Medical Xpress

Funder involved in all aspects of most industry-funded clinical trials

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In most industry funded trials reported in high impact medical journals, all aspects of the trial involved the industry funder, finds a study published by *The BMJ* today.

The results show that, although both funder and academic authors were

involved in the design, conduct, and reporting of most trials, few industry funded trials were completely independently conducted by academics, and sometimes industry involvement was downplayed or omitted.

They also show that while most academics view collaboration with industry as beneficial, some report loss of academic freedom.

Collaboration between industry and academics is common in the development of vaccines, drugs, and devices, as it can be mutually beneficial, but the degree of independence and the roles of academics and industry vary across trials.

There is also some evidence that industry funders may influence how trials are designed and reported, sometimes serving financial rather than public interest.

To better understand the nature of these collaborations, researchers set out to determine the role of academic authors, funders, and contract research organisations (CROs) in industry funded trials of vaccines, drugs, and devices and to determine lead academic authors' experiences with industry funder collaborations.

The researchers analysed the most recent 200 trials of vaccines, drugs, and devices with full industry funding, at least one academic author, published in one of the top seven high impact general medical journals.

Trials from all over the world were included. Most trials were published in the *New England Journal of Medicine* (*NEJM*) and the *Lancet* and 83% were drug trials.

In most trials, both funder and academic authors were involved in the design, conduct, and reporting. Nevertheless, the role of academic

authors, funders, and CROs varied greatly.

For example, 183 (92%) trials reported funder involvement in design and 167 (84%) academic author involvement. Trial reporting involved the funder in 173 (87%) trials and academic authors in 197 (99%), while contract research organisations were involved in the reporting of 123 (62%) trials.

In contrast, the results show that data analysis was most often done by funder or CRO employees, without academic involvement. For example, data analysis involved the funder in 146 (73%) trials and the academic authors in 79 (40%).

Only 8 (4%) trials were classified as independent trials (that is, all aspects of the industry funded trial were carried out by academic authors without involvement of the funder or a CRO).

The researchers then surveyed the lead academic author of each trial. Questions covered design, analysis, and reporting of the trial, data access, trial agreements, and experience with the collaboration.

Eighty (40%) responded, of whom 29 (33%) reported that academics had final say on the design. Ten described involvement of an unnamed funder and/or CRO employee in the data analysis and/or reporting.

Most of the authors reported access to data, but the researchers say that reported access to data does not always mean access to the entire trial dataset.

Most authors found the collaboration with industry funder beneficial, but 3 (4%) experienced delay in publication due to the industry funder and 9 (11%) reported disagreements with the industry funder, mostly concerning trial design and reporting, although disagreements were

generally described as minor.

This is an observational study, so no firm conclusions can be drawn about cause and effect, but the findings should prompt more accurate reporting of contributorship "to give patients greater confidence in trial results and conclusions," say the researchers.

Trials from high impact journals have important effect on clinical decisions, yet only a few of the included trials had independent analysis, they note. "However, academics can demand control over design, data storage, and full data ownership, analysis, and reporting, thereby improving independence and greater reliability of trial results," they conclude.

"Independent trials are the way forward," add the researchers in a linked opinion article. "Our clinical recommendations depend on clinical trials being reliable and conducted in the patients' best interests, without commercial considerations ... the academic community should refuse collaboration where industry demands control over trial design, conduct, data, statistical analysis, or reporting."

More information: Collaboration between academics and industry in clinical trials: cross sectional study of publications and survey of lead academic authors www.bmj.com/content/363/bmj.k3654

Opinion: Shining a light on industry collaboration
blogs.bmj.com/bmj/2018/10/03/s … dustry-collaboration

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