Transparency of Results Reporting in Cancer Clinical Trials

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Introduction

The COVID-19 pandemic highlighted the importance of timely access to clinical trial results for public health. Despite decades-long efforts to improve results reporting for clinical research, problems persist.1 Trial investigators have 3 key platforms to disseminate results: trial registries,2 medical journals,3 and medical conferences. These platforms vary in their accessibility, scope, and depth. Trials presented as abstracts at conferences are limited in word count length and audience (conference attendees). Additionally, while ClinicalTrials.gov offers publicly accessible trial result summaries, journal publications often require payment for more detailed trial reports. Accordingly, we characterized results reporting across these platforms for trials registered in ClinicalTrials.gov completed between 2008 to 2021 with an oncologic indication, the second leading cause of death in the United States.4

Methods

This cross-sectional study followed the STROBE reporting guideline. Per the Common Rule, the study did not need institutional review board approval or informed consent owing to its use of publicly available data.

We identified oncology clinical trials registered in ClinicalTrials.gov and completed between 2008 and 2021, extracting data on their characteristics, including results reporting dates on ClinicalTrials.gov and indexed publications (Figure). We then determined whether trials reported results at any American Society of Clinical Oncology (ASCO) Annual Meeting from 2008 to 2021. We investigated the proportion of interventional phase 2 and 3 trials with results reporting within 1 and 3 years of trial primary completion dates and analyzed factors associated with reported proportions. We used Stata statistical software version 16.1 (StataCorp). Statistical tests were 2-sided, with a significance threshold set at \( P = .05 \).
Results

Among 10,442 eligible trials, results reporting was low within 1 year (6.8% in publications, 17.9% on ClinicalTrials.gov, and 18.3% at ASCO meetings) and 3 years (10.5% in publications, 40.0% on ClinicalTrials.gov, and 21.9% at ASCO meetings) of completion (Table). The reporting rates within 1 year were similar for ClinicalTrials.gov and ASCO meetings ($P = .53$). However, for reporting at 3 years, ClinicalTrials.gov had a higher rate vs ASCO ($P < .001$). Furthermore, reporting was more common on ClinicalTrials.gov and ASCO vs publications at 1 ($P < .001$) and 3 ($P < .001$) years. Overall, 44 trials (0.4%) reported results across all platforms and 3,787 trials (36.3%) reported results on at least 1 platform by 1 year, which increased to 121 trials (1.2%) and 5,853 trials (56.1%) at 3 years.

Results reporting on at least 1 platform was similar across industry- and National Institutes of Health (NIH)-funded trials at 1 year (43.2% vs 41.8%; $P = .51$). However, results reporting rates among NIH-funded trials were higher at 3 years (62.7% vs 73.4%; $P < .001$).

Table. Characteristics of Clinical Trials by Dissemination Platform and Reporting Year

