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TOGETHER: Pooled real-world datasets of *MET*ex14 skipping NSCLC and adjusted comparison of upfront (chemo-)immunotherapy with tepotinib from VISION

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CONCLUSIONS

- This large retrospective analysis shows poor real-world outcomes for patients with *MET*ex14 skipping NSCLC receiving standard treatments prior to the uptake of novel MET inhibitors
- Matched indirect treatment comparison (ITC) suggests longer rwPFS and rwOS with 1L tepotinib compared to 1L immunotherapy (IO) + chemotherapy (CT) or IO monotherapy
 - Similar observations were made for IO monotherapy, CT, and crizotinib, in 2L+

INTRODUCTION

- Guidelines recommend that patients with *MET*ex14 skipping, present in 3–4% of advanced NSCLC^{1–4}, receive MET inhibitors such as tepotinib, as 1L treatment⁵
- In the single-arm, Phase II **VISION study** (NCT02864992; data cut-off: Nov 2022), tepotinib demonstrated robust and durable clinical activity, particularly in 1L patients with *MET*ex14 skipping NSCLC detected through tissue biopsy (T+; N=111): **ORR 58.6%** (95% CI: 48.8, 67.8), median **DOR 46.4 months** (95% CI: 15.2, ne), **median PFS 15.9 months** (95% CI: 11.0, 49.7), and **median OS 29.7 months** (95% CI: 18.8, ne)⁶
- The lack of large datasets evaluating outcomes of patients with *MET*ex14 skipping NSCLC treated with 1L IO with or without CT prior to the approval of MET inhibitors necessitates the exploration of alternative comparative data sources
- TOGETHER** was designed for flexible pooling of RW datasets comprising patients with *MET*ex14 skipping NSCLC to characterize RW outcomes prior to the uptake of novel MET inhibitors

METHODS

- Patient-level data were available from seven real-world data sources of *MET*ex14 skipping NSCLC (**Table S1**)
- Patient records were imported into a common data model with aligned definitions for baseline characteristics, such as smoking history and histology, and inclusion/exclusion criteria aligned with the VISION study were applied (**Figure S1**)
- First line of therapy was defined as the first treatment received after diagnosis of advanced or metastatic disease, with subsequent lines counted accordingly
- Treatment types were categorized as: IO, CT, IO+CT or MET inhibitors (crizotinib at the time of data collection)
- In datasets where progression events were not captured, TTNTD was used as a proxy for PFS; time on treatment was used when TTNTD was also not available
- ITCs were performed with propensity score reweighting of 1L and 2L+ patients from TOGETHER to match the characteristics of 1L (N=111) and 2L+ (N=97) T+ patients from the VISION study (data cut-off: Nov 2022)
 - The variables deemed to be relevant by clinicians and order of relevance, were: whether a patient had received a previous line of therapy for their advanced or metastatic cancer, age (as a mean), whether a patient had advanced or metastatic disease, sex, adenocarcinoma histology, and smoking history

