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Conclusion

- Nivolumab treatment showed trends of improvement in both Oesophageal-specific and general HRQoL
- Patients treated with nivolumab did not experience a reduction in HRQoL, further supporting clinical data to demonstrate treatment benefit and tolerability for adjuvant nivolumab in gastric cancer patients

Background

- A combination of genetic factors and environmental factors influences cancer development. The global burden of gastric cancer and gastroesophageal junction cancer is immense
- Esophago-gastric cancers are among the most common and deadly cancers in the world
- In the management of gastric cancer, Nivolumab has emerged as a promising immunotherapeutic agent. However, measuring the impact on patient quality of life (QoL) requires going beyond traditional clinical analysis<sup>1</sup>

Objective

- The SLR aims to evaluate the existing literature on patient-reported outcomes (PROs) with Nivolumab across gastric cancers

Methodology

- The review was conducted in accordance with PRISMA guidelines<sup>2</sup>, Cochrane Handbook<sup>3</sup> and National Institute for Health and Care Excellence (NICE)<sup>4</sup> standard approach for conducting reviews
- Embase<sup>®</sup> and MEDLINE<sup>®</sup> were searched from inception to June 2023, for all randomized controlled studies reporting PROs with Nivolumab across gastric cancer
- The SLR followed two review and quality control process as recommended by various HTAs

