ClinicalTrials.gov vs. Drugs@FDA: A comparison of results reporting for new drug trials

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Dartmouth Institute researchers Lisa Schwartz and Steven Woloshin recently worked with researchers from the National Library of Medicine to compare results reporting for new drug trials posted on ClinicalTrials.gov with information on Drugs@FDA. Credit: Dartmouth-Hitchcock

Pharmaceutical companies and other sponsors of clinical drug trials are required to report results to ClinicalTrials.gov, a registry run by the U.S. National Library of Medicine (NLM) at the National Institutes of Health (NIH). It's the largest clinical trials database, currently holding registrations from about 200,000 trials. Researchers Lisa Schwartz and Steven Woloshin from The Dartmouth Institute for Health Policy and Clinical Practice recently worked with researchers from the NLM to compare the validity of sponsor-submitted results posted on ClinicalTrials.gov with corresponding information on Drugs@FDA. The latter is a searchable and publicly accessible catalogue of FDA-approved prescription and over-the-counter drugs.

After examining a sample of 100 trials, they found that while Drugs@FDA may be useful for validating primary outcome results found on ClinicalTrials.gov, it was far less useful validating secondary outcomes and information about adverse events including deaths. (Primary outcomes answer the the most important question being asked by a trial, such as whether a new treatment is better at treating a disease than existent therapies. Secondary outcomes measure other relevant questions related to the study, such as, whether the new treatment reduces the overall cost of treating patients.)

In a study recently published in the *Annals of Internal Medicine*, the researchers describe how they matched all of the primary outcome measures posted on ClinicalTrials.gov with publically available data from Drugs@FDA in their sample, and found they were largely consistent. In contrast, only about half (51%) of the secondary outcomes listed on ClinicalTrials.gov were identified as secondary at Drugs@FDA. Serious adverse events and deaths also could not be validated for most trials because Drugs@FDA typically only reports such data aggregated across trials.

The researchers conclude conclude that even if all the numbers reported

in ClincalTrials.gov were completely accurate, "questions would remain about the trial design, conduct or analysis" which could affect conclusions about the trial results assessed in Drugs@FDA, and state that better integration between the two sites would result in "better information, and perhaps ultimately, better health."

More information: Lisa M. Schwartz et al, ClinicalTrials.gov and Drugs@FDA: A Comparison of Results Reporting for New Drug Approval Trials, *Annals of Internal Medicine* (2016). DOI: 10.7326/M15-2658

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