

An Evaluation of the Rising Significance of Patient-Reported Outcomes in Oncology Clinical Trials

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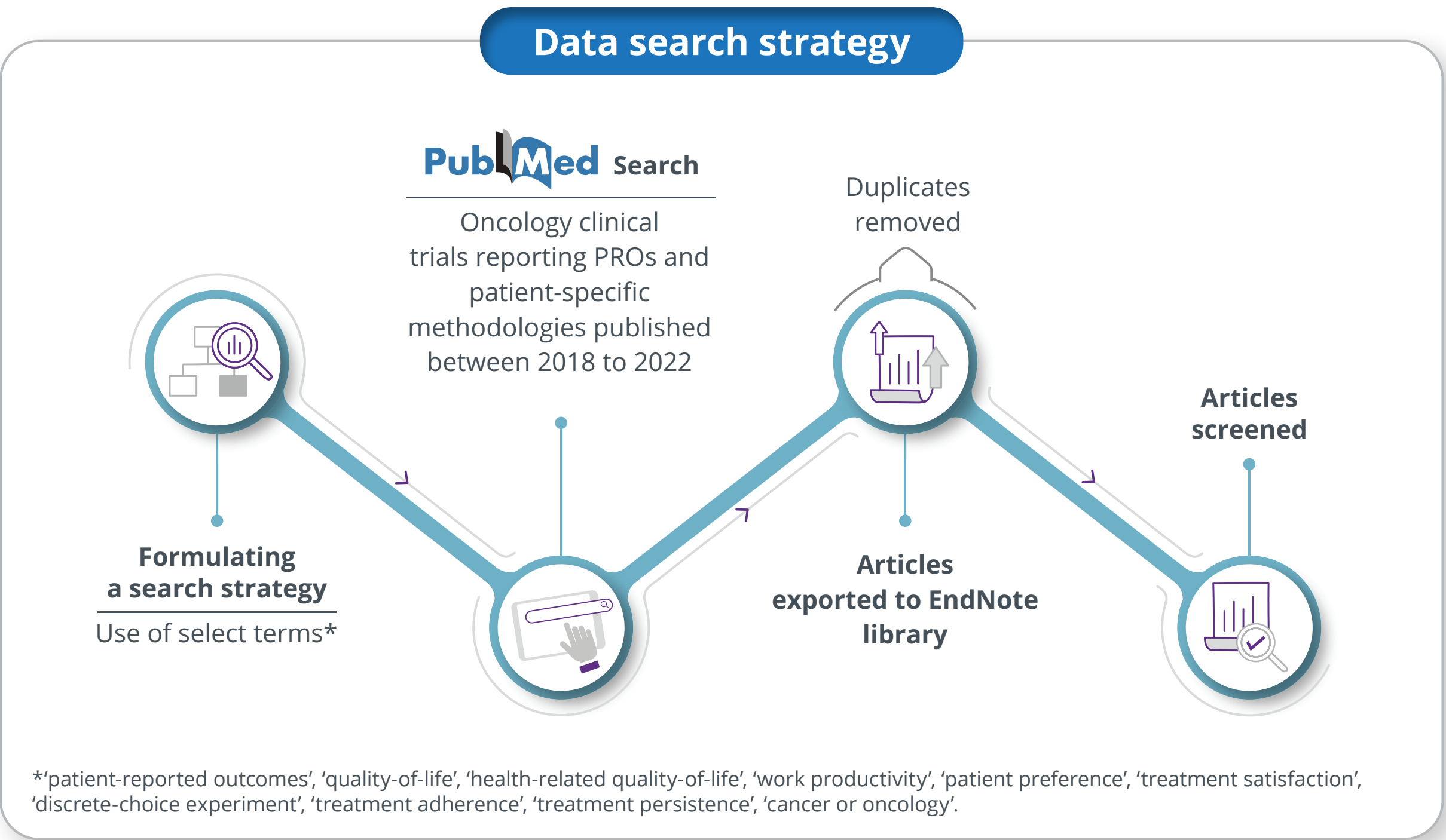
BACKGROUND

