Prescrire International Editorial

Translated from ***Rev Prescrire*** **October 2012; 32 (348): 773**

Clinical research: access to raw data is necessary

Pharmaceutical companies design and fund many clinical trials of the drugs that they market. They have in their possession all of the data collected for each patient ("raw data"), which are subsequently coded, collated, and analysed. Do academic authors have access to the raw data when writing up the results of clinical trials for publication?

Limited access. A team from the Nordic Cochrane Centre in Copenhagen investigated whether the academic authors of articles reporting clinical trial results, published by the *Lancet* in 2008 and 2009, had in fact had access to all raw data. The team reviewed the trial protocols and questioned the authors of these articles (1).

Of the 69 industry-funded clinical trials identified, 27 protocols stated that the company owned the data. In 67 protocols, no information was provided on authors' access to raw data, but 64 published articles indicated that authors had access to this data (1).

The team received responses from 39 authors about their access to data (57% of the articles). Only 26 reported that they had access to raw data, while the others reported having access to data that had already been processed to some degree (coded, compiled, analysed, etc.) by the drug company (1).

Only 13 authors checked the drug company's statistical analyses using the raw data (1).

The team that published this study considers that these results, undoubtedly underestimated because they were self-reported, call for profound changes: journals should demand access to the raw data for all clinical trials submitted for publication. The Cochrane team goes one step further by calling for this raw data to be made publicly available (1).

Clinical raw data: public property. Access to clinical trial and pharmacovigilance raw data is the only way of examining how the data were coded, collated and analysed. It enables researchers to perform new analyses. It is essential for teams, like those of the Cochrane Collaboration, that carry out meta-analyses of clinical trials.

As of 2012, drug companies and drug regulatory agencies too often oppose access to raw data. The European Medicines Agency (EMA) however is considering releasing the raw data in its possession (2). The plan has yet to materialise, but it is good news for patients, who have the right to receive treatment based on all available data.

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Selected references from Prescrire's literature search.

1- Lundh A et al. "Access to data in industry-sponsored trials" *Lancet* 2011; **378**: 1995-1996.

2- Hirschler B "EU agency lifts lid on drug data secrets" 15 July 2012. www.reuters.com accessed 24 July 2012: 2 pages.