

Association of medical writing support with time to publication

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Conclusions

- This study suggests that medical writing support may facilitate more timely publication of phase III oncology clinical trial results.
- The redirection of journal and healthcare resources and focus due to the Covid-19 pandemic^{4,5} may have impacted time to publication. This is also suggested by the fluctuating number of papers during the pandemic years before a recovery in 2023.
- Further research would be needed to investigate whether similar trends were observed for publication of phase III trials in other journals and therapy areas, as well as publications of early phase clinical trials.

Introduction

- Timely reporting of clinical research is important for informing clinical practice.
 - The World Health Organization recommends submission of the main findings of a clinical trial to a journal within 12 months of trial completion.¹
- Medical writers may help authors with the timely, ethical, and accurate disclosure of research.^{2,3}
- During the coronavirus disease 2019 (Covid-19) pandemic, there was a substantial decrease in the initiation of new clinical trials in cancer.⁴
 - Recruitment for many trials was halted/delayed, with the aims of protecting patients from infection and reassigning clinical research staff to support healthcare services involved with management of Covid-19.⁵
- We explored the association between medical writing support and time to publication of data from phase III oncology trials published from 2019 to 2023 in two high-tier general medical journals, as well as the impact of the Covid-19 pandemic on publication volume.

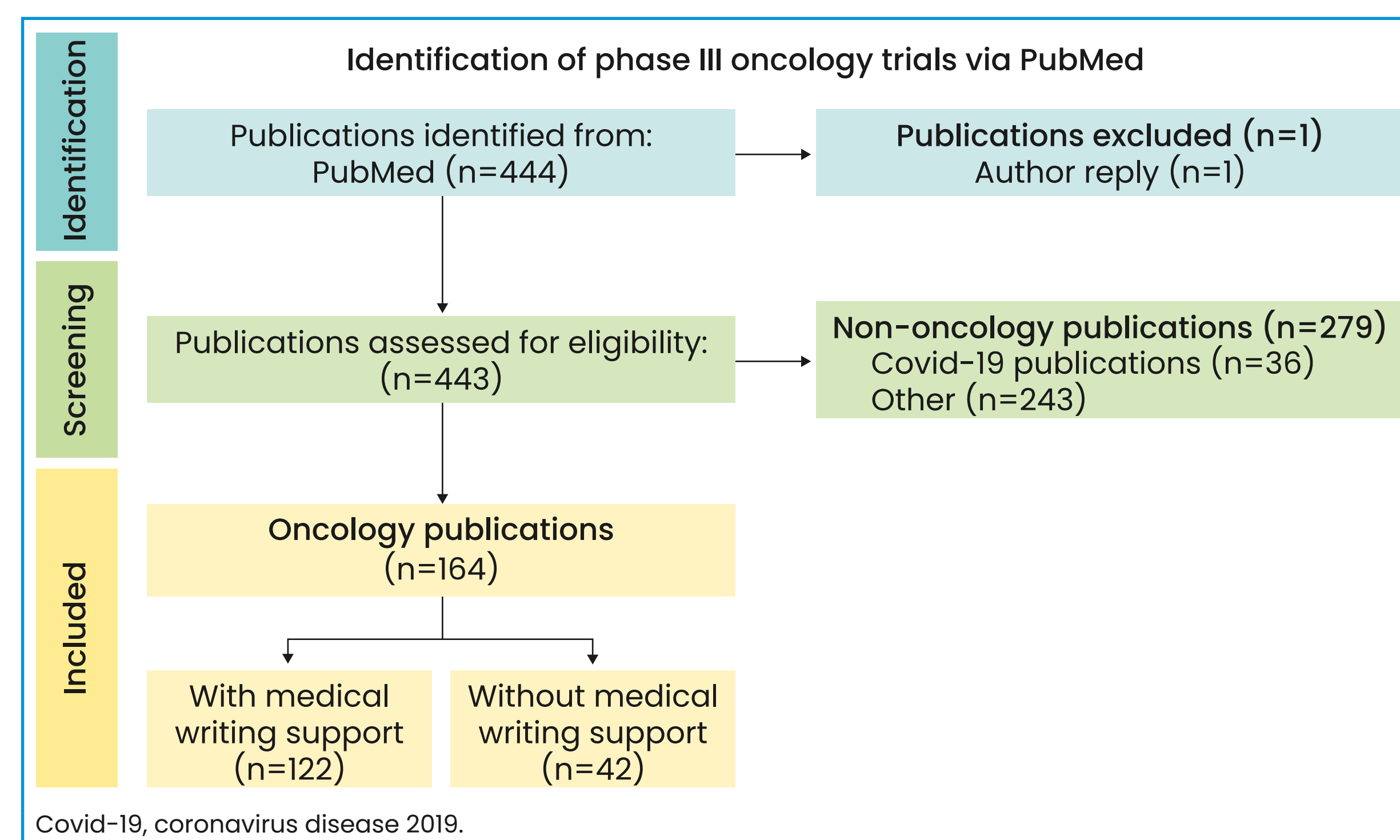
Methods

- We searched PubMed for phase III clinical trials published in *NEJM* and the *Lancet* between January 1, 2019, and December 31, 2023.
 - Therapy area, publication date, and journal were documented for each publication.
 - Papers were subdivided into oncology, Covid-19-related, and other therapy areas.
- Publications reporting oncology trials were reviewed in full to document acknowledgment of medical writing/editorial support, the data cut-off date, tumor type, number of participants randomized, outcome of the primary/key endpoint(s), Altmetric attention score, and number of citations.