- Early detection and advanced treatments have shown remarkable improvements in cancer patients' locoregional control and overall survival in recent decades.¹ As healthcare shifts towards a more value-based framework for improving HRQoL, PRO measures are increasingly being assessed in oncology for individual patient care management.^{2,3}
- PROs provide physicians with a wealth of information about the patient's perspective of cancer care processes. In oncology, PRO collection and its incorporation in routine clinical practice has been pivotal for better clinical outcomes, patient satisfaction, patient compliance, and overall quality of care.⁴

OBJECTIVE

- To assess the number of oncology clinical trials reporting PROs in peer-reviewed literature over the past 5 years as a proxy indicator of the growing importance of PROs. This study also looked into the types of PRO instruments utilized.

METHODS



Inclusion Criteria

- Clinical trials including randomized-controlled trials
- Articles published in English language only

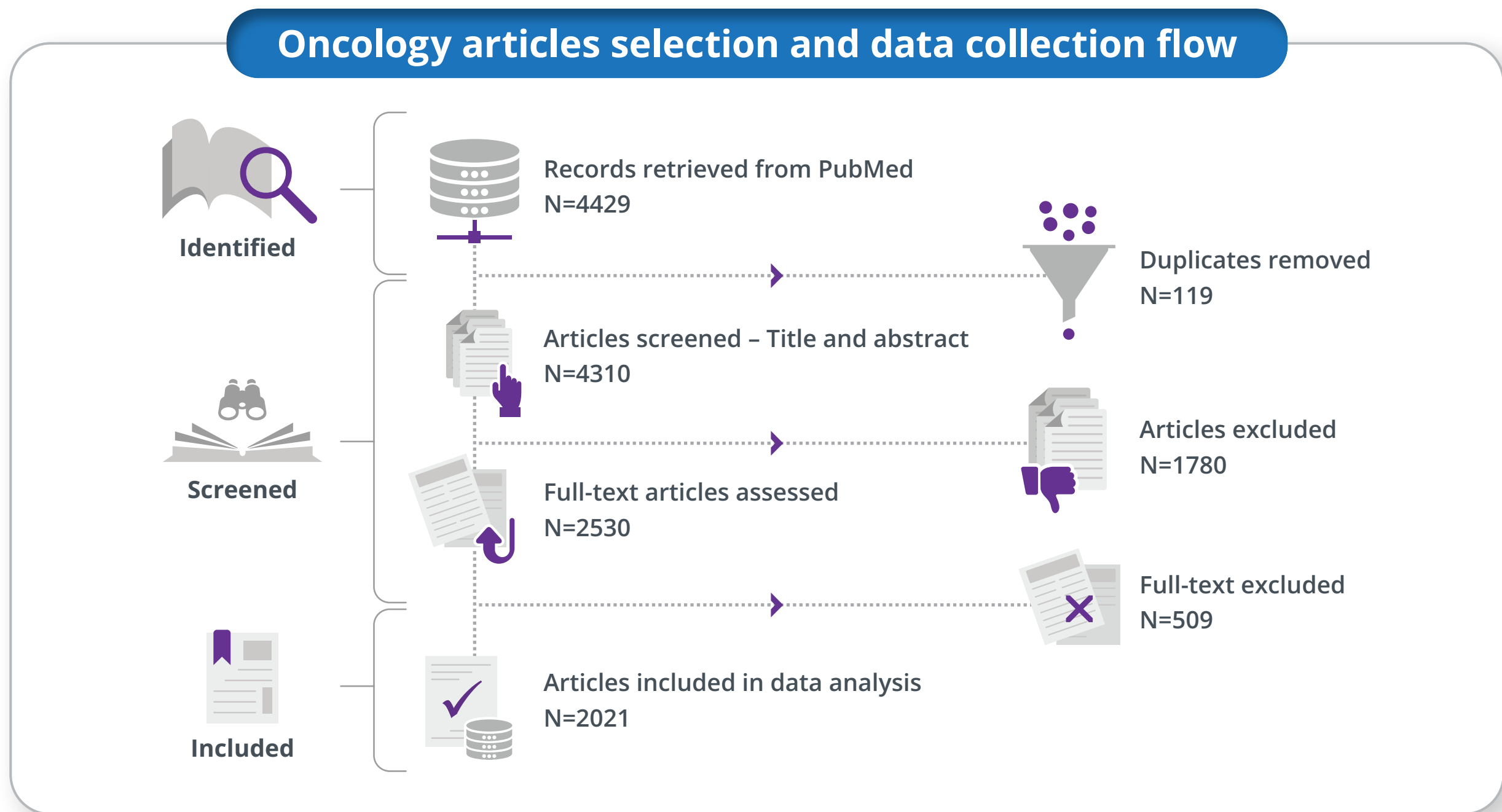
Exclusion Criteria

- Published protocols, guidelines, opinions, commentaries, and review articles
- Articles with only keyword mentions
- Articles focusing entirely on communication or palliative/supportive care education

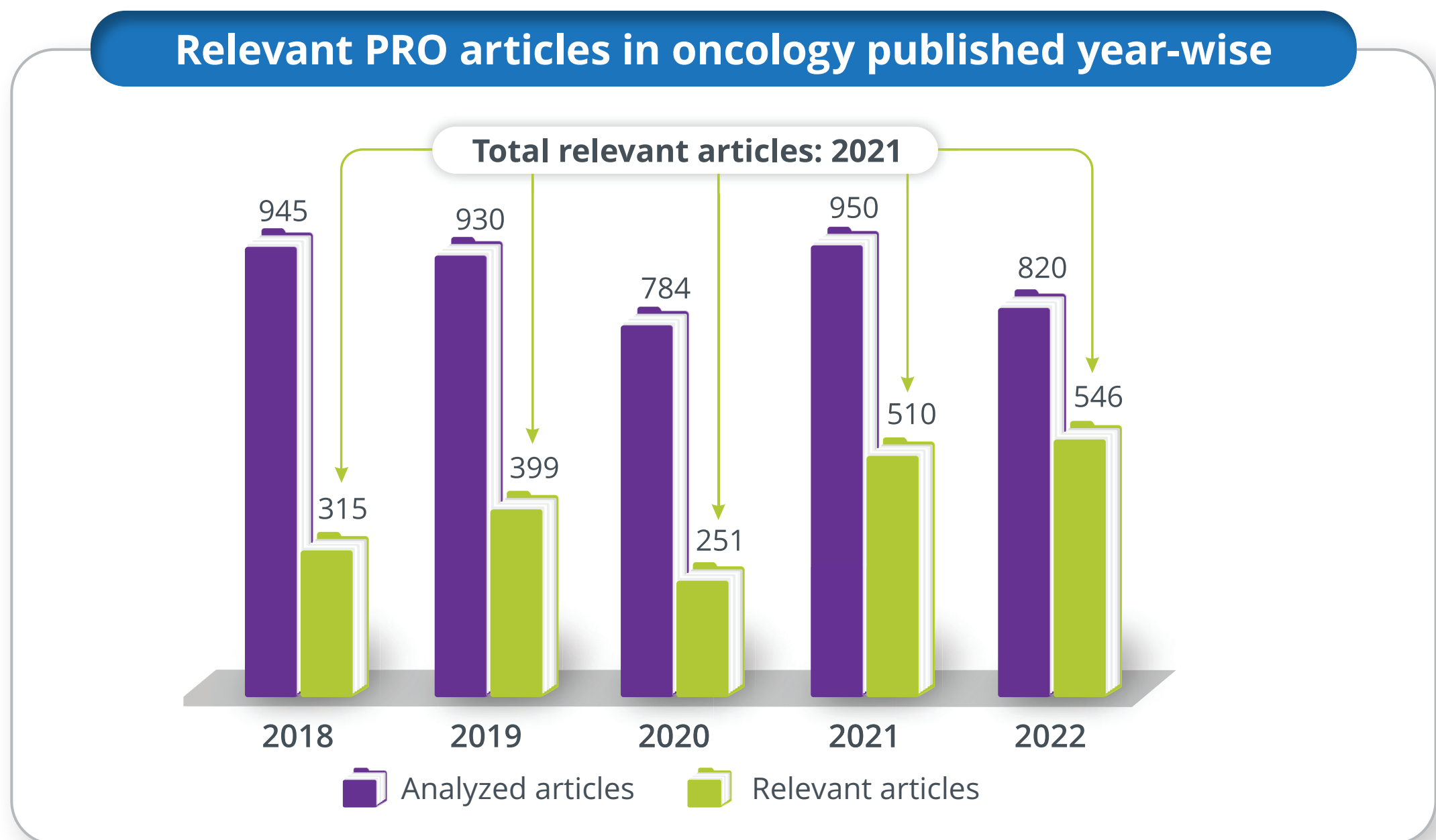
- In all, 4 reviewers independently screened the articles and extracted data from the selected studies using a Microsoft Excel spreadsheet, and discrepancies were identified and resolved through discussion with a fifth reviewer.
- The extracted data items included title, PMID, DOI, year of publication, study design, country, cancer type, endpoints, and types of PRO instruments used.
- Two reviewers independently assessed 20% of the data to verify the consistency of the extraction process and solved discrepancies.
- The extracted data were descriptively analyzed.

