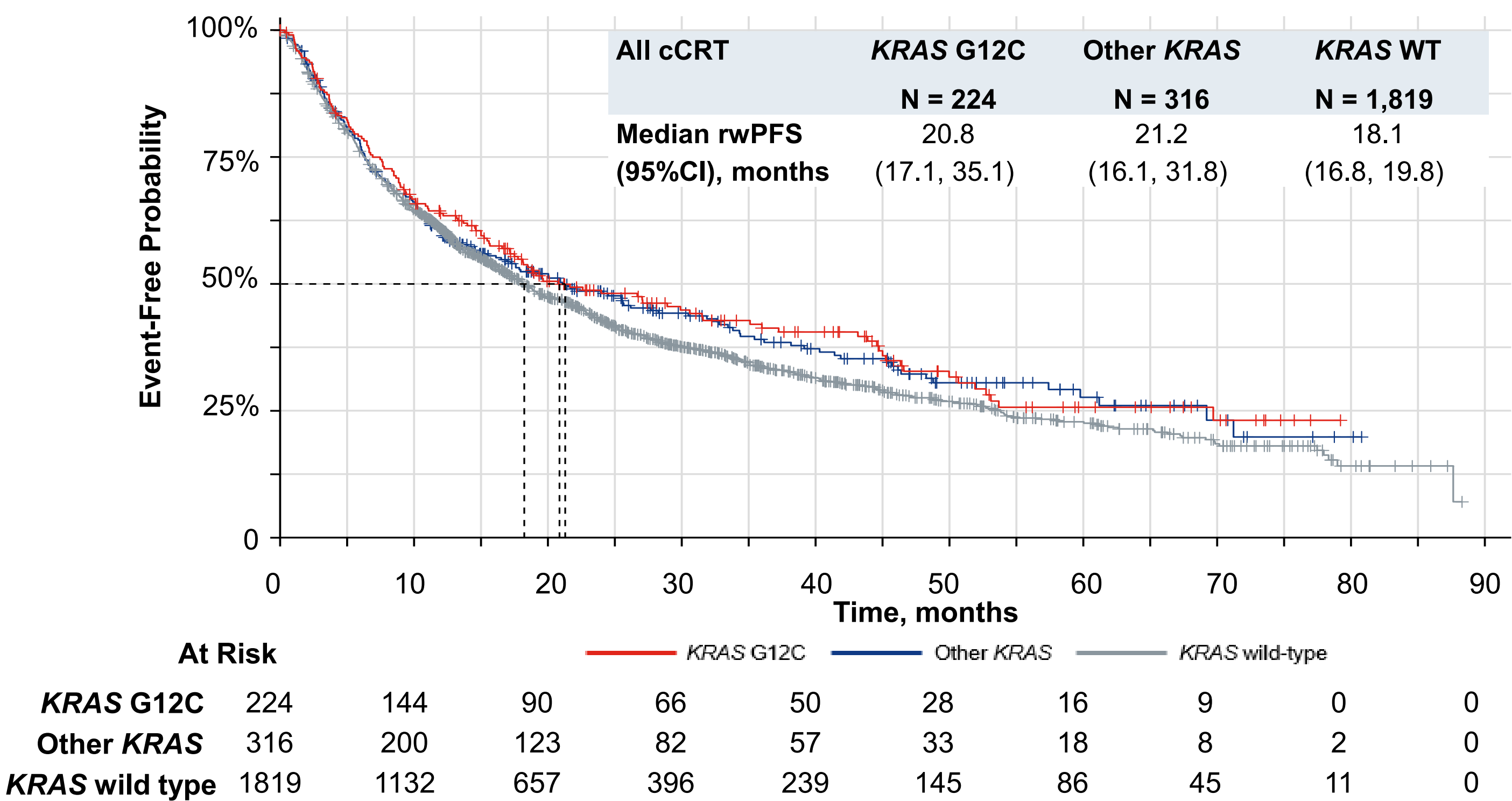
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- Median TTD (95% CI) from first drug episode of consolidation durvalumab following cCRT was 10.1 (7.4–10.8), 9.7 (7.9–10.3), and 8.5 (7.8–9.2) months for *KRAS* G12C (N=225), other *KRAS* (N=322), and *KRAS* WT (N=1,833), respectively.