 - Oncology trials were defined as those that investigated the treatment or prevention of a solid tumor or hematological malignancy; trials reporting interventions for the management of sequelae of a malignant neoplasm were also included.
 - Outcome of the primary/key endpoint(s) was classified as met, not met, or partially met (when at least one, but not all, of the co-primary endpoints were met).
 - Altmetric attention scores and Dimensions citation data were sourced from Altmetric.com on March 11, 2024.
- Characteristics of publications were summarized using descriptive statistics.
- Time from trial data cut-off, or similar key dates, to publication date was compared for publications with and without medical writing support in the overall analysis set using an unpaired t-test (GraphPad Prism version 10.2.1 [395]).
 - In cases where multiple data cut-off dates were reported in a publication, we selected the most recent date as the basis for our analysis.
 - Primary completion date, trial completion date, or stated cut-off date for posted results (documented in the trial's registry [ClinicalTrials.gov, Australian New Zealand Clinical Trials Registry, or UMIN Clinical Trials Registry]) were used in instances where a data cut-off date (or similar key date) was not reported in the publication and the posted results matched the data reported in the publication.

Results

- We identified a total of 443 papers reporting results from phase III clinical trials published in *NEJM* and the *Lancet* between January 1, 2019, and December 31, 2023, of which 164 (37%) reported oncology clinical trials (Figure 1).

Figure 1. Identification of phase III clinical trials



- Key characteristics of publications included in this analysis are summarized in Table 1.
 - Medical writing support was disclosed in 122 (74%) of the oncology papers.
 - The proportion of papers published in *NEJM* (63%) was higher than in the *Lancet* (37%); the proportion of papers with and without medical writing support was similar for both journals.

Table 1. Characteristics of publications reporting phase III clinical trials in oncology¹

