

Drug trial protocol redactions by industry sponsors exposed

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New research published by the *Journal of the Royal Society of Medicine* exposes the extent of redactions in protocols for industry-sponsored randomised drug trials. Trial protocols are needed for a proper assessment of the veracity of drug trial reports. The researchers, from the Nordic Cochrane Centre in Copenhagen, found widespread redactions in the protocols for commercially sponsored trials they received from research ethics committees in Denmark. The study is believed to be the first systematic assessment of which information in trial protocols pharmaceutical companies do not wish to disclose to independent researchers.

Professor Peter Gøtzsche, director of the Nordic Cochrane Centre, said: "We wished to compare the [information](#) in the protocols with the information provided to the patients in order to evaluate whether the [trials](#) were ethical and necessary and whether essential information about the benefits and the harms of the drugs had been hidden from the patients."

It is difficult to get access to [drug](#) trial protocols so Professor Gøtzsche and his colleagues used the Danish Freedom of Information Act to request access to 78 trial protocols approved by a research ethics committee from October 2012 to March 2013. Eight protocols were excluded because they did not meet the research inclusion criteria. Only 17 of 34 protocols for commercially sponsored trials were unredacted, compared to 34 of 36 non-commercially sponsored trials.

The redactions were most widespread in those sections of the [protocol](#) where there is empirical evidence of substantial problems with the trustworthiness of published drug trials. These include the definition of patient outcomes, the detection and analysis of adverse events and the sponsor's access to incoming data while the study is running.

Professor Gøtzsche said: "The amount of redactions in the protocols we received was so vast that it made them rather useless for assessing the ethical justification for the studies and to identify discrepancies with subsequent publications.

"We could not identify any legitimate rationale for the redactions. The current mistrust in industry-sponsored [drug trials](#) can only change if the industry offers unconditional access to its trial protocols and other relevant documents and data."

More information: Mikkel Marquardsen et al. Redactions in protocols for drug trials: what industry sponsors concealed, *Journal of the Royal Society of Medicine* (2018). [DOI: 10.1177/0141076817750554](https://doi.org/10.1177/0141076817750554)

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