Discrepant analyses of industry-sponsored clinical trials

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Discrepancies between internal and published analyses of industry-sponsored clinical trials lead to further calls for transparency

Internal pharmaceutical company documents detailing the planned and completed analyses for clinical trials do not always match the publically available report of the completed trial, highlighting a concerning lack of transparency, according to a study published in this week's PLOS Medicine.

These findings are important as they provide support for reporting standards for clinical randomized controlled trials (such as the universally used CONSORT statement) to recommend transparent descriptions and definitions of all of the analyses performed, including if any study participants were excluded from the analysis; and for pharmaceutical companies to make data available for review.

The authors from the Johns Hopkins Bloomberg School of Public Health in Baltimore in the USA, led by Kay Dickersin and Swaroop Vedula, reached these conclusions by comparing internal company documents (released in the course of litigation against the pharmaceutical company Pfizer regarding the off-label use of the drug gabapentin) to the published reports of the trial.

The authors found that in three out of 10 trials there were differences in the internal research report and the main publication regarding the number of randomized participants. Furthermore, in six out of 10 trials,

the authors were unable to compare the internal research report with the main publication for the number of participants analyzed for the beneficial effect of the drug (efficacy) because the research report either did not describe the main outcome or did not describe the type of analysis.

The authors say: "Our findings highlight the need for standardizing the definitions for various types of analyses that may be conducted to assess intervention effects in clinical trials, delineating the circumstances under which different types of analyses are meaningful, and educating those who are involved in conducting and reporting trials such that the standards are consistently adopted."

They continue: "We believe that our findings lend support to policy considerations such as extending mandatory registration to include all clinical trials, making full trial protocols and trial data publicly available through trial registration or other means, and ensuring that regulations pertaining to compulsory reporting of results apply both to trials conducted for regulatory authority-approval and to trials in off-label indications of interventions."

The authors add: "It is time for the balance of power in access to information from clinical trials to be shifted from those sponsoring the trials to the public at large."

More information: Vedula SS, Li T, Dickersin K (2013) Differences in Reporting of Analyses in Internal Company Documents Versus Published Trial Reports: Comparisons in Industry-Sponsored Trials in Off-Label Uses of Gabapentin. PLoS Med 10(1): e1001378. doi:10.1371/journal.pmed.1001378