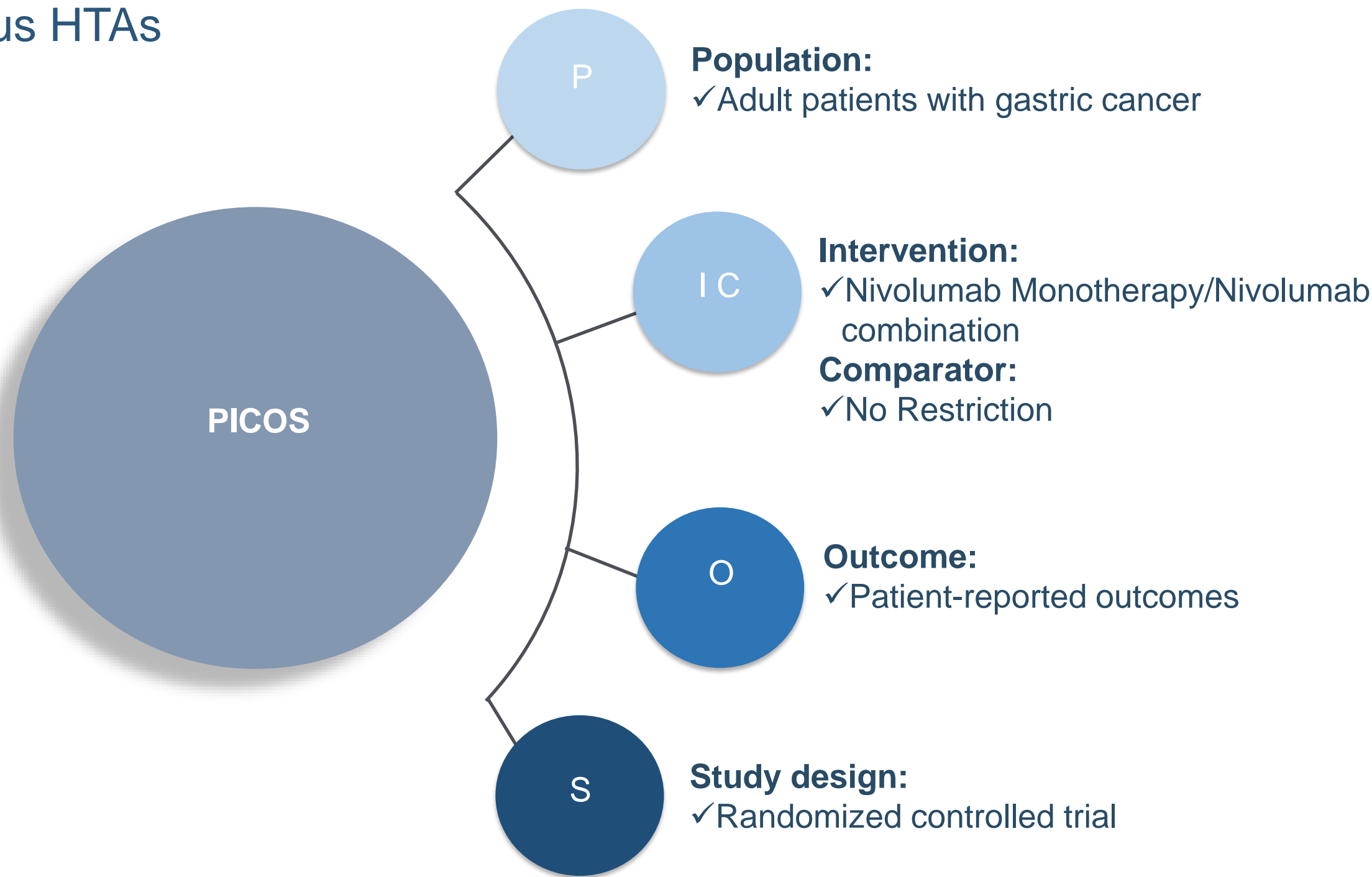


Figure 1: Presents the eligibility criteria for selection of evidence

Results

- A PRISMA diagram for the screening process is presented in Figure 2
- Out of 1246 screened publications, four studies assessing advanced Oesophageal or gastric carcinoma met the inclusion criteria

