

Nearly half of pediatric clinical trials go unfinished or unpublished

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Recent legislation is encouraging clinical trials in children, including the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. Yet clinical trials in children commonly go either uncompleted or unpublished, finds a comprehensive study conducted by researchers at Boston Children's Hospital. Results were published online August 4 by the journal *Pediatrics*.

In all, 19 percent of [trials](#) were discontinued early, and 30 percent of completed trials remained unpublished in the [medical literature](#) several years later. "We feel there is a lot of inefficiency and waste that could be addressed," says senior investigator Florence Bourgeois, MD, MPH, of Boston Children's Hospital.

Overall, trials sponsored by industry were more likely to be completed than trials sponsored by academic institutions, the investigators found. However, completed trials sponsored by industry were less likely to be published than trials sponsored by academia. These findings are similar to those seen for [clinical trials](#) in adults.

"Our findings are in line with previously published studies focusing on adult trials, which may speak to how commonplace discontinuation and non-publication are in medical research in general," says coauthor Natalie Pica, MD, PhD, a resident at Boston Children's. "We need to make sure that when [children](#) participate in clinical trials, their efforts are contributing to broader scientific knowledge."

Pica and Bourgeois tracked 559 randomized, controlled pediatric trials registered on ClinicalTrials.gov from 2008 to 2010 and whose final status (completed or discontinued) was confirmed by the end of 2012. They then searched for related peer-reviewed publications through September 1, 2015. When no publication could be found, they inquired with study investigators and sponsors via email.

Their findings:

- Of the 559 trials, 104 (19 percent) were discontinued early. Two thirds of these had already enrolled participants.
- Of the 455 completed trials, 136 (30 percent) remained unpublished after an average of 58 months post-completion. (Forty-two of these, or 31 percent, did post results to ClinicalTrials.gov.)
- Of the 104 discontinued trials, 39 percent were sponsored by industry and 55 percent by [academic institutions](#). (The rest were funded by other sources.)
- Two years after trial completion, academia-sponsored trials accounted for 30 percent of unpublished trials, and industry-sponsored trials for 63 percent. Three years after trial completion, academia-sponsored trials accounted for 23 percent of unpublished trials, and industry-sponsored trials for 70 percent.
- In a multivariate analysis, the likelihood of non-publication was more than doubled for industry-sponsored trials two years after completion (odds ratio, 2.21) and more than tripled three years after completion (OR, 3.12).
- Overall, more than 8,000 children were enrolled in trials that were never completed, and more than 69,000 children were enrolled in completed trials that were never published.

"This is the first study to look systematically at discontinuation and

nonpublication of interventional pediatric clinical trials," says Bourgeois. "A number of legislative initiatives have been implemented to increase the study of interventions in children. Now we need to make sure that the proper resources are in place to ensure that information gleaned from these studies reaches the scientific community."

One proposed initiative cited by the paper is RIAT (Restoring Invisible and Abandoned Trials), which is supported by some high-profile journals. RIAT invites researchers with unpublished trials to either commit to publish within a year or provide public access to their data, allowing independent investigators to become "restorative authors."

"It's hard to reanalyze others' data," says Pica, "but this may be a useful mechanism to make sure that findings from completed trials are disseminated in the medical literature."

Provided by Children's Hospital Boston

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