Characteristic	With medical writing support (n=122)	Without medical writing support (n=42)	Overall (N=164)
Journal, n (%)			
NEJM	79 (65)	25 (60)	104 (63)
Lancet	43 (35)	17 (40)	60 (37)
Publication year, n (%)			
2019	25 (20)	14 (33)	39 (32)
2020	20 (16)	4 (10)	24 (20)
2021	21 (17)	4 (10)	25 (20)
2022	18 (15)	9 (21)	27 (22)
2023	38 (31)	11 (26)	49 (40)
Cancer type, n (%)			
Solid	97 (80)	35 (83)	132 (80)
Hematologic	25 (21)	7 (17)	32 (20)
Number of randomized patients, median (range)	630 (120–1836)	669 (103–4446)	646 (103–4446)
Primary endpoint met, n (%)			
Yes	106 (87)	33 (79)	139 (85)
No	4 (3)	8 (19)	12 (7)
Partially	12 (10)	1 (2)	13 (8)
Altmetric attention score ² , median (range)	382 (62–2077)	218 (32–1181)	333 (32–2077)
Number of citations ³ , median (range)	346 (4–3993)	113 (4–1521)	260 (4–3993)

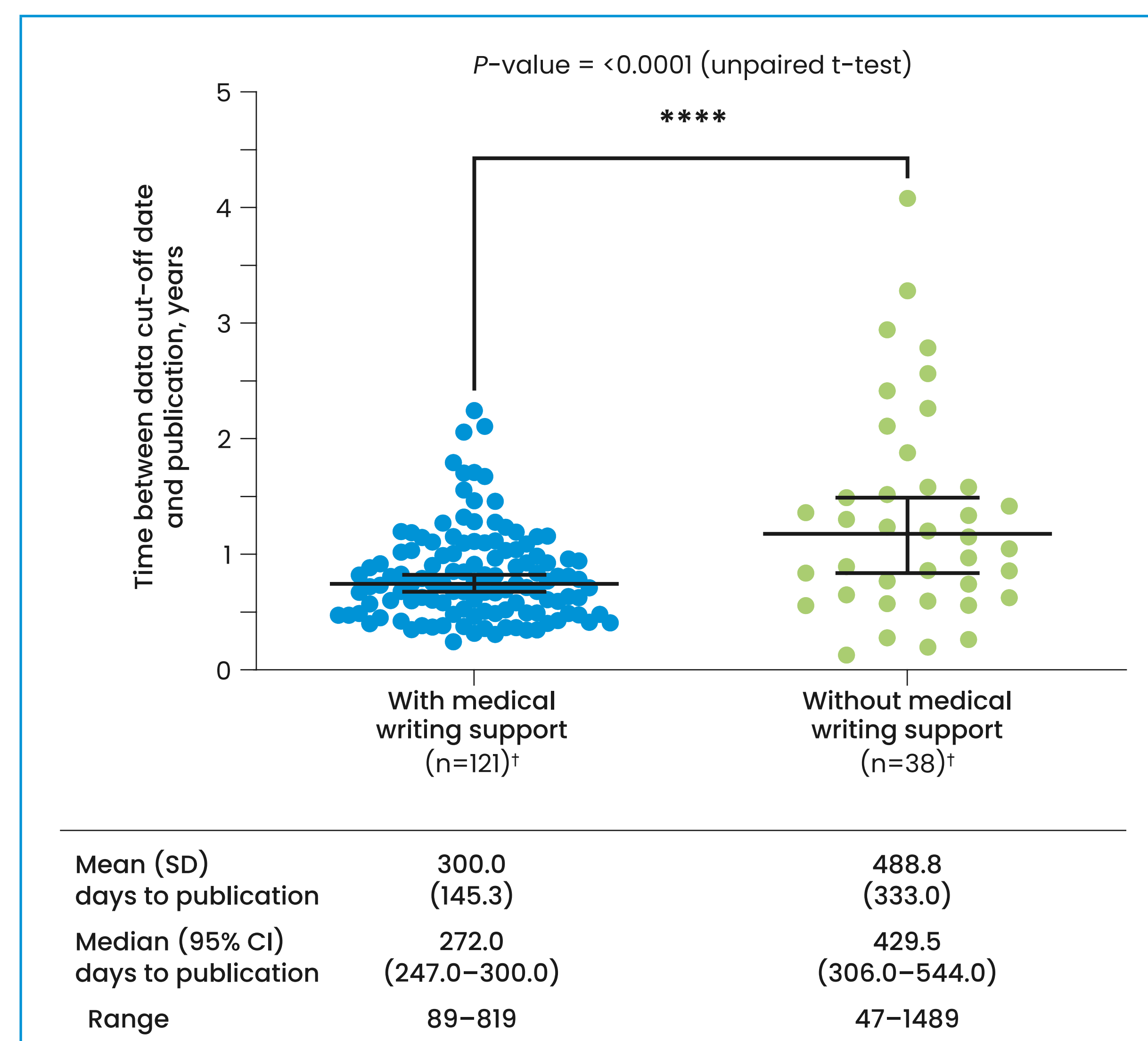
¹Published in *NEJM* and the *Lancet* between January 1, 2019, and December 31, 2023.