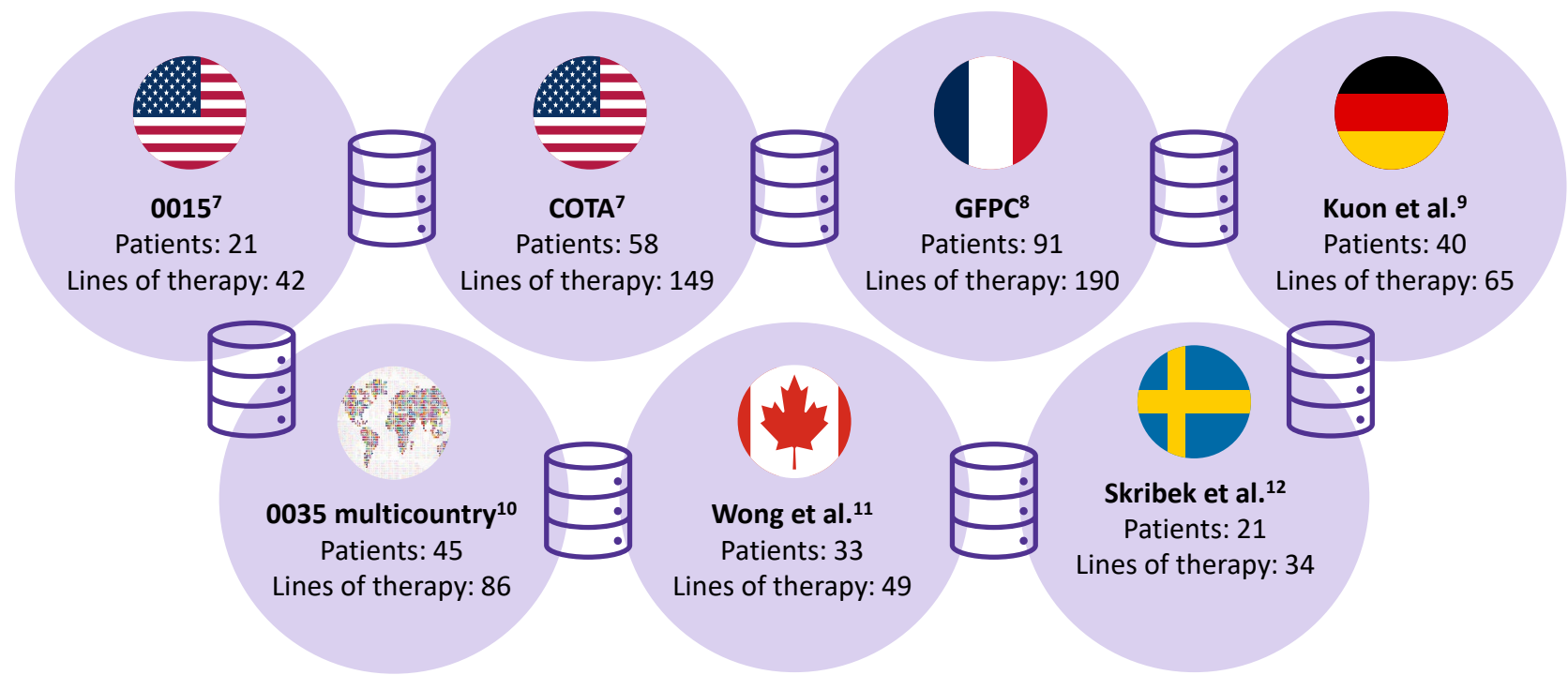


RESULTS

Patient characteristics

- As of January 2023, TOGETHER included 309 patients, who received a total of 615 lines of therapy between 2004 and 2022 (**Figure 1**); 289 lines of therapy were received in 1L, and 326 in 2L+

Figure 1. TOGETHER: Patients and lines of therapy



- The median age of patients in the overall population was 72.0 years, 48% were male, and 52% had smoking history (**Table S2**)
- Patients who received 1L IO+CT or CT alone in TOGETHER were younger than patients who received 1L crizotinib or IO mono in TOGETHER or 1L tepotinib in VISION, supporting a potential CT-sparing selection bias for older, frailer patients (**Table 1**)
- More patients receiving 1L IO, either alone or with CT, had a smoking history, consistent with a reportedly higher PD-L1 expression and higher benefit from IO treatment.¹³ However, in VISION, patients with *MET*ex14 skipping NSCLC with a smoking history, still reported a higher benefit from 1L tepotinib compared with 1L IO¹⁴

Table 1. Characteristics of patients receiving 1L treatment in VISION or TOGETHER

