

Clinical trial outcomes more complete in unpublished reports than published sources

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Clinical trial outcomes are more complete in unpublished reports than in publicly available information

Publicly available sources of information reporting findings from clinical trials provide much less information on patient-relevant outcomes than unpublished reports, according to a study by German researchers published in this week's *PLOS Medicine*. The results of the study by Beate Wieseler and colleagues from the Institute for Quality and Efficiency in Health Care in Cologne, Germany, found that the publicly available information contained less information about both the benefits and potential harms of an intervention than the unpublished report.

These findings highlight the importance of recent initiatives, such as the AllTrials initiative, that aim to make clinical trial outcome data publicly available, in order to provide complete and transparent information to help patients and clinicians reach decisions about clinical care.

In this study, the researchers compared the information available in clinical study reports, which are detailed but usually unpublished accounts of clinical trials, to publicly available sources, including journal publications and registry reports. They found that that unpublished reports included complete information for 86% of the patient-relevant outcomes, whereas the combined publicly available sources provided complete information for only 39% of the outcomes.

Although the trials included in this study may not be representative of all trials, the findings support a draft policy released in June 2013 by the European Medicines Agency calling for the routine publication of complete clinical trial data.

The authors say: "Our findings show that a substantial amount of [information](#) on patient-relevant outcomes required for unbiased trial evaluation is missing from the public record."

They continue: "[Clinical study reports] should be made publicly available as they may substantially influence conclusions concerning the actual position of an individual drug in a therapeutic area."

"In line with our point of view, a further initiative to promote trial registration and reporting of full methods and results, the [AllTrials initiative](#), also specifically refers to 'past and present' [clinical trials](#)."

More information: Wieseler B, Wolfram N, McGauran N, Kerekes MF, Vervo" lgyi V, et al. (2013) Completeness of Reporting of Patient-Relevant Clinical Trial Outcomes: Comparison of Unpublished Clinical Study Reports with Publicly Available Data. *PLoS Med* 10(10): e1001526. [DOI: 10.1371/journal.pmed.1001526](https://doi.org/10.1371/journal.pmed.1001526)

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