RESULTS

- A total of 4429 articles were retrieved from the PubMed search for oncology articles.
 - After removing duplicates, 4310 articles were screened for title and abstract.
 - 2530 articles were identified as eligible for full-text review.



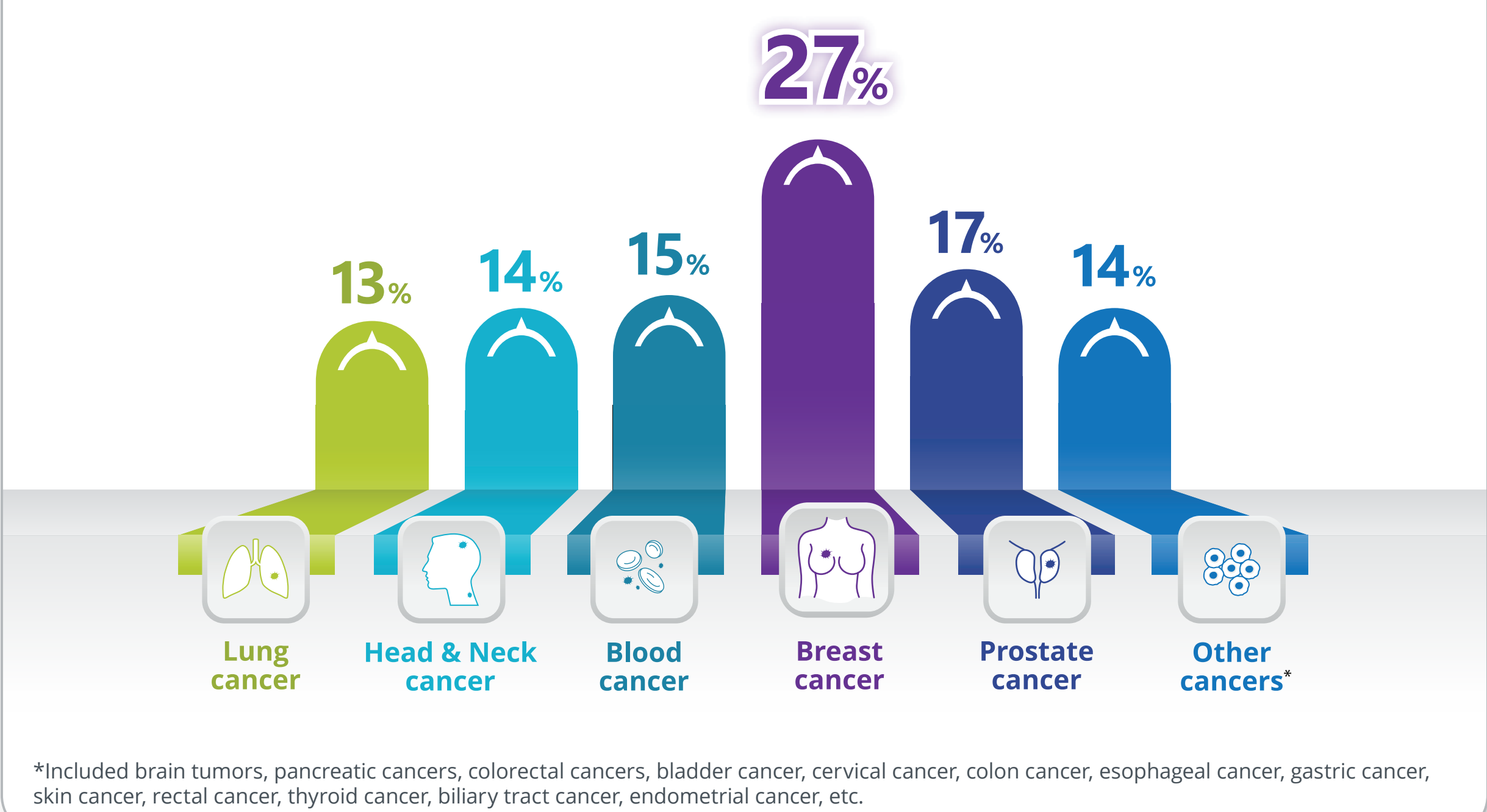
- In total, 2021 (46.89%) oncology articles were included in the data analysis for PROs, displaying an exponential growth from 33% (315/945) publications in 2018 to 66% (546/820) in 2022. The low number of articles reported for 2020 (n=251) could be attributed to the pandemic situation.