*i.e., no regimen ≤ 90 days after end date of CRT

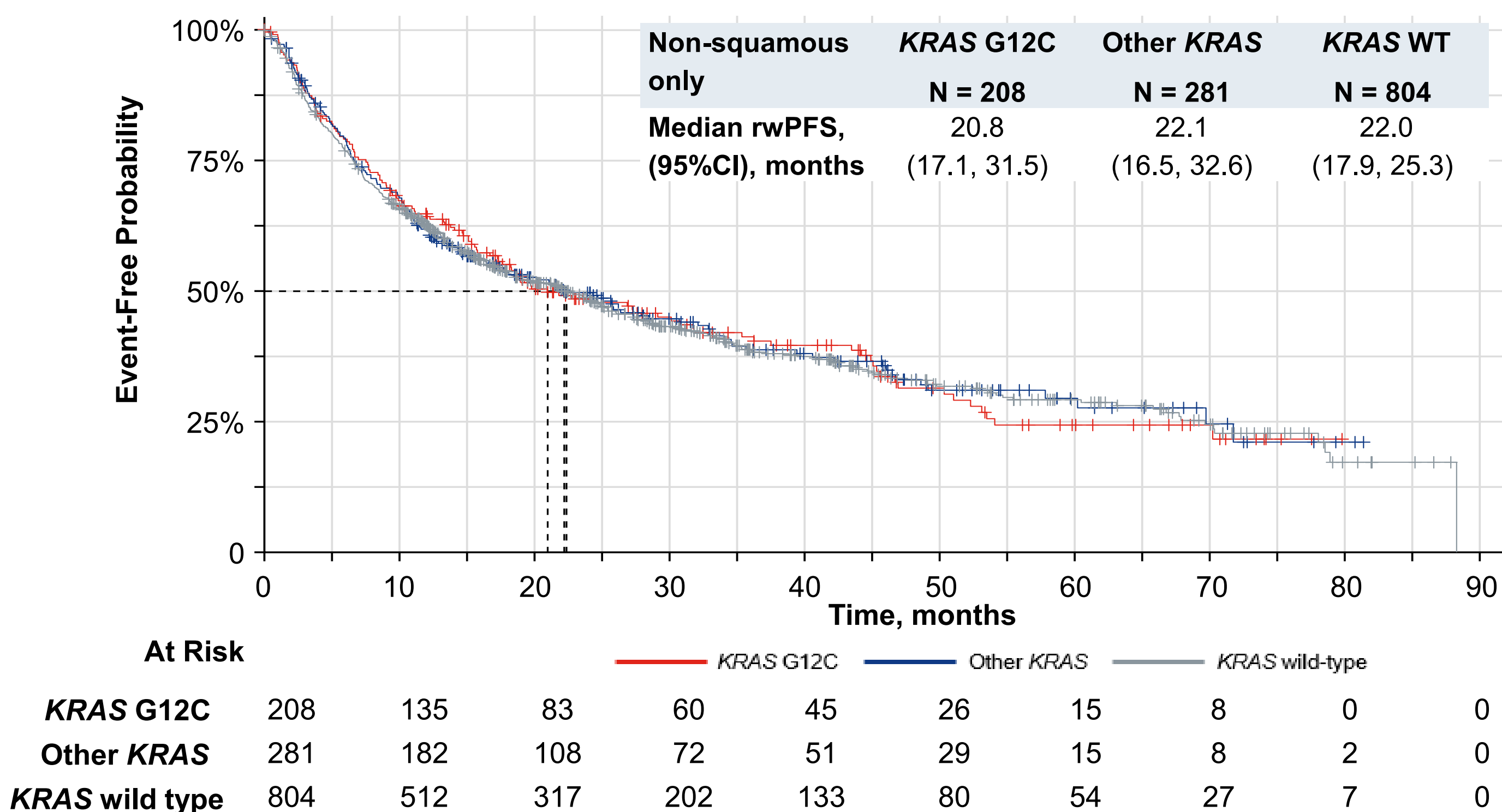
CRT, chemoradiotherapy; cCRT, concurrent CRT; *KRAS*m, *KRAS* mutant; *KRAS* WT, *KRAS* wild-type; N, no. of patients; n, no. of patients in subgroup, NSCLC, non-small cell lung cancer; Q, quartile; TTD, time to treatment discontinuation.