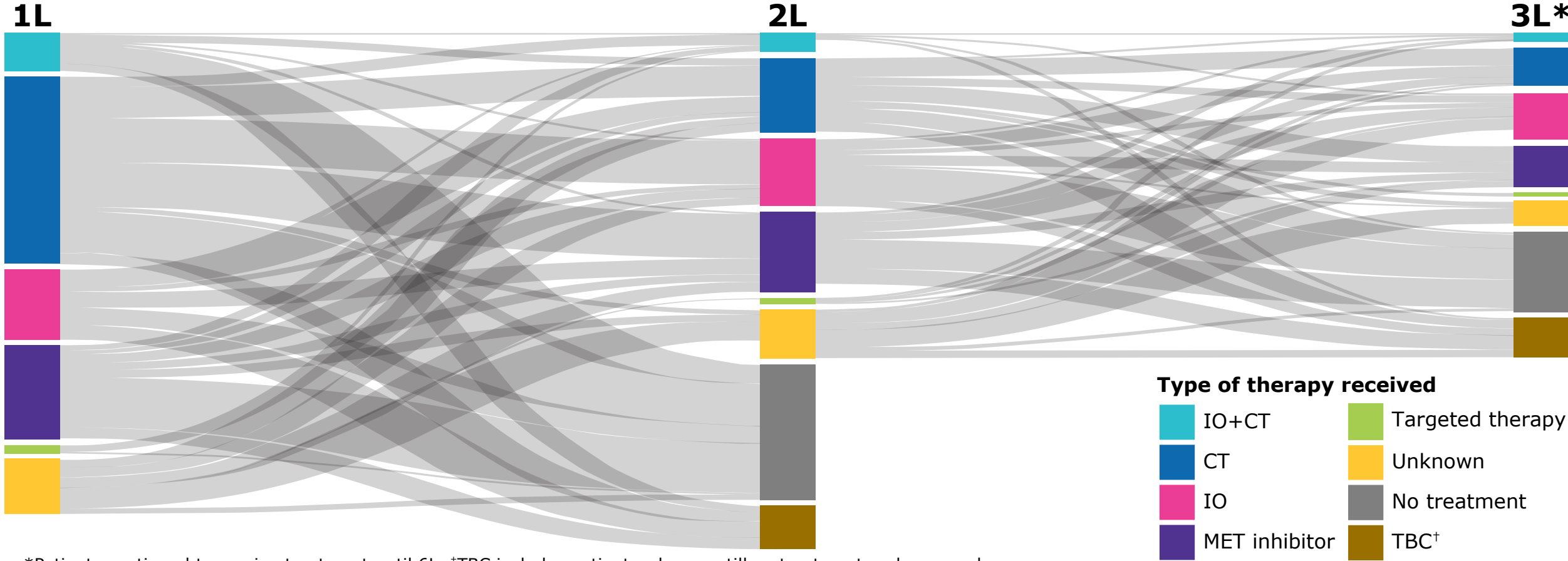
		VISION 1L T+	TOGETHER 1L				
Characteristic, n (%)		Tepotinib (N=111)	All (n=289)	IO mono (n=48)	IO+CT (n=26)	CT (n=128)	Crizotinib (n=62)
Age	Median (IQR)	75 (68.0, 80.0)	72.2 (64.3, 78.9)	74.0 (67.0, 79.5)	68.9 (59.0, 76.5)	71.0 (63.0, 77.0)	76 (66.2, 82.0)
	Mean (SD)	74.2 (8.50)	71.4 (9.8)	73.2 (9.1)	66.8 (12.4)	69.3 (9.5)	74.6 (11.0)
Sex	Male	59 (53)	137 (47)	26 (54)	14 (54)	53 (41)	28 (45)
	Female	52 (47)	152 (53)	22 (46)	12 (46)	75 (59)	34 (55)
Race*	White	68 (61)	80 (28)	17 (35)	1 (4)	32 (25)	22 (35)
	Asian	42 (38)	19 (7)	1 (2)	0	11 (9)	2 (3)
Smoking history†	Yes	58 (52)	165 (57)	32 (67)	17 (65)	70 (55)	35 (56)
	No	52 (47)	124 (43)	16 (33)	9 (35)	58 (45)	27 (44)
Stage‡	IIIB+	7 (6)	13 (4)	1 (2)	2 (8)	7 (5)	3 (5)
	IV	103 (93)	118 (41)	20 (42)	8 (31)	50 (39)	25 (40)
Histology§	ADC	90 (81)	221 (76)	32 (67)	21 (81)	95 (74)	52 (84)
	Squamous	6 (5)	32 (11)	6 (13)	2 (8)	20 (16)	3 (5)
	Sarcomatoid	3 (3)	8 (3)	2 (4)	0	6 (5)	0

*Race was Black/African American/Other/not collected/missing in one patient in VISION and 190 patients in TOGETHER. †Smoking status was missing for one patient in VISION. ‡Stage was IIIA in one patient in VISION and was missing in 158 patients in TOGETHER. §Histology was Other/missing in 12 patients in VISION and 28 patients in TOGETHER.