- Based on study design, the majority of studies were randomized-controlled trials either retrospective or prospective (1542/2021 [76.30%]).
- PROs were reported as a secondary and/or exploratory endpoint in the majority of trials (1196/2021 [59.18%]), and as a primary endpoint in 825 studies (40.82%). Most trials specifically explored HRQoL (1205/2021 [59.62%]).

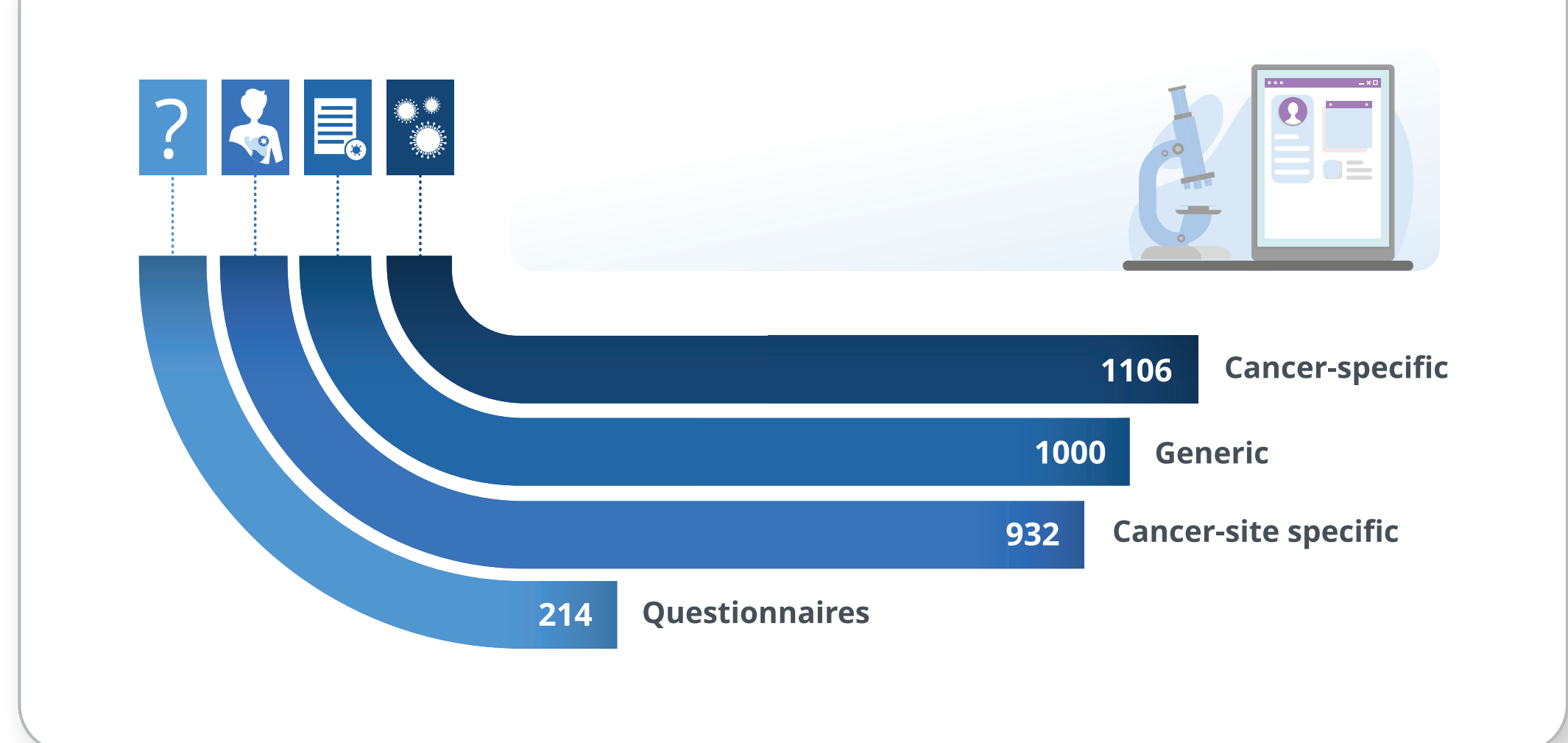


Distribution of PRO articles in oncology based on the cancer type



- The use of instruments was observed to be overlapping. Cancer-specific PRO instruments (e.g., EORTC-QLQ-C30) were the most frequently used (54.73%), followed by generic (49.50%; e.g., EQ-5D-5L), cancer-site specific (46.11%; e.g., EORTC-QLQ-BR23), and questionnaires (10.61%).
- The most frequently used PRO instruments were:
 - Cancer-specific: EORTC-QLQ-C30 (701/1106 [63.38%]) and FACT-G or FACT-F (220/1106 [19.89%]).
 - Generic: EQ-5D-5L (248/1000 [24.80%]) and HADS (189/1000 [18.90%]).
 - Cancer-site specific: EORTC-QLQ-based (348/932 [37.34%]) and FACT-based (255/932 [27.36%]).

Distribution of PRO instruments used in oncology trials



CONCLUSIONS

- Our findings demonstrate that reporting of PROs in oncology peer-reviewed literature has increased substantially in the past 5 years and this trend will likely continue to grow since PRO instruments are a significant measure of disease burden and treatment effect.
- Cancer-specific PRO instruments were observed to be the most commonly used in oncology clinical trials.
- Despite their increasing use in clinical trials, PROs are rarely used in routine clinical practice. As PROs play a vital role in decision-making for patients support in oncology, implementation of PRO in routine oncology clinical practice could bring about a paradigm shift in cancer care.

FUTURE SCOPE

- In addition to the published articles, unpublished ongoing clinical trials to be investigated.
- Considering the heterogeneity of the identified publications, a quality assessment to be performed as part of the literature review to formally evaluate the strength of evidence.

Abbreviations: DOI, digital object identifier; EORTC-QLQ-C30, European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; 30-item core cancer-specific questionnaire; EORTC-QLQ-BR23, EORTC QLQ 23-item breast cancer-specific module; EQ-5D-5L, European Quality of Life Group, 5 Dimension, 5 Level; FACT-F, Functional Assessment of Cancer Therapy; Fatigue; FACT-G, FACT General; HADS, Hospital Anxiety and Depression Scale; HRQoL, health-related quality of life; PMID, PubMed unique identifier; PRO, patient-reported outcome.

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