rwPFS from start of durvalumab among cCRT patients by *KRAS* status

(a) All patients treated with cCRT and durvalumab



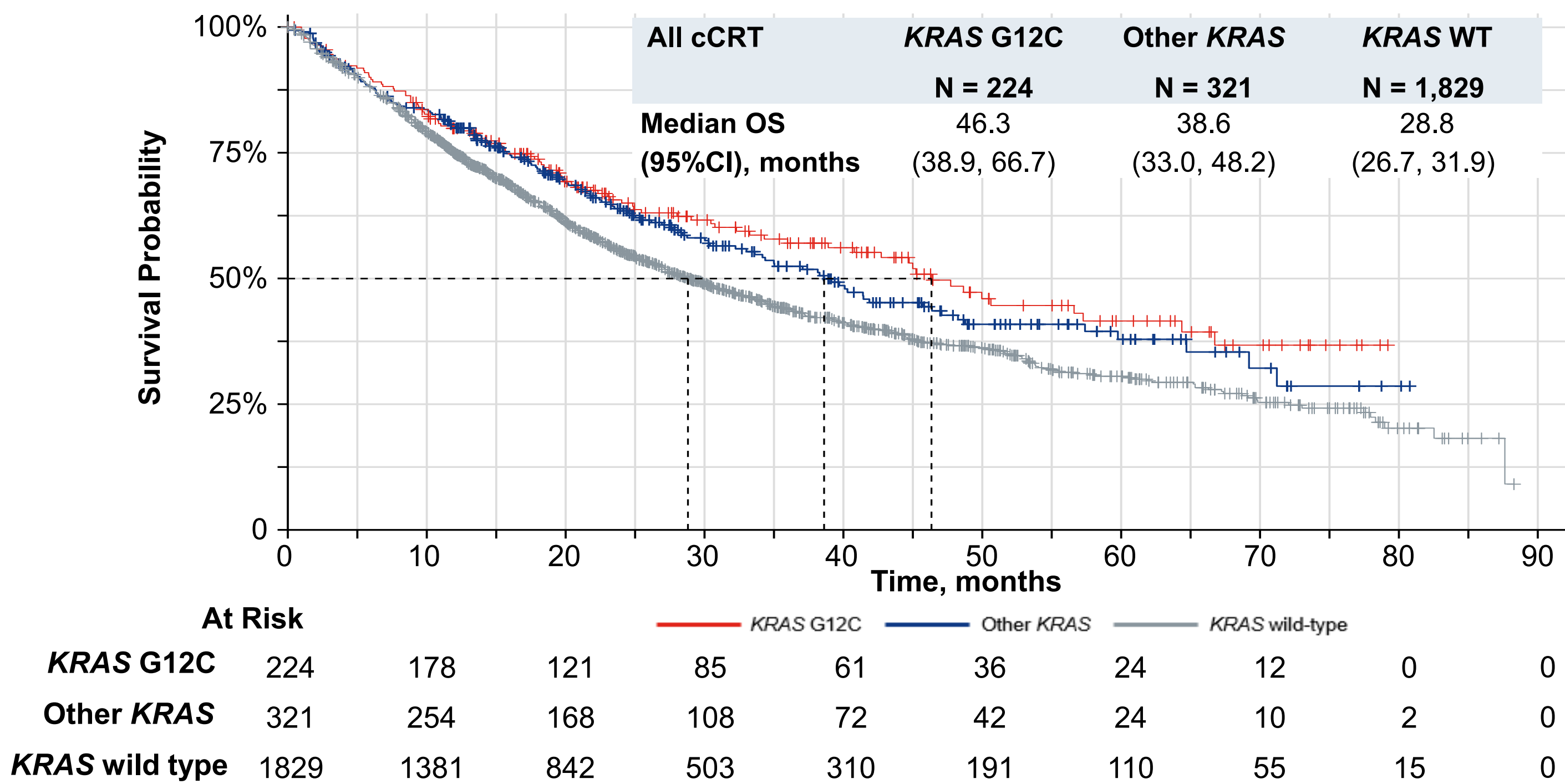
(b) Subgroup of patients with non-squamous histology