²Altmetric attention score and the number of times cited as of March 11, 2024.

³Number of citations as reported in the Dimensions citations tab in each publication's Altmetric attention score details page from Altmetric.com as of March 11, 2024.

- Overall, the primary endpoint was met in 85% of the papers.
- Mean time to publication was significantly shorter for papers that disclosed medical writing support than those that did not (300.0 versus 488.8 days; P -value < 0.0001; Figure 2).
- Median time to publication for papers with medical writing support appeared stable from 2019 to 2023 (Figure 3).
- Similarly, the year of publication did not appear to influence time to publication for papers without medical writing support, although there were few papers in 2020 and 2021 (three publications each).

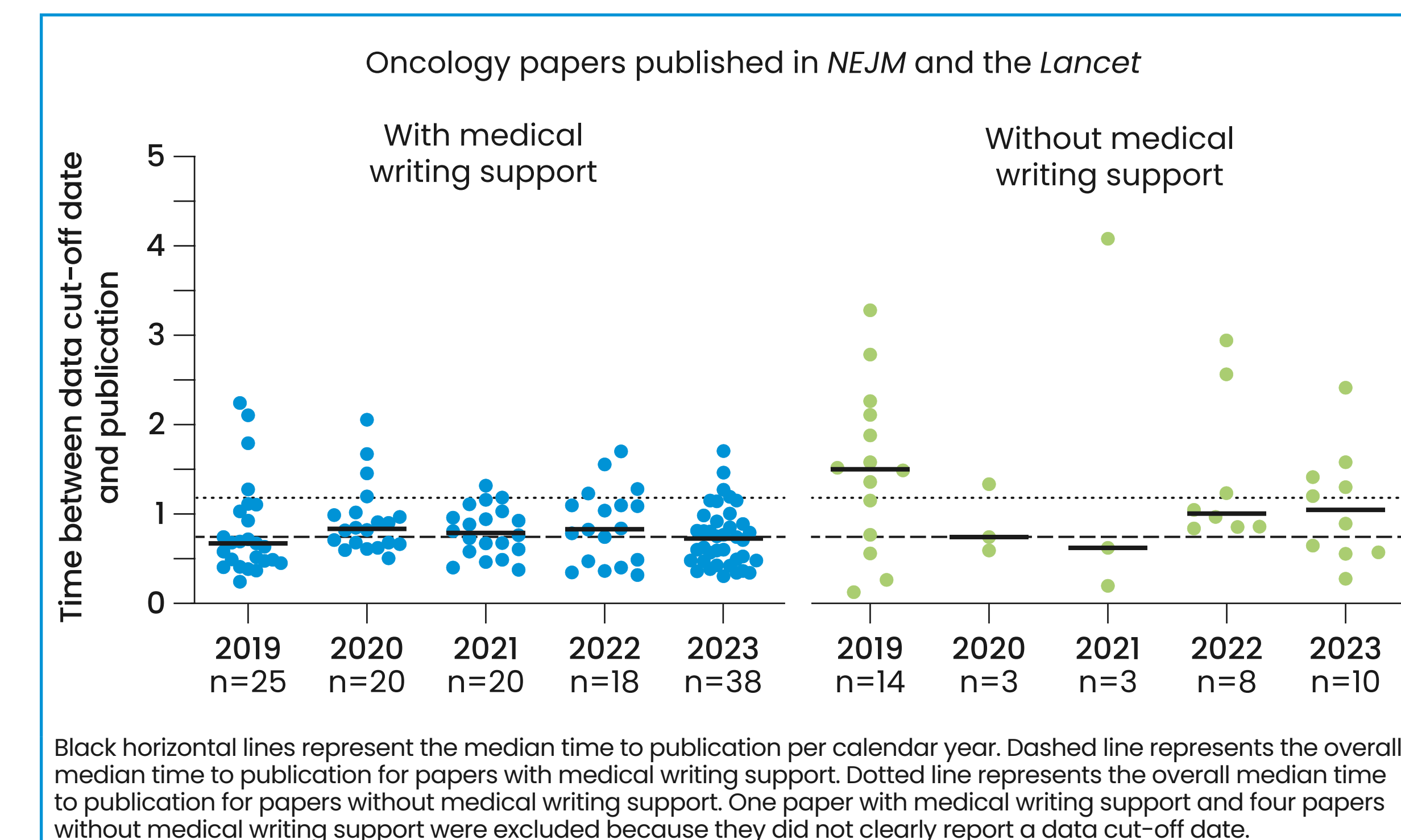
Figure 2. Time from reported cut-off date to publication