Treatment sequencing

- Of 48 patients receiving 1L IO, 11 (23%) patients received subsequent MET inhibitors; of 26 patients receiving 1L IO+CT, one patient received subsequent MET inhibitors (**Figure 2**)

Figure 2. TOGETHER: Sankey plot of treatment sequencing

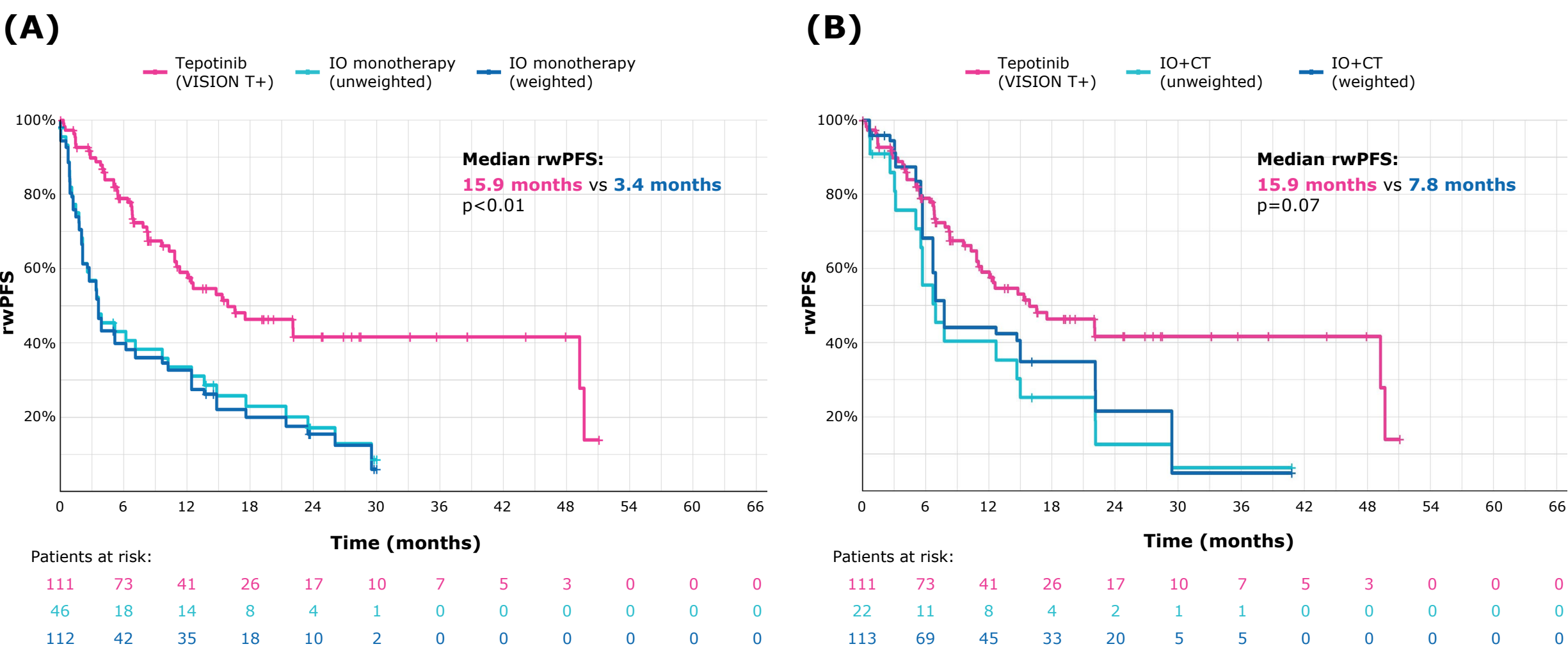


*Patients continued to receive treatment until 6L. †TBC includes patients who are still on treatment and censored.

