

## Are All Clinical Studies Sponsored by Industry Not Valid?

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### Abstract

Industry-sponsored studies have such a bad reputation that some journals require an additional statistical analysis by an independent statistician. This commentary discusses some of the reasons why academic people tend to believe that “academic” science is better than industry-driven science. Most likely, when it comes to publications, the risk of fraud exists in both worlds as the pressure to publish “significant” data is prevalent in both worlds. In contrast to the academic world, the level of control by regulatory bodies for industry-sponsored studies is much higher. Therefore, the quality of industry-driven studies is high, at least when it comes to the quality of data. One of the main reasons why academic people are so skeptical about the pharmaceutical industry is a lack of knowledge about the work done in industry. It is as demanding and scientific as in other industries. In turn, many physicians working in the pharmaceutical industry have low self-esteem. Also, the pharmaceutical industry should improve its self-presentation adequately to get rid of its bad image. There is a clear need for more communication between both worlds in order to better understand the mutual difficulties and needs.

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### Introduction

If you take a look at the instructions for authors of the *Journal of the American Medical Association* (JAMA) you will find under the subheading Data Access and Responsibility the following: “For industry-sponsored studies, an analysis of the data (based on the entire raw data set and evaluation of the study protocol, and prespecified plan for data analysis) must be conducted by an independent statistician at an academic institution, rather than by statisticians employed by the sponsor or by a commercial contract research organization. The independent biostatistician must be a faculty member

at a medical school or academic medical center, or an employee of a government research institute, that has oversight over the person conducting the analysis and that is independent of the commercial sponsor. Details of this independent statistical analysis, the name and institutional affiliation of the independent statistician, and whether compensation or funding was received for conducting the analyses should be reported in the Acknowledgment section of the manuscript. The results of this independent statistical analysis should be the results reported in the manuscript.”

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One wonders why JAMA sets these astonishing rigid demands and what are the consequences? When an accredited journal (where articles about diabetes are published rarely...) implements such limitations, it can only be interpreted that, in the opinion of the editor and his/her team, the study results coming from an author bound to industry are "manipulated," that is, show a (massive) risk of bias. In fact, it is well known that in publications of companies their own products appear more favorably than studies on those products that had been conducted by independent sites ("publication bias"). Concurrently, not necessarily all results of a study will be published, but only the results that appear to be opportune, which furthermore will be accordingly interpreted positively ("report bias"). Therefore, this suspicion cannot be denied. Nevertheless, this course of action seems to overshoot. This induced a fierce discussion when JAMA introduced this policy (see, e.g., Rothman KJ, Evans S. Extra scrutiny for industry funded trials. *BMJ*. 2005;331(7529):1350-1, and letters in subsequent issues).

I have heard people say that they only trust physicians in the academic world because they are upright and don't cheat, whereas all those employed in industry are purchased and dishonest. In fact, I believe the number of black sheep in both worlds is probably the same! If one alleges that an author employed by a pharmaceutical company had financial interests, then it is a matter of pointing out that the financial pressure is more direct and larger for persons holding an academic position. For people in the academic world who are sponsored by third-party funds, the dependency of positive results of their own studies and good publications is very immediate. Please keep in mind that if a certain publication is not printed in journal X, then the research promotion for a whole research group will be left out as the impact factor is not sufficient. This could mean that the academic career of one or more scientists will not continue as planned. A "failure" to get a study published could also mean that one will need a new job; this could be connected to relocation and so on. Isn't the financial pressure much more vehement and clearer under such circumstances as it is in industry? Wouldn't we, on such a general setup, possibly also tend to remove the one-off from data to "correct" the  $p$  value that initially was shown as 0.0525 in the analysis to 0.0475 when this essentially improves the chance for publication? Anyway, hardly anyone can verify this. The very rigid monitoring of industry-sponsored clinical studies regarding data quality and data evaluation does not easily permit such

manipulation nowadays! For example, if a chief research officer's fault or data manipulation can be proven, the company can de facto fold up.

The reason the pharmaceutical industry is very rigid is simple: if a "fault" is detected in the documents in the context of the submission of new drug approval by the regulatory authorities (i.e., Food and Drug Administration or European Medicines Agency), even if it's just a formal one, the study will not be accepted. That means that the entire approval can be put at risk; this in turn means that an investment of several hundreds of millions of dollars can go over the brink, which explains why companies greatly stress the correctness comprising all aspects of studies nowadays (in the past these matters were clearly more lax). Determined by the strict guidelines (which is to be considered extremely positive!), the quality of the documents submitted for approval is very good today, at least when it comes to the quality of data.

In comparison, the quality of study conduction in the academic field (including the evaluation) is probably rather bad. However, there aren't enough resources in the academic world to greatly care for all the details of studies (the work of monitors is quite expensive, as it is quite labor- and time-intensive). Formally, many academic studies are not so "waterproof" because of this. Is there a difference when it's about publications? As it is always about the problem of how to sell the own study results ("is the glass half-full or half-empty"), everybody will be moving toward placing special emphasis on the positive/new results and outline the critical/negative aspects in passing. Here, too, the academic world, as well as the pharmaceutical industry, does probably not differ from each other.

It would be fair if all studies that were to be submitted to, for example, JAMA were analyzed identically. In consideration of the rather small amount of statisticians with corresponding skills (and will!!!) in free positions (this number is pretty small!) and the extreme time-consuming expense that is necessary for the analysis of complex studies, such a guideline would imply a serious detention of publication and significant additional costs. If one is willing to accept this with the meaning of an optimal validity of data, it should apply to all. In general, it's ignored here that the statisticians often do not agree on the appropriate method of evaluation of studies (statistics is a flowing science, too) and can argue splendidly.

Altogether the aspect discussed here again reflects the fact that many academics have a rather negative assessment of the work of physicians in industry. They in turn unfortunately do a poor job when it comes to describing the importance and necessity of their own work. Many of them seem to have some kind of “bad conscience” or a “feeling of inferiority” not to work in everyday life immediately with patients, that is, not to hold an academic position any more. That the work they do, in terms of most possible safety and efficiency of new diagnostic and therapeutic objectives, is extremely important and markedly challenging, many of them do not have this kind of “pride,” that is, do not represent it to the outside. A better illustration of their work and its relevance could work miracles! Altogether the self-display of the pharmaceutical industry and their work conveys a rather clumsy-looking impression, especially if the activities are rather marginal compared to the sales promotion.

As in many other cases, more communication between physicians of the academic and the pharmaceutical worlds would contribute to eliminating prejudices and to a better understanding of the mutual difficulties and needs. Unfortunately, there are hardly any good communication platforms. All involved (especially the patients as well) would benefit from a constructive (and critical!) closer collaboration between the academic world and the pharmaceutical industry. First of all, both sides would have to give an ample value to such a communication to meet at eye level.

Let's come back to the starting point. At latest, it is unknown who manipulates what and to which extent. The incentives (see earlier discussion) are great on both sides. In this sense the guidelines of JAMA are comprehensible, but a man-made differentiation between academic and pharmaceutical worlds makes no sense.

For those interested in reading more about this topic [Heinemann L, Hompesch M. Role of physicians in the pharmaceutical industry and clinical research organizations: take more pride in your work. *J Diabetes Sci Technol.* 2008;2(4):707-9] or who want to swap ideas on the topic of publishing with other physicians, please visit ([www.ismpp.org](http://www.ismpp.org)).