Half of clinical trial outcomes never published

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Healthcare providers and patients enrolled in clinical trials have a major stake in a proposal by the National Institutes of Health that would significantly expand the amount of clinical trial data posted on the publicly available government website, www.ClinicalTrials.gov.

Since 2007, all public or private sponsors of clinical trials that test the clinical effectiveness of Food and Drug Administration-approved products have to register those trials when they begin. They also must publish their final results on the government's website, but not until three years after their conclusion.

The law has been a major boon to drug or device formulary committees at hospitals and large physician practices, which are in the business of comparing the relative effectiveness of competing products. More than half the 15,000 trials in the database have never appeared in a medical journal, according to a special report from top officials at the National Library of Medicine, which appeared this week in the New England Journal of Medicine.

NIH's proposed rule (PDF) will extend the requirement to clinical trials for products that were never approved by the FDA. It also ups the ante on the data reporting by requiring more specifics on a trial's goals when it is initially registered and on the outcomes and adverse events after it is completed.

The proposed rule doesn't tamper with the inordinately long three-year time frame for reporting results, however, which were put in place to protect the proprietary concerns of drug and device manufacturers. They aren't keen to see negative information leek to competitors or stock market analysts and traders. European regulators, by comparison, give trial sponsors only a year before public posting is required.

In defending the new proposal, NIH officials say its primary purpose is to help other researchers avoid going down fruitless pathways. But this isn't just a research question or a stock market question.

Human subjects voluntarily participate in clinical trials to further the cause of medical science (and hopefully benefit by being in the arm of a trial with positive outcomes). They deserve to have knowledge of the final results spread among the general public.

Comments on the proposed ruled, which close Feb. 19, can be filed at www.regulations.gov. Search for NIH–2011–0003.