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All trials, No. (column% N = 10,442)b</th>
<th>Trials reporting results, No. (row%) a</th>
<th>In a publication</th>
<th>In all platforms</th>
<th>In ≥1 platform</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>In ClinicalTrials.gov At ASCO In a publication In all platforms In ≥1 platform</td>
<td>By 1 y (n = 1873 [17.9%])</td>
<td>By 3 y (n = 4,181 [40.0%])</td>
<td>By 1 y (n = 1,906 [18.3%])</td>
<td>By 3 y (n = 2,291 [21.9%])</td>
</tr>
<tr>
<td>Funding sourcec</td>
<td>Industry 3618 (34.6) 916 (25.3) 1,748 (48.3) 874 (24.2) 1,090 (30.1) 238 (6.6) 23 (0.6) 59 (1.6) 1563 (43.2) 2,269 (62.7)</td>
<td>NIH 627 (6.0) 147 (23.4) 413 (65.9) 122 (19.5) 138 (22.0) 53 (8.5) 79 (12.6) 4 (0.6) 262 (41.8) 460 (73.4)</td>
<td>Otherd 6197 (59.3) 8107 (13.1) 2,020 (32.6) 910 (14.7) 1,063 (17.2) 521 (8.4) 778 (12.6) 17 (0.3) 1,962 (31.7) 3,124 (50.4)</td>
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<tr>
<td>Primary purpose</td>
<td>Treatment 9,465 (90.6) 1,731 (18.3) 3,813 (40.3) 1,858 (19.6) 2,229 (23.5) 648 (6.8) 955 (10.5) 42 (0.4) 1,177 (12.2) 3,557 (37.6) 5,405 (57.1)</td>
<td>Prevention 352 (3.4) 48 (13.6) 121 (34.4) 11 (3.1) 12 (3.4) 25 (7.1) 40 (11.4) 0 0 74 (21.6) 149 (42.3)</td>
<td>Othere 577 (5.5) 88 (15.3) 235 (40.7) 34 (5.9) 45 (7.8) 36 (6.2) 58 (10.1) 2 (0.3) 40 (1.1) 147 (25.5) 284 (49.2)</td>
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<td>Intervention group</td>
<td>Drug 9,762 (93.5) 1,761 (18.3) 3,924 (40.2) 1,805 (18.5) 2,166 (22.2) 659 (6.8) 1,020 (10.4) 40 (0.4) 1,240 (12.5) 3,570 (36.6) 5,504 (56.4)</td>
<td>Biologic 1,462 (14.0) 265 (18.1) 644 (44.0) 279 (19.1) 337 (23.1) 129 (8.8) 192 (13.1) 9 (0.6) 20 (1.4) 558 (38.2) 884 (60.5)</td>
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<td>Phase</td>
<td>1-2 1,504 (14.4) 238 (15.8) 564 (35.7) 347 (23.1) 388 (25.8) 112 (7.4) 146 (9.7) 8 (0.5) 22 (1.5) 580 (38.6) 825 (54.9)</td>
<td>2 6,288 (60.2) 1,143 (18.2) 2,578 (41.0) 1,139 (18.1) 1,342 (21.3) 399 (6.3) 645 (10.3) 24 (0.4) 64 (1.0) 2,291 (36.4) 3,606 (57.3)</td>
<td>2-3 210 (2.0) 16 (7.6) 44 (21.0) 37 (17.6) 41 (19.5) 19 (9.0) 25 (11.9) 1 (0.5) 1 (0.5) 61 (29.0) 85 (40.5)</td>
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<tr>
<td>No. of patients enrolled</td>
<td>1817 (17.4) 409 (22.5) 823 (45.3) 370 (20.4) 503 (27.7) 143 (7.9) 228 (12.5) 11 (0.6) 34 (1.9) 751 (41.3) 1,126 (62.0)</td>
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Abbreviations: ASCO, American Society of Clinical Oncology; NIH, National Institutes of Health.

a Percentages are out of the total number of trials per characteristic.
b Percentages are out of the total number of trials in the sample (10,442 trials).
c The funding source was derived from data about the study lead sponsor.
d Other funding sources include other government institutions, academic institutions, individual investigators, research networks, ambiguous institutions, and other institutions.
e Other primary purposes include basic science; device feasibility; diagnostic use; educational, counseling, or training use; health services research; screening; supportive care; and other.

Discussion

This cross-sectional study found that one-third of oncology clinical trials reported results in at least 1 of 3 platforms (ClinicalTrials.gov, publications, or ASCO Annual Meetings) within 1 year of completion and just over half within 3 years. NIH-funded trials had higher results-reporting rates compared with trials sponsored by other funders. Results were more likely to be reported on ClinicalTrials.gov compared with in publications or at ASCO meetings. Given the importance of detailed results reporting and peer review facilitated through journal publication, our results suggest that efforts may be needed to understand low rates of publication observed.

Limitations included that we could not rule out that results reporting occurred in other platforms, including preprints, press releases, and clinical study reports released by regulators like Health Canada. Our findings may not generalize to postmarketing studies; previous studies have found higher results reporting in such studies. Our findings echo previous studies on clinical research reporting, suggesting insufficient progress by investigators and peer-reviewers in addressing key barriers, such as prioritizing reporting of all results, including inconclusive findings. More efforts are needed to improve access to clinical trial results to advance patient care, innovation, and the protection of individuals involved in clinical research.

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Author Contributions: Dr Kao had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Kao, Miller.

Acquisition, analysis, or interpretation of data: All authors.

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Supervision: Kao, Miller.

Conflict of Interest Disclosures: Dr Ross reported receiving grants from the Food and Drug Administration (FDA), Johnson & Johnson, Medical Devices Innovation Consortium, Agency for Healthcare Research and Quality, Arnold Ventures, and National Institutes of Health National Heart, Lung, and Blood Institute outside the submitted work and serving as an expert witness for the Greene Law Firm in a qui tam suit alleging violations of the False Claims Act and Anti-Kickback Statute against Biogen Inc that was settled September 2022. Dr Miller reported receiving grants from the FDA and Arnold Ventures, and Bioethics International outside the submitted work. No other disclosures were reported.

Data Sharing Statement: See the Supplement.

REFERENCES


SUPPLEMENT.
Data Sharing Statement