rwPFS and rwOS according to line of therapy

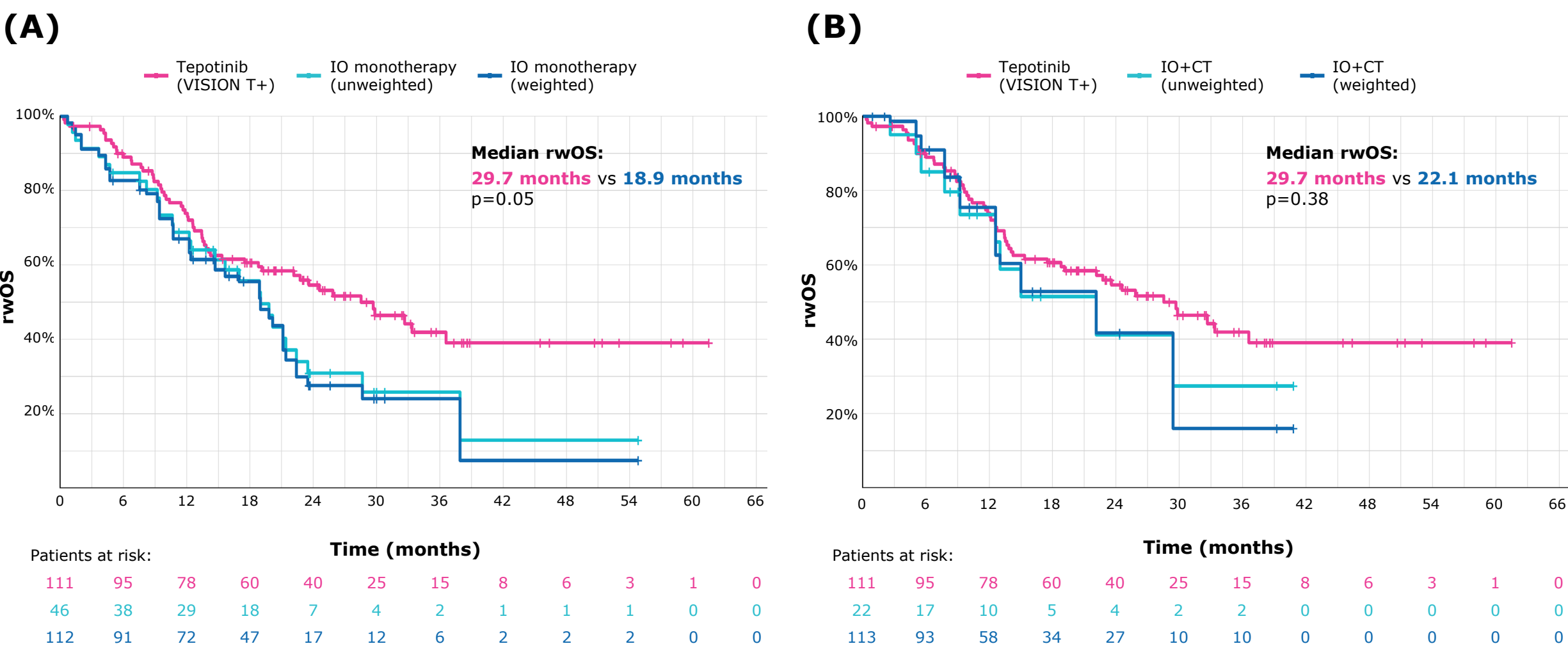
- ITCs were performed with propensity score reweighting of patients in TOGETHER who received 1L IO alone or 1L IO+CT to match the characteristics of 111 patients with T+ *MET*ex14 skipping NSCLC who received 1L tepotinib in the VISION study
- For **1L IO monotherapy**, median rwPFS was 3.9 months (95% CI: 2.7, 7.1) before and 3.4 months (95% CI: 2.0, 9.7) after weighting compared with 15.9 months for 1L tepotinib (HR 0.37 [0.24, 0.58]; p<0.01) (**Figure 3A**)
- For **1L IO+CT**, median rwPFS was 6.9 months (95% CI: 5.5, 22.1) before and 7.8 months (95% CI: 5.7, 29.4) after weighting, compared with 15.9 months (95% CI: 11.3, ne) for 1L tepotinib (HR 0.57 [0.31, 1.05]; p=0.07) (**Figure 3B**)
- Other 1L treatments were CT alone with a median rwPFS of 4.8 months (95% CI: 4.1, 6.2) before and 5.2 months (95% CI: 4.5, 8.8) after weighting, and crizotinib with a median rwPFS of 6.2 months (95% CI: 3.5, 10.3) before and 7.4 months (95% CI: 4.4, 10.9) after weighting

Figure 3. ITC rwPFS for 1L (A) IO and (B) IO+CT compared with 1L tepotinib in VISION



- Although confounded by subsequent treatments, median rwOS was also longer for tepotinib with 29.7 months (95% CI: 19.1, ne) compared with 18.9 months (HR 0.64; p=0.05) for **1L IO monotherapy** and 22.1 months (HR 0.77; p=0.38) for **1L IO+CT** (**Figure 4**)

Figure 4. ITC rwOS for 1L (A) IO and (B) IO+CT compared with 1L tepotinib in VISION