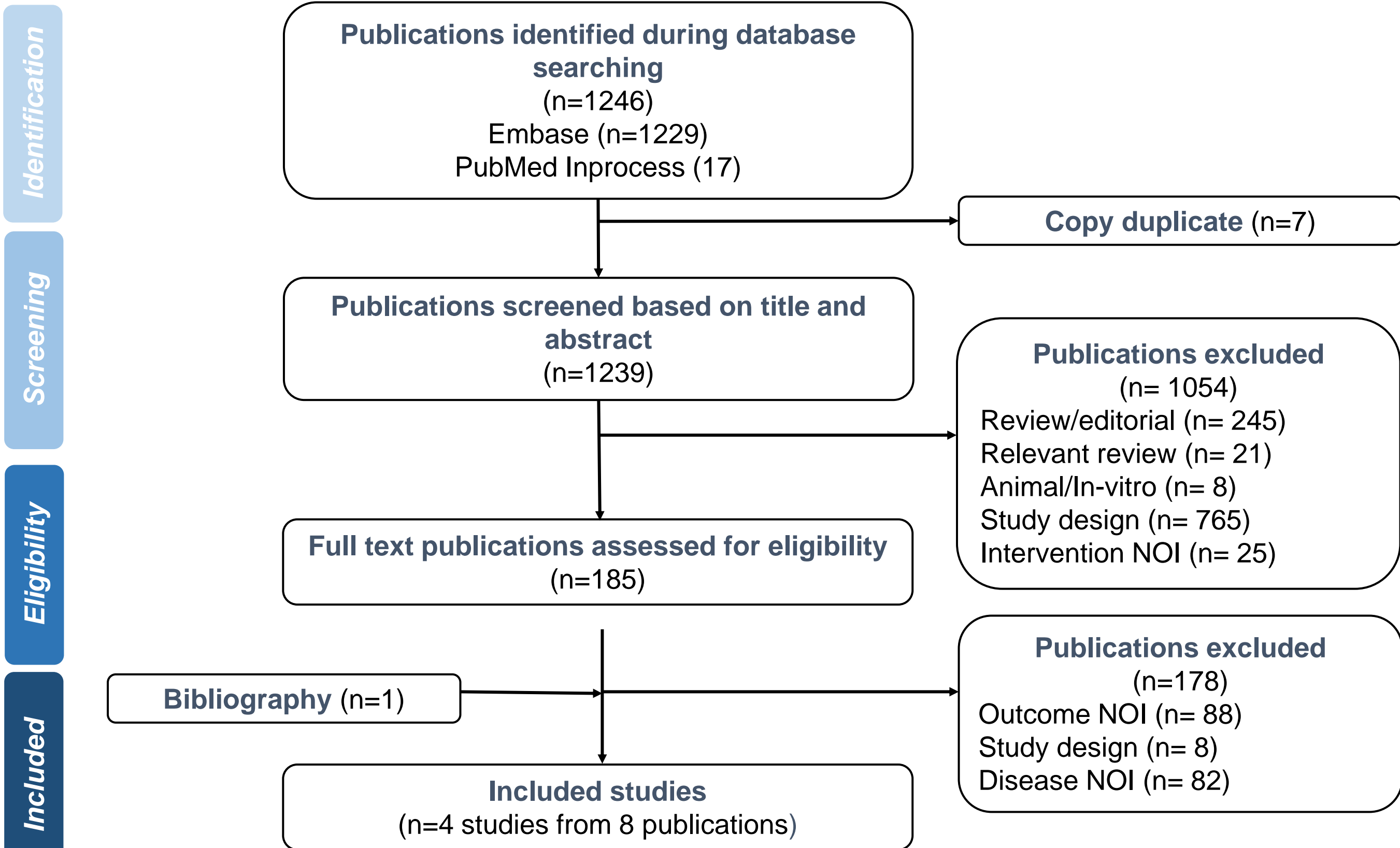


Figure 2: Flow of studies through the systematic literature review

Results (Cont'd)