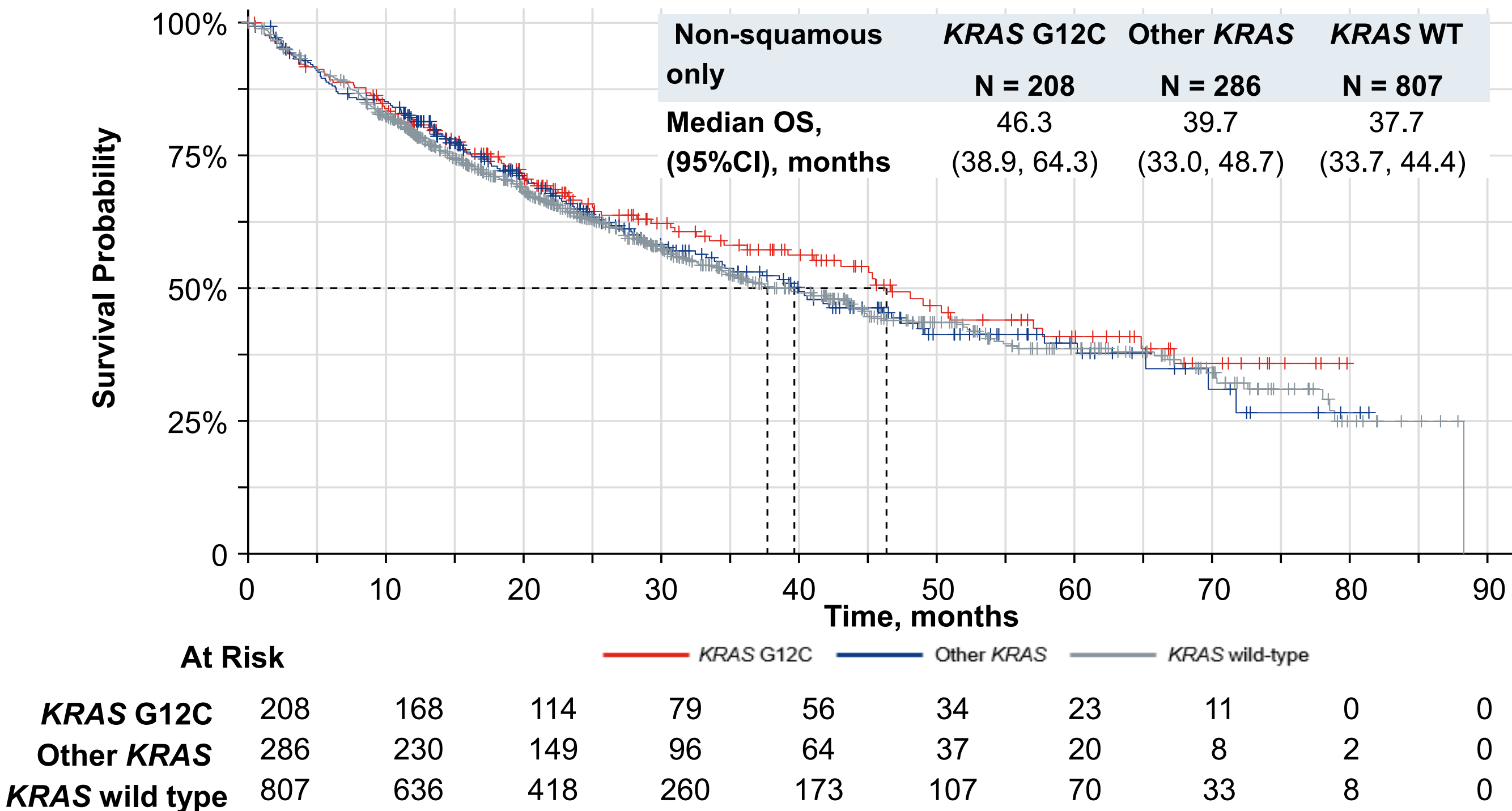
cCRT, concurrent chemoradiation; CI, confidence interval; *KRAS* WT, *KRAS* wild-type; rwPFS, real-world progression-free survival.

