Association of medical writing support with time to publication

No. 30

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Key findings:

Medical writing support may facilitate more timely publication of phase III oncology clinical trial results.

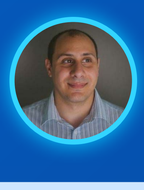
The redirection of journal and healthcare resources and focus due to the Covid-19 pandemic may have impacted time to publication. This is also suggested by the fluctuating number of papers during the pandemic years before a recovery in 2023.

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.


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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]
- 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 *N Engl J Med* 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, tumour type, number of participants randomised, outcome of the primary/key endpoint(s), Altmetric attention score, and number of citations.
- Characteristics of publications were summarised 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]).

Additional detail on the methods can be found in the mobile-friendly website version of this poster

Results

- We identified a total of 442 papers reporting results from phase III clinical trials published in *N Engl J Med* and the *Lancet* between January 1, 2019, and December 31, 2023, of which 164 (37%) reported oncology clinical trials.

Additional information on the trials screened can be found in the mobile-friendly website version of this poster

- Key characteristics of publications included in this analysis are summarised in Table 1.
- Mean time to publication was significantly shorter for papers that disclosed medical writing support than those that did not (307 vs 466 days; *P*-value <0.0001; Figure 1).
- Median time to publication for papers with medical writing support appeared stable from 2019 to 2023 (Figure 2).
- The number of phase III oncology clinical trial papers published in 2023 was the highest in the analysis period (Figure 3).
- The total number of phase III studies published in *N Engl J Med* and the *Lancet* between 2019 and 2023 was lowest in 2020 (n=70) and highest in 2023 (n=110) (Figure 3).

Limitations

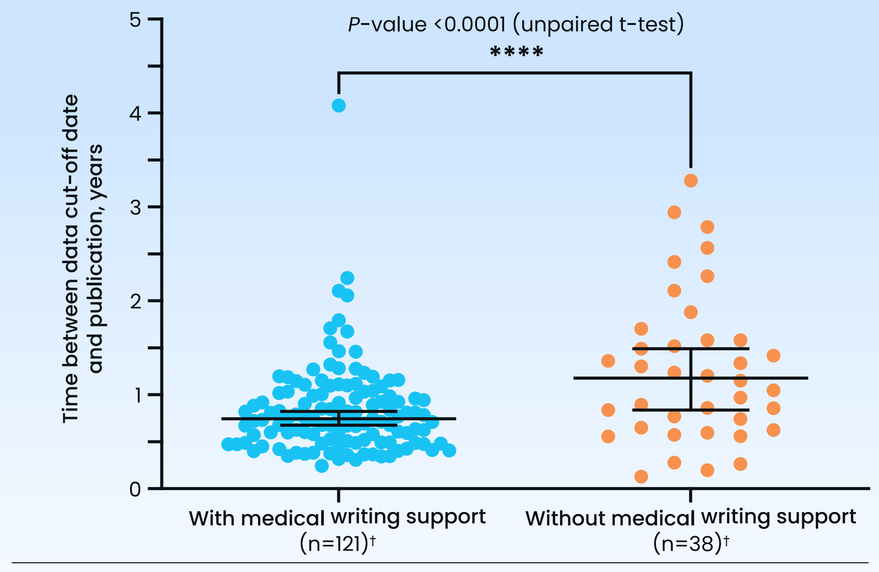
- The PubMed creation date was used to represent the publication date for each paper. In addition, phase III clinical trials were identified using the side bar filter function in PubMed.
- The analysis reports a snapshot of the Altmetric attention scores and the number of citations for papers; both measures 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.

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

Characteristic	With medical writing support (n=122)	Without medical writing support (n=42)	Overall (N=164)
Journal, n (%)			
N Engl J Med	80 (66)	16 (38)	96 (59)
Lancet	42 (34)	26 (62)	68 (41)
Publication year, n (%)			
2019	25 (20)	14 (33)	39 (32)
2020	20 (16)	4 (10)	24 (20)
2021	22 (18)	3 (7)	25 (20)
2022	17 (14)	10 (24)	27 (22)
2023	38 (31)	11 (26)	49 (40)
Number of randomised patients, median (range)	630 (120–3470)	608 (103–4446)	646 (103–4446)
Primary endpoint met, n (%)			
Yes	106 (87)	33 (79)	139 (85)
No	5 (4)	7 (17)	12 (7)
Partially	12 (10)	1 (1)	13 (8)
Altmetric attention score‡, median (range)	382 (62–2077)	218 (32–1181)	333 (32–2077)
Number of citations‡,§, median (range)	321 (4–3993)	129 (4–1521)	260 (4–3993)

†Published in *N Engl J Med* and the *Lancet* between January 1, 2019, and December 31, 2023.
‡Altmetric attention score and the number of times cited as of March 11, 2024.
§Number 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.

