

## Reporting of clinical trial results by top academic centers remains poor

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Dissemination of clinical trial results by leading academic medical centres in the United States remains poor, despite ethical obligations - and sometimes statutory requirements - to publish findings and report results in a timely manner, concludes a study in *The BMJ* this week.

Researchers found that only 29% of completed <u>clinical trials</u> led by investigators at major US academic centers were published within two years of completion and only 13% reported results on the largest clinical trial registry, ClinicalTrials.gov.

They say action is needed to rectify this lack of timely reporting and publication, "as they impair the research enterprise and threaten to undermine evidence based clinical decision making."

Randomized clinical trials are the ideal means for evaluating the efficacy and safety of medical drugs and devices.

Timely <u>dissemination</u> of trial results is required to honor the commitment of study participants, advance the scientific process, and improve clinical care, but little is known about the performance of academic medical centers in this endeavor.

US law also requires that certain trials be registered and their results posted.

Yet previous studies have shown that between 25% and 50% of clinical



trials remain unpublished, sometimes years after completion, and that the results of many trials are not reported promptly on trial registries.

So, a team led by Professor Harlan Krumholz at Yale School of Medicine, examined rates of publication and reporting of results within two years for 4,347 registered trials completed between October 2007 and September 2010 across 51 leading US academic institutions.

Results show that only 29% (1,245/4,347) of completed clinical trials led by investigators at major US academic centers were published within two years of study completion and only 13% (547/4,347) reported results on ClinicalTrials.gov.

The study also revealed marked variation in rates of dissemination of clinical trial results across academic institutions, with more than a twofold variation in the average time from study completion to dissemination of results and more than a threefold variation in the rate of dissemination across institutions.

However, no academic center published more than 40% of completed clinical trials within two years of completion or reported results for more than 41% of its trials.

"We found noticeable variation and poor performance across leading academic medical centers in the dissemination of clinical trial results," write the authors. And they point out that there is "no effective enforcement mechanism and no repercussions to academic institutions or individual investigators" for failing to report results.

"The lack of timely reporting and publication fundamentally impairs the research enterprise, violates the commitment made by investigators to patients and funders, squanders precious time and resources, and threatens to compromise evidence based clinical decision making," they



conclude.

**More information:** Publication and reporting of clinical trial results: cross sectional analysis across academic medical centers, <a href="https://www.bmj.com/cgi/doi/10.1136/bmj.i637">www.bmj.com/cgi/doi/10.1136/bmj.i637</a>

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