- Median rwPFS was shorter for **2L+ IO monotherapy** (3.3 months [95% CI: 2.5, 6.0]), **2L+ CT** (4.3 months [95% CI: 3.4, 5.3]), and **2L+ crizotinib** (8.1 months [95% CI: 5.8, 12.9]) compared with 2L+ tepotinib (11.5 months [95% CI: 8.2, 14.7]) (**Figure S2**)
- Median rwOS was also shorter for **2L+ IO monotherapy** (15.3 months [95% CI: 11.7, 21.7]), **2L+ CT** (11.1 months [95% CI: 8.3, 17.9]), and **2L+ crizotinib** (14.3 months [95% CI: 10.6, 22.4]) compared with 2L+ tepotinib (20.4 months [95% CI: 17.0, 25.5]) (**Figure S3**)

Abbreviations: 1L, first line; 2L, second line; 2L+, second-or-later line; 3L, third line; 4L, fourth line; 6L, sixth line; ADC, adenocarcinoma; CI, confidence interval; CT, chemotherapy; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; IO, immunotherapy; IQR, interquartile range; ITC, indirect treatment comparison; MET, mesenchymal–epithelial transition factor; *MET*ex14, *MET* exon 14; N/A, not available; ne, not estimable; NIS, non-interventional study; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; rw, real-world; SD, standard deviation; T+, *MET*ex14 skipping detected in tissue biopsy; TBC, to be confirmed; TKI, tyrosine kinase inhibitor; TTNTD, time to next treatment or death.

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SUPPLEMENTARY RESULTS

Table S1. Sources of real-world data

Data source	Description	Location(s)	Data collection	Outcome data
0015 ^{1*}	EMR data from the US ConcertAI database	US	2004–2018	PFS, OS, response
0035 ^{2*}	EMR data from a multi-country chart review study	US, Israel, Taiwan, Netherlands	2010–2018	TTNTD, OS, response
COTA ¹	US COTA Healthcare EMR database	US	2010–2019	PFS, TTNTD, OS, response
GFPC ³	Data from routine practice across multiple specialist centers	France	2013–2020	TTNTD, OS, response
Wong et al. ⁴	Data from routine practice across multiple centers in a Canadian province	Canada	2016–2019	TTNTD, OS, response
Skribek et al. ⁵	Retrospective analysis of data from two Swedish University hospitals	Sweden	2014–2022	PFS, OS, response
Kuon et al. ⁶	Retrospective analysis of data from a series of German hospitals	Germany	2015–2022	PFS, OS, response

*NIS sponsored by Merck Healthcare KGaA, Darmstadt, Germany.

Figure S1. Eligibility criteria for inclusion of individual patients in the pooled analysis

Inclusion criteria

- Age ≥18 years
- *MET*ex14 skipping advanced NSCLC



Exclusion criteria

- Stages I–IIIA
- Missing disease stage and advanced/metastatic disease status
- ECOG PS ≥2
- Patients treated with tepotinib



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SUPPLEMENTARY RESULTS

Table S2. Patient characteristics in TOGETHER study (Overall and 2L+ population)

Characteristic		Overall (N=309)	2L+			
			All (n=195)	IO mono (n=79)	CT (n=70)	Crizotinib (n=66)
Age	Median, years (IQR)	72.0 (63.1, 78.0)	72.0 (64.5, 77.2)	70.0 (63.0, 76.3)	70.2 (63.5, 75.8)	72.0 (63.2, 76.8)
	Mean, years (SD)	70.3 (10.8)	70.2 (10.3)	69.0 (10.6)	68.3 (11.2)	69.5 (10.4)
Sex, n (%)	Male	148 (48)	87 (45)	31 (39)	39 (56)	28 (42)
	Female	161 (52)	108 (55)	48 (61)	31 (44)	38 (58)
Race, n (%)	White	88 (28)	67 (34)	25 (32)	22 (31)	18 (27)
	Asian	23 (7)	14 (7)	1 (1)	12 (17)	2 (3)
	Black/African American	2 (1)	3 (2)	1 (1)	1 (1)	0
	Other	4 (1)	1 (1)	2 (3)	1 (1)	0
	N/A	192 (62)	110 (56)	50 (63)	34 (49)	46 (70)
Smoking history, n (%)	Yes	161 (52)	93 (48)	41 (52)	36 (51)	34 (52)
	No	148 (48)	102 (52)	38 (48)	34 (49)	32 (48)
Stage, n (%)	IIIB+	13 (4)	4 (2)	2 (3)	3 (4)	0
	IV	131 (42)	93 (48)	31 (39)	39 (56)	23 (35)
	N/A	165 (53)	98 (50)	46 (58)	28 (40)	43 (65)
Histology, n (%)	ADC	233 (75)	141 (72)	59 (75)	48 (69)	45 (68)
	Squamous	33 (11)	26 (13)	12 (15)	11 (16)	10 (15)
	Sarcomatoid	9 (3)	8 (4)	1 (1)	2 (3)	6 (9)
	Other	25 (8)	15 (8)	7 (9)	6 (9)	2 (3)
	N/A	9 (3)	5 (3)	0	3 (4)	3 (5)

Abbreviations: 2L+, second-or-later line; ADC, adenocarcinoma; CT, chemotherapy; IO, immunotherapy; IQR, interquartile range; N/A, not available; SD, standard deviation.

