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Public Access to Results: An Analysis of Publication Availability Across Industry-Sponsored Clinical Trials

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Abstract

Objective

Timely, accurate, and complete reporting of all company-sponsored clinical trials, regardless of their findings, is a critical component of Good Publication Practice (GPP). Despite this guidance, industry-sponsored research is often not submitted to medical journals for a variety of reasons. The goal of this analysis is to determine the proportion of completed trials hosted on ClinicalTrials.gov that were subsequently published in medical journals cataloged on PubMed.

Research Design & Methods

A search of ClinicalTrials.gov was conducted across 3 therapeutic areas: “non-small cell lung cancer (NSCLC),” “schizophrenia,” and “hypertension.” The search was limited to phase 2/3, industry-sponsored, completed, interventional studies with results reported on ClinicalTrials.gov. ClinicalTrials.gov and PubMed were searched for publication details for each trial meeting the inclusion criteria.

Results

A total of 332 trials were identified from ClinicalTrials.gov as having completed results. Schizophrenia had the highest proportion of trials cataloged on PubMed (49%; n=39 of 80 total trials), followed by NSCLC (42%; n=55/131) and hypertension (39%; n=47/121). There is slight variation between trials cataloged on PubMed and citations subsequently updated on ClinicalTrials.gov; only 47% (n=38/80) of schizophrenia trials have citations on ClinicalTrials.gov, followed by NSCLC (40%, n=52/131) and hypertension (37%; n=45/121). Open access rates were similar for all therapeutic areas. Among trials listed on PubMed, 64% of NSCLC (n=55/131) were open access, followed by 45% of hypertension (n=47/121) and 44% (n=39/80) of schizophrenia trials.

Conclusions

Despite strong guidance to publish clinical data within 12 months of trial completion, relatively few industry-sponsored trials are cataloged in the journals indexed by PubMed or ClinicalTrials.gov. Additional efforts are required to ensure clinical trial results are reported and published in a timely manner.

Background

- The US National Library of Medicine’s (NLM) trial registry at ClinicalTrials.gov is a repository for completed and ongoing clinical trials. ClinicialTrials.gov is complementary to PubMed, the NLM citation database.[1]
- Updated Good Publication Practice (GPP3) guidance requires the design and results of all company-sponsored clinical trials to be reported in a complete, accurate, transparent, and timely manner, ideally in a peer-reviewed journal.[2]
- Manuscripts should be submitted within 12 months of study completion and submitted for publication regardless of therapeutic area, study results, or investigated compound intervention.[2]
- Despite this guidance, there is a disconnect between registered and subsequently published clinical trials in the United States.
- Less than half (46%) of National Institutes of Health (NIH)-funded trials registered on ClinicalTrials.gov were published on PubMed within 12 months.[3]
- Additionally, only 43% of industry-sponsored trials supporting a new drug application before the FDA were published within 5 years of completion.[4]

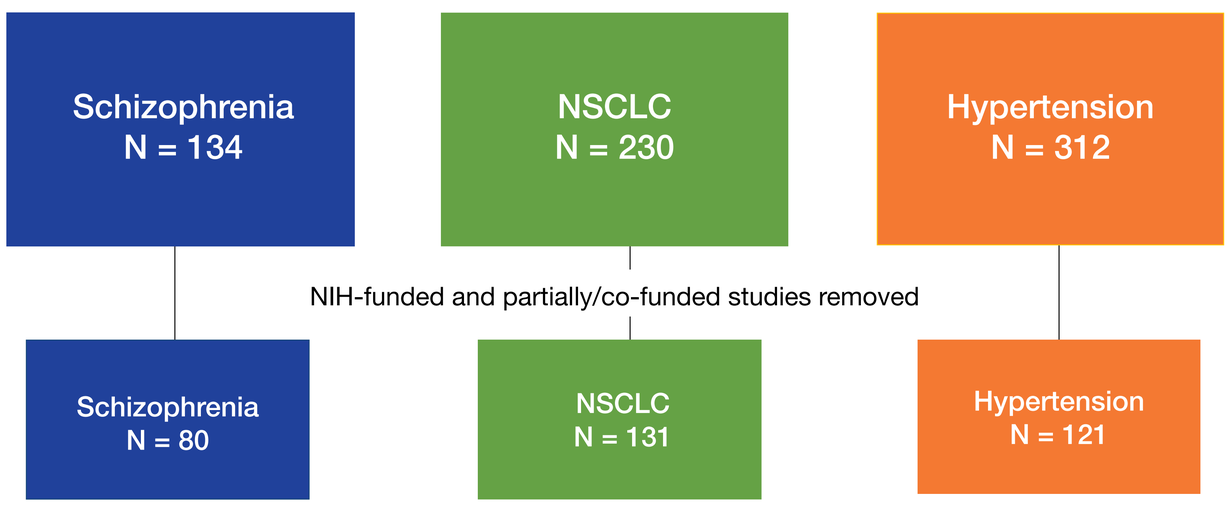
Purpose

- Incomplete publication of clinical trial data distorts the evidence base for clinicians seeking to make informed treatment decisions.[5] Clinical trial registries meet the letter but not the spirit of medical reporting guidelines and the medical literature remains the primary mechanism for consumers, clinicians, policymakers, and payers to make informed healthcare decisions.[4]
- There is scant research on the publication rates of industry-sponsored biopharmaceutical clinical trials in the United States, despite industry guidance and claims made by individual companies.[6]
- This analysis focuses on the publication rates of industry-sponsored clinical trials in 3 commonly researched therapeutics areas: schizophrenia, NSCLC, and hypertension.

Methods

- A search of 3 therapeutics areas was conducted on ClinicialTrials.gov for “non-small cell lung cancer,” “schizophrenia,” and “hypertension.”
- The search was limited to phase 2 or 3, industry-sponsored, completed, interventional studies with results reported on ClinicalTrials.gov.
- Studies funded by the NIH were excluded to focus on industry-sponsored clinical trials.
- ClinicalTrials.gov and PubMed were searched for publication details for each of the trials meeting the inclusion criteria.
- Data on Open Access availability on PubMed were also recorded.

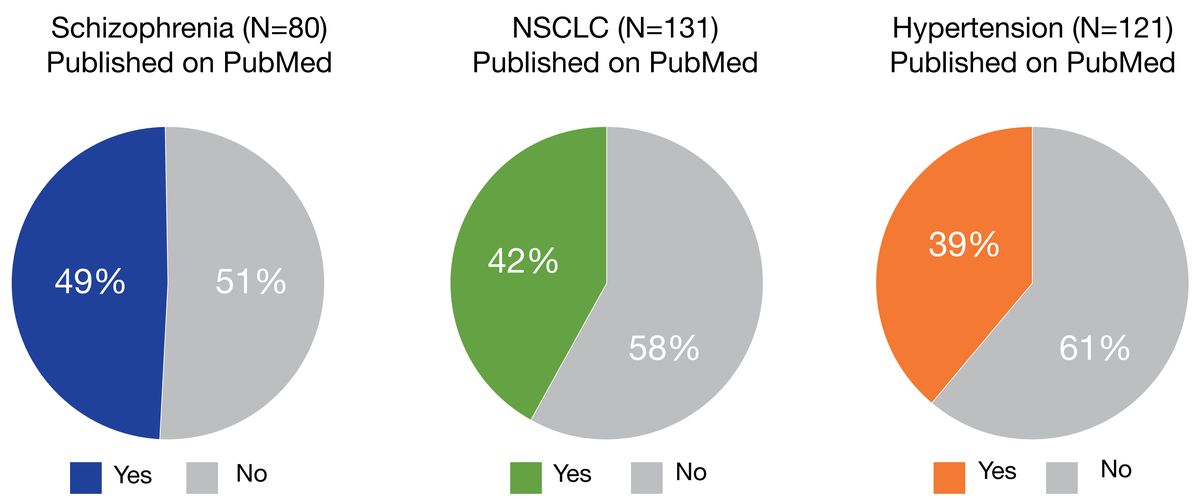
Figure 1 - Included Industry-Sponsored Phase 2 or 3 Clinical Trials



Results

- A total of 332 trials were included from ClinicalTrials.gov (schizophrenia, n=80; NSCLC, n=131; hypertension, n=121) **(Figure 1)**.
- Schizophrenia had the highest proportion of trials indexed on PubMed (49%), followed by NSCLC (42%) and hypertension (39%) **(Figure 2)**.

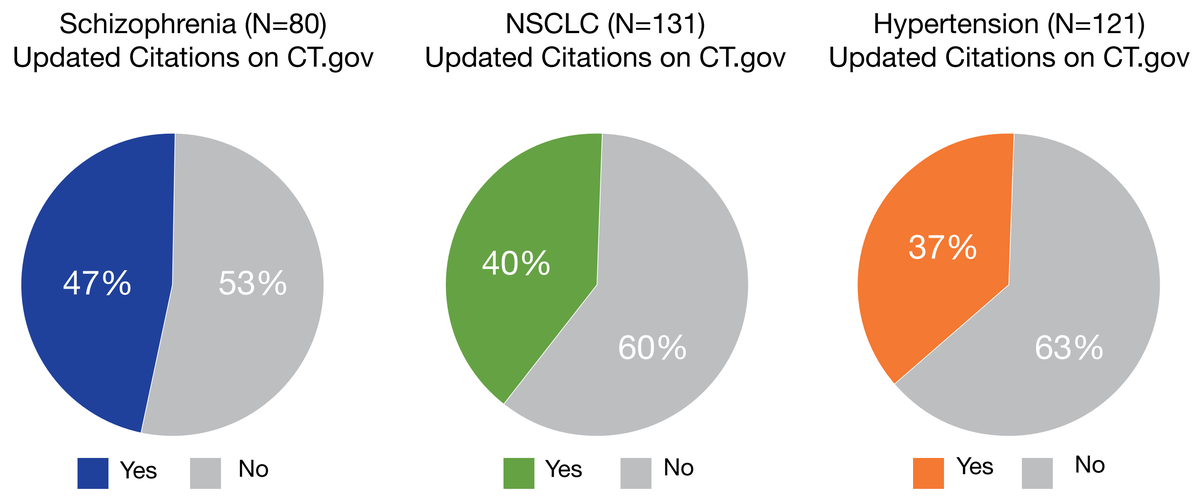
Figure 2 - Trials Listed on ClinicalTrials.gov and Indexed on PubMed



Results

- There was a slight discrepancy between trials indexed on PubMed and those with citation fields updated on ClinicalTrials.gov; 47% of schizophrenia trials had up-to-date citations on ClinicalTrials.gov, followed by NSCLC (40%) and hypertension (37%) **(Figure 3).**

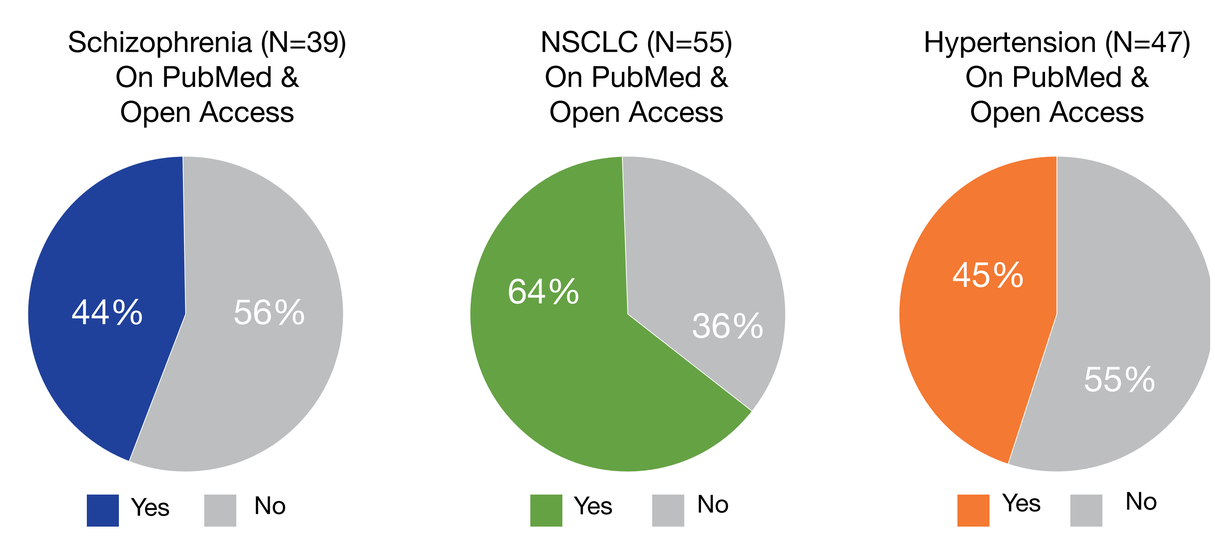
Figure 3 - Trials With Updated Citations on ClinicalTrials.gov



Results

- Open Access rates were similar for all therapeutic areas **(Figure 4)**. Among trials published on PubMed, 64% of NSCLC trials were Open Access, followed hypertension (45%) trials, and schizophrenia (44%) trials.

Figure 4 - Open Access Trials Indexed on PubMed



Conclusions

- Despite strong guidance from professional organizations and disclosure efforts from biopharmaceutical companies, less than half of industry-sponsored trials in commonly studied therapeutic areas are available on PubMed within 12 months of completion.
- Inadequate reporting of clinical trial data prevents medical professionals, consumers, and policymakers from making informed, evidence-based decisions regarding available care.
- Additional coordination between biopharmaceutical companies, medical publications professionals, government agencies, and clinicians is required to publish available clinical data in a timely, transparent, and widely available manner.

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