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Transparency lacking in clinical trials, study finds

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A significant percentage of completed drug clinical trials, especially those funded by industry, are not disclosed to the public, years after being completed—a trend that "threatens the validity of the clinical research literature in the U.S.," according to a study led by a Boston University School of Public Health (BUSPH) researcher.

The study, published in the journal *PLOS ONE*, found that close to 30 percent of 400 randomly selected clinical trials completed in 2008 had not resulted, four years later, in either publication in a journal or the posting of results to the ClinicalTrials.gov (CTG) web site.

Studies that were funded solely by industry, or that involved smaller sample sizes, were less likely to be published, the research shows.

The study's lead author, Dr. Christopher Gill, director of BUSPH's Pharmaceuticals Program and an associate professor of global health, said the review raises ethical, as well as scientific, problems.

"Individuals who volunteer for clinical trials often do so out of a sense of altruism," said Gill, a researcher with BU's Center for Global Health and Development. "I can imagine that many would be dismayed to learn that the results of a study that they participated in, that they took physical risks for, might never generate results known beyond the company that sponsored the trial.

"Science learns from mistakes, as well as successes," he said. "If we only

learn about the scientific success stories, we are really only seeing part of the picture."

Gill and a former student, Hiroki Saito, found that 118 of the 400 clinical trials did not result in publication within four years of completion. The median length of time from completion to public disclosure was 602 days.

Among industry-funded studies, rates of posting to the CTG site were high for phase 3 or 4 studies, but extremely low for phase 2 studies.

"As an overall synthesis, these findings provide strong evidence of reporting bias," Gill and Saito wrote. They said the associations between publication or posting rates and funding sources "merit further consideration, and may reflect differing motivations" among researchers.

Among academics working under a "publish or perish" model, and who represent the majority of non-industry funded studies, the study phase "may be less critical than the need to publish research findings in journals," Gill and Saito said. By contrast, the pharmaceutical industry may publish more results for products that have advanced to phase 3 or beyond and are perceived to be commercially viable.

Gill and Saito suggested that regulatory requirements could be driving the differences in rates of posting results to the CTG. Among industry-funded, phase 3 or 4 studies, the majority of researchers posted their results at about one year from completion—coinciding closely with a one-year deadline established in 2007 by the Food and Drug Administration Amendments Act (FDAAA).

Regardless of the reasons, Gill and Saito said, transparency in clinical trials is "an essential public health good. The public must be informed if the premise of a clinical trial was confirmed or invalidated, and expects

that, once a study involving human subjects is completed, its results will be published in the medical literature or posted to some other open-access platform."

They said that in order to maintain the public's faith in clinical research, and to protect the fidelity of the scientific literature, "it is essential that the research community unite around the common goal of maximizing transparency. "

In 2012, Gill reported that among US-based, industry-funded phase 2 or higher clinical studies, less than 25 percent had posted their results to CTG within a year of completion. Another study found that, among National Institutes of Health-funded trials, 32 percent remained unpublished after the median follow-up of 51 months from completion.

Provided by Boston University Medical Center