- Sample size across the included studies ranged from 419 to 1581

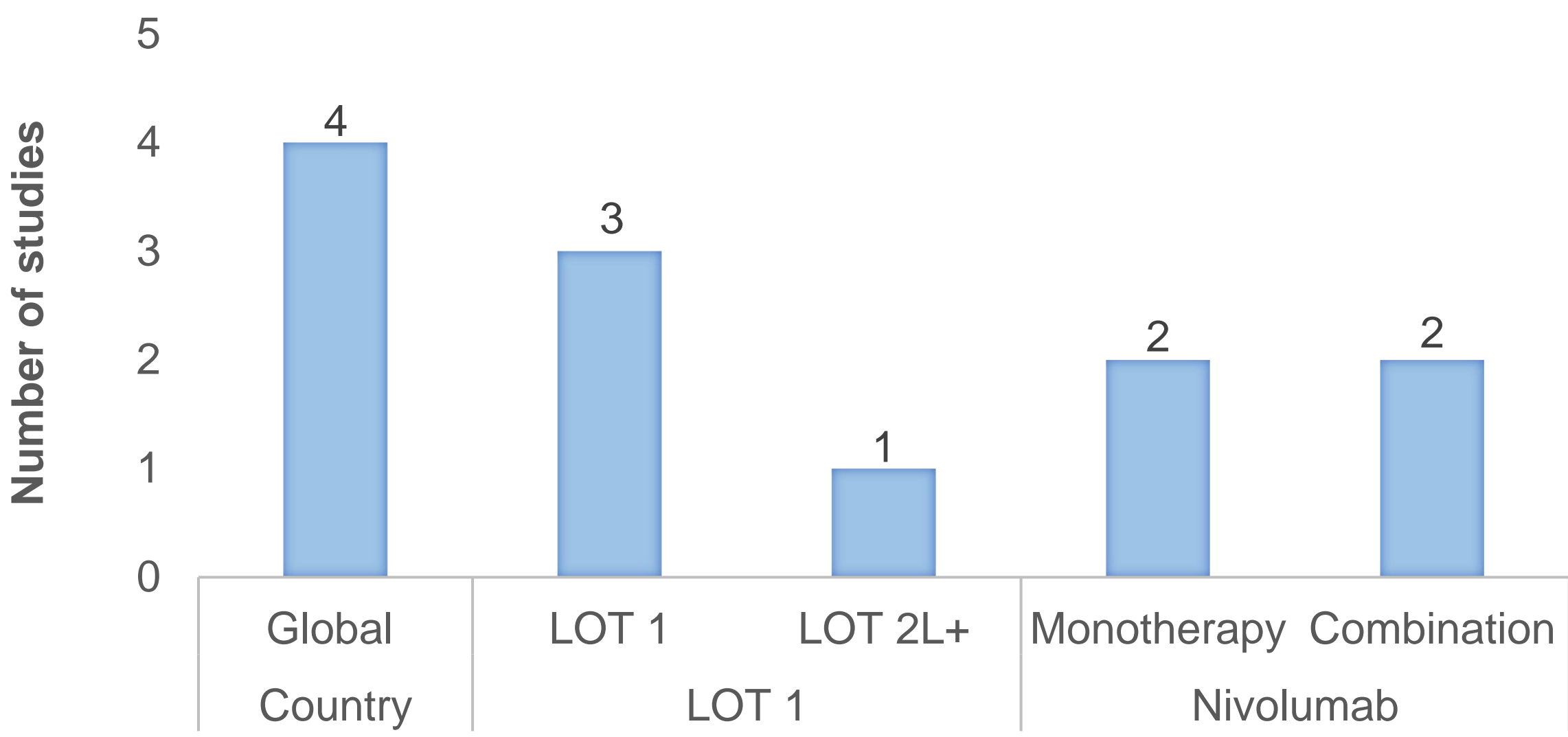


Figure 3: Study details reported across the included studies

- Two studies each assessed Nivolumab as monotherapy and combination therapy
- EQ-5D VAS (n=2), EQ-5D UI (n=2), FACT-E (n=2), and FACT-Ga (n=1) were the PRO scales assessed across studies. Three studies assessed first-line of therapy (LOT1) and one assessed ≥2 lines (LOT≥2)
- First-line treatment (LOT1) with nivolumab showed clinically meaningful improvement (CMI) (CFB cut-off 7) in EQ-5D VAS score (CFB: 9.78 (95% CI 6.88, 12.72) at several time points over 1 year, while LOT≥2 treatment showed no CMI (1.13 (-4.83, 7.62) at 42 weeks. Although showing trends of improvement, both LOT1 and LOT≥2 nivolumab studies did not meet the CMI cut-off (0.08) for EQ-5D UI
- Similar results were observed in LOT1 studies of nivolumab ± chemotherapy for FACT-E (cut-off 9.5) and FACT-Ga (cut-off 15.1) scales indicating maintained QoI over the treatment duration. Nivolumab ± chemotherapy was associated with better QoI and decreased risk of symptom deterioration as compared to chemotherapy alone
- However, the significance level was achieved on EQ-5D VAS (HR 0.65, 95% CI 0.49, 0.86, p=0.0030), FACT-Ga (0.77 [0.63, 0.95]) and EQ-5D UI (0.73 [0.55, 0.97], p=0.032) scales only

Scale	Trial	Nivolumab Monotherapy	Nivolumab + CT	Nivolumab + IPI	Placebo/CT
FACT-E (CMI: 9.5)	CheckMate 648	-	4.98 (2.68, 7.27)	3.45 (0.96, 5.94)	1.54 (-1.26, 4.33)
	CheckMate 577	3.01 (0.06, 6.09)	-	-	6.03 (1.68, 10.43)
FACT-Ga (CMI: 15.1)	CheckMate 649	-	7.02 (3.86, 10.24)	-	2.51 (-1.76, 6.87)
EQ-5D UI (CMI: 0.08)	CheckMate 577	0.01 (-0.03, 0.04)	-	-	0.01 (-0.05, 0.06)
	Attraction-3	0 (-0.05, 0.06)	-	-	-0.08 (-0.22, 0.06)
EQ-5D VAS (CMI: 7)	CheckMate 577	9.78 (6.88, 12.72)	-	-	9.10 (5.13, 13.29)
	Attraction-3	1.13 (-4.83, 7.62)	-	-	-1.65 (-6.85, 3.21)

Table 1: Change from baseline (mean (95% CI)) values for various PRO scales with nivolumab: mean (95% CI)

FACT-Ga: Functional Assessment of Cancer Therapy-Gastric; FACT-E: Functional Assessment of Cancer Therapy-Esophageal; EQ-5D UI: European Quality of Life-5 Dimensions questionnaire-Utility index; EQ-5D VAS: European Quality of Life-5 Dimensions questionnaire-Visual analogue scale; CMI: Clinically meaningful improvement (CMI) ; CT: Chemotherapy; IPI: Ipilimumab

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Disclosure

GK, GB, BS, the authors, declare that they have no conflict of interest