CI, confidence interval; SD, standard deviation.

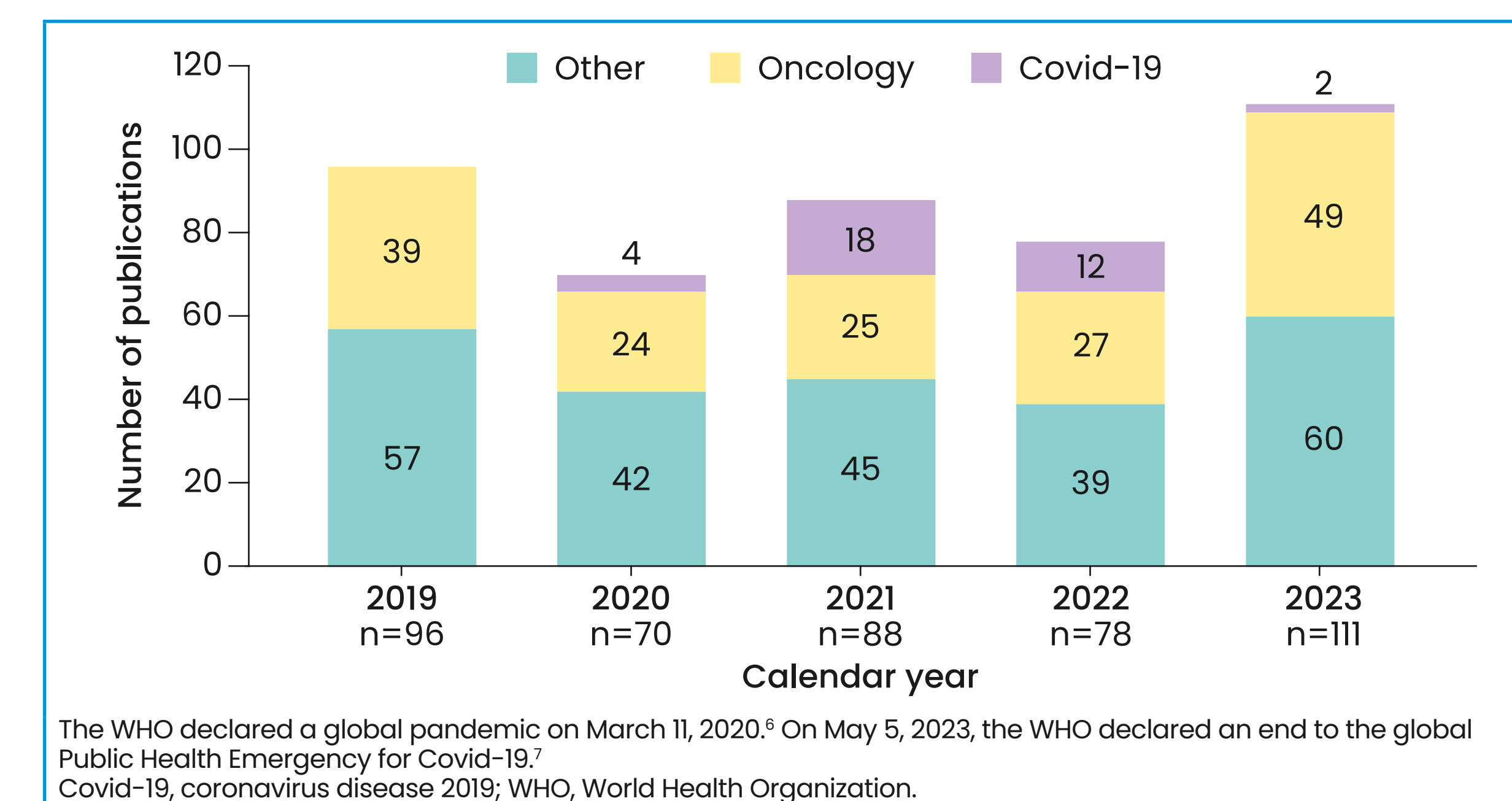
Black horizontal line represents the median, and whiskers represent 95% confidence intervals. *One paper with medical writing support and four papers without medical writing support were excluded because they did not clearly report a data cut-off date.