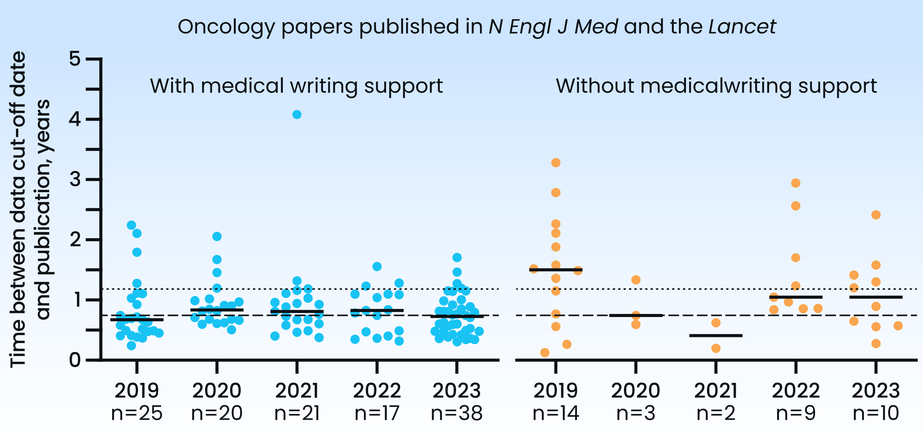
Figure 1. Time from reported cut-off date to publication



	With medical writing support (n=121)†	Without medical writing support (n=38)†
Mean (SD) days to publication	307.1 (178.8)	466.0 (289.5)
Median (95% CI) days to publication	272.0 (247.0–300.0)	429.5 (306.0–544.0)
Range	89–1489	47–1197

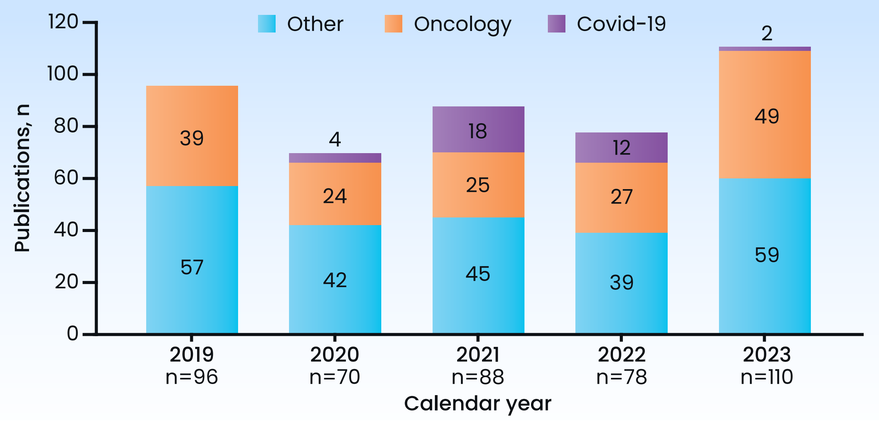
CI, confidence interval; SD, standard deviation.
Black horizontal line represents the median, and whiskers represent 95% CIs. †One paper with medical writing support and four papers without medical writing support were excluded because they did not clearly report a data cut-off date.

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



Black horizontal lines represent the median time to publication per calendar year. Dashed line represents the overall median time to publication for papers with medical writing support. Dotted line represents the overall median time to publication for papers without medical writing support. 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. Total number of phase III clinical trial papers by therapy area over the 2019–2023 period



The WHO declared a global pandemic on March 11, 2020.[5] On May 5, 2023, the WHO declared an end to the global Public Health Emergency for Covid-19.[6]
Covid-19, coronavirus disease 2019; WHO, World Health Organization.

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