OS from start of durvalumab among cCRT patients by *KRAS* status

(a) All patients treated with cCRT and durvalumab



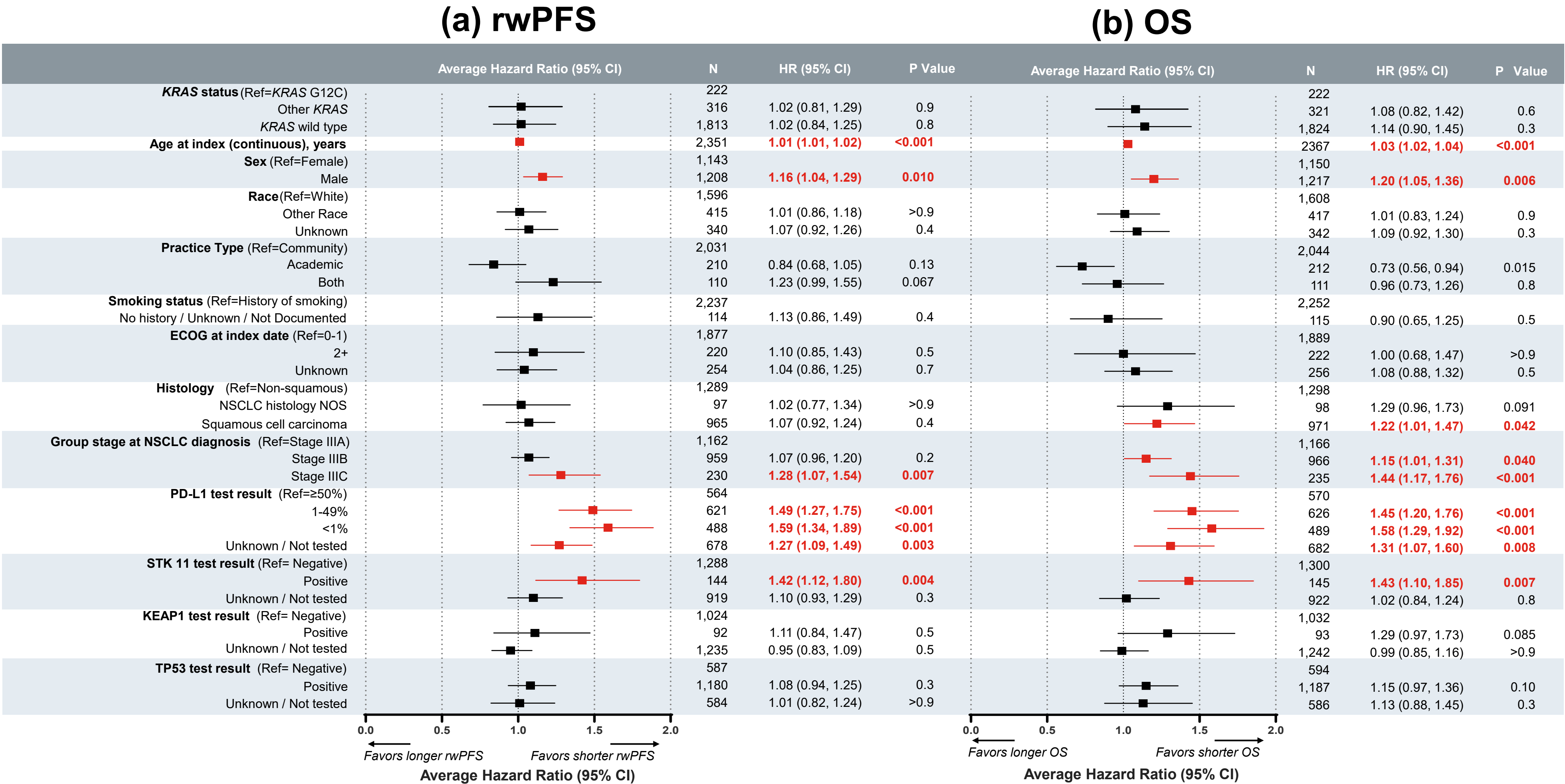
(b) Subgroup of patients with non-squamous histology