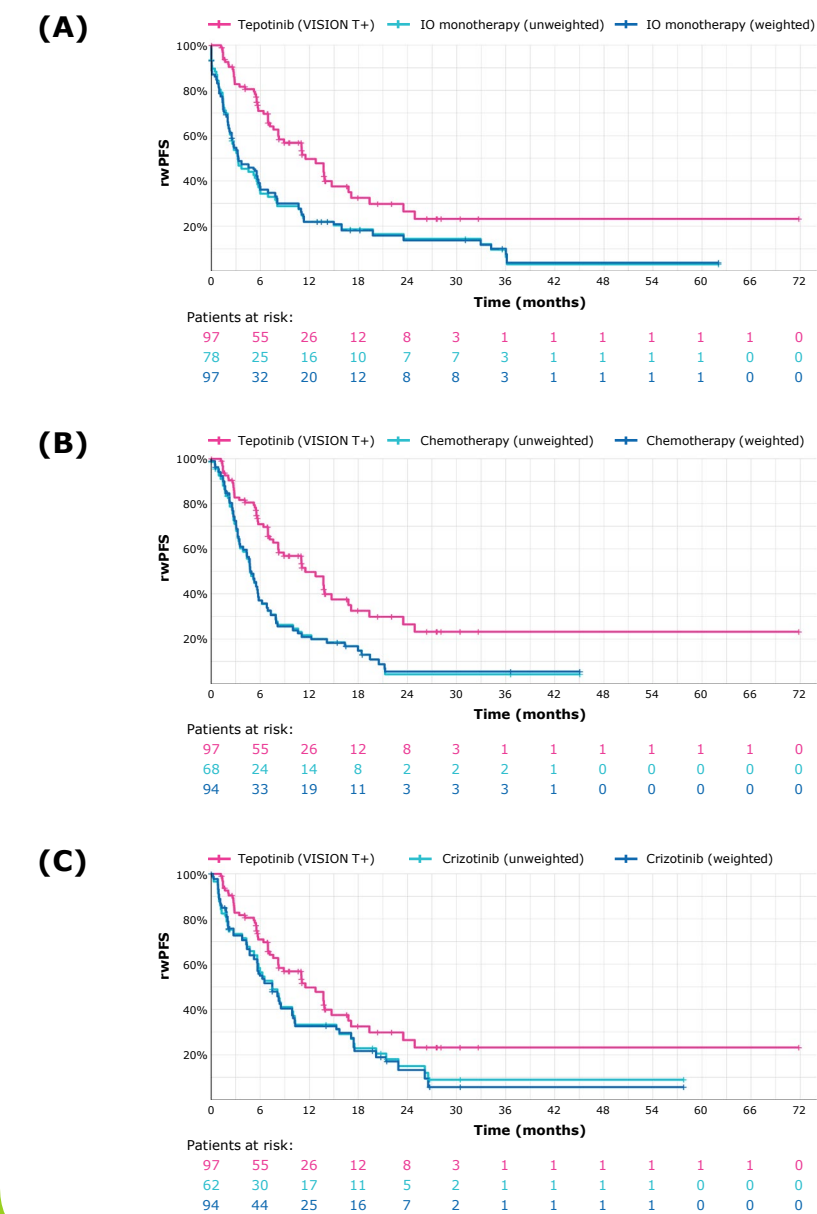
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SUPPLEMENTARY RESULTS

Figure S2. rwPFS for 2L+ (A) IO monotherapy, (B) chemotherapy, and (C) crizotinib compared with 2L+ tepotinib in VISION



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SUPPLEMENTARY RESULTS

Figure S3. rwOS for 2L+ (A) IO monotherapy, (B) chemotherapy, and (C) crizotinib compared with 2L+ tepotinib in VISION

