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Phase I trials: end the secrecy!

● **Investigators should take the initiative in lifting the veil of secrecy.**

Not all clinical trial results are published, especially when they are considered "negative" by the investigators and sponsors – in other words, when results are unfavourable to the drug tested (1). Studies of this publication bias generally concern comparative trials in patients with a specific disease.

A retrospective study published in 2009 focused on phase I trials, i.e. the initial stage of clinical drug development. These studies only involve healthy volunteers and do not assess therapeutic efficacy in patients. The authors examined 444 phase I trials registered in 1994 with 25 of the 48 French ethics committees (2).

Key information missing. Only 17% of completed phase I studies were published, representing only 25% of studies with results favourable to the sponsor, and none of the studies with negative results. Investigators cited confidentiality as the main reason for withholding publication (2).

However, phase I trials can provide valuable information, especially in terms of adverse effects, and their non-publication can have serious consequences. For example, in 2006, 6 healthy volunteers suffered very severe adverse effects during a British phase I trial of an experimental drug (TGN1412) (2). Similar adverse effects had been observed in a study of a similar drug 12 years earlier, but the results had not been published (3).

Phase I trial results must also be registered and published. Phase I trials, like all other clinical trials, should be included in clinical trial registries. Although the World Health Organization has recommended registration of these trials, drug companies are still reluctant to disclose information on phase I trials (3