cCRT, concurrent chemoradiation; CI, confidence interval; *KRAS*m, *KRAS* mutant; *KRAS* WT, *KRAS* wild-type; OS, overall survival.

Weighted multivariable Cox regression models for association with rwPFS and OS*

Among patients treated with durvalumab following cCRT, rwPFS and OS did not differ significantly across *KRAS* G12C, other *KRAS*, and *KRAS* WT groups in multivariable weighted Cox regression models



Variables associated with significantly shorter rwPFS included age, male sex, Stage IIIC, PD-L1 expression of <1% and 1-49%, and STK11 mutation. Results were consistent in the non-squamous subgroup, except for male sex, no history of smoking, and Stage IIIC (data not shown).

Variables associated with significantly shorter OS included age, male sex, squamous cell carcinoma, Stage IIIB, Stage IIIC, PD-L1 expression of <1% and 1-49%, and STK11 mutation. Results were consistent in the non-squamous subgroup except male sex and Stage IIIB (data not shown).

*Multivariable weighted Cox models controlled for age, sex, race, practice type, smoking status, ECOG performance status, histology (all cCRT models only), stage, PD-L1 status, STK11, KEAP1, and TP53. Index date is start of consolidation durvalumab. Biomarker test results are from 14 days prior to and 60 days after the initial diagnosis date

cCRT, concurrent chemoradiation; CI, confidence interval; AHR, average hazard ratio; *KRAS*m, *KRAS* mutant; *KRAS* WT, *KRAS* wild-type; NSCLC, non-small cell lung cancer; OS, overall survival; rwPFS, real-world progression-free survival

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Conclusions

- This is the largest real-world study to date evaluating outcomes in patients with stage III unresected *KRAS* G12Cm NSCLC treated with cCRT and durvalumab consolidation.
- The majority of patients in this study received cCRT followed by durvalumab consolidation.
- Among patients treated with cCRT and durvalumab consolidation, rwPFS and OS were consistent across *KRAS* subgroups, with no significant differences for Other *KRAS* or *KRAS* WT versus *KRAS* G12C in multivariable models.
- More than half of the patients experienced disease progression or death within 2 years from the initiation of consolidation with durvalumab.
- Despite comparable outcomes across *KRAS* subgroups, the high rate of disease progression or death within 2 years reflects an unmet need; these findings support the prospective evaluation of *KRAS* G12C inhibitors in combination with durvalumab following cCRT, as evaluated in SUNRAY-02 Part B (NCT06890598).

Limitations

- This study was not designed for formal comparative inference; between-group differences in outcomes should be interpreted with caution
- The study used a proxy for rwPFS based on dates of diagnosis of locoregional recurrence, advanced or metastatic diagnosis, rather than clinician-assessed disease progression.

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