Figure 3. Time from reported cut-off date to publication by year of publication



- The total number of phase III studies published in *NEJM* and the *Lancet* between 2019 and 2023 was lowest in 2020 (n=70) and highest in 2023 (n=111) (Figure 4).
- Phase III Covid-19 studies published in these journals peaked in 2021 (Figure 4).
- The number of phase III non-Covid-19-related study papers was lower between 2020 and 2022 (66 papers in 2020, 70 papers in 2021, and 66 papers in 2022) than in 2019 and 2023 (96 papers and 109 papers, respectively; Figure 4).
- The number of phase III clinical trial papers published in 2023 was the highest in the analysis period.
 - It is unclear whether this finding is coincidental or represents a rebound in publication volume due to pandemic-related delays in clinical trial readouts.

Figure 4. Total number of phase III clinical trial papers by therapy area over the 2019–2023 period



Limitations

- The PubMed creation date was used to represent the publication date for each paper. In addition, phase III clinical trials were identified using the side bar filter function in PubMed.
- The analysis reports a snapshot of the Altmetric attention scores and the number of citations for papers; both measures are known to change over time.
- The primary analysis was confined to one therapy area (oncology). Another limitation is the focus on phase III trials published in only two medical journals.
- Differences in the design of trials reported in papers with medical writing support versus those without were not accounted for; trials reported in papers with medical writing support may be more likely to have pharmaceutical-industry sponsorship, investigate pharmacological interventions, and have different regimen comparisons.

References

- World Health Organization. WHO statement on public disclosure of clinical trial results. Apr 9, 2015. Available from: <http://www.who.int/news/item/09-04-2015-japan-primary-registries-network>. [Accessed Mar 19, 2024].
- American Medical Writers Association (AMWA); European Medical Writers Association (EMWA); International Society for Medical Publication Professionals (ISMPP). *Medical Writing*. 2017;26:7–8.
- DeTora LM, et al. *Ann Intern Med*. 2023;176:e1220490.
- Wilkinson E. *Lancet Oncol*. 2021;22:305.
- Ali JK, Riches JC. *Cancers (Basel)*. 2021;13:5924.
- World Health Organization. WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020. Available from: <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>. [Accessed Mar 19, 2024].
- World Health Organization. Statement on the fifteenth meeting of the IHR (2005) Emergency Committee on the COVID-19 pandemic: 5 May 2023. Available from: [https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic) [Accessed Mar 19, 2024].

Disclosures

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