

Discrepancies between trial results reported on clinical trial registry and in journals

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During a one year period, among clinical trials published in high-impact journals that reported results on a public clinical trial registry (ClinicalTrials.gov), nearly all had at least 1 discrepancy in the study group, intervention, or results reported between the 2 sources, including discrepancies in the designated primary end points for the studies, according to a study in the March 12 issue of *JAMA*.

The 2007 Food and Drug Administration (FDA) Amendments Act expanded requirements for ClinicalTrials.gov, mandating results reporting within 12 months of trial completion for all FDA-regulated medical products. "To our knowledge, no studies have examined reporting and accuracy of trial results information. Accordingly, we compared trial information and results reported on ClinicalTrials.gov with corresponding peer-reviewed publications," write Jessica E. Becker, A.B., of the Yale University School of Medicine, New Haven, Conn., and colleagues.

The researchers identified 96 [trials](#) reporting results on ClinicalTrials.gov that were published in high-impact journals from July 1, 2010 and June 30, 2011. For 70 trials (73 percent), industry was the lead funder. Cohort, [intervention](#), and efficacy end point information was reported for 93 percent to 100 percent of trials in both sources. However, 93 of 96 trials had at least one discordance among reported trial information or reported results.

Among trials reporting each cohort characteristic (enrollment and

completion, age/sex demographics) and trial intervention information, discordance ranged from 2 percent to 22 percent and was highest for completion rate and trial intervention, for which different descriptions of dosages, frequencies, or duration of intervention were common.

Among 132 primary efficacy end points described in both sources, results for 23 percent could not be compared and 16 percent were discordant. The majority (n = 15) of discordant results did not alter trial interpretation, although for 6 the discordance did. Overall, 52 percent of primary efficacy end points were described in both sources and reported concordant results.

Among 619 secondary efficacy end points described in both sources, results for 37 percent could not be compared, whereas 9 percent were discordant. Overall, 16 percent of secondary efficacy end points were described in both sources and reported concordant results.

"... because articles published in high-impact journals are generally the highest-quality research studies and undergo more rigorous peer review, the trials in our sample likely represent best-case scenarios with respect to the quality of results reporting. Our findings raise questions about accuracy of both ClinicalTrials.gov and publications, as each source's reported results at times disagreed with the other. Further efforts are needed to ensure accuracy of public clinical trial result reporting efforts."

More information: [DOI: 10.1001/jama.2013.285634](https://doi.org/10.1001/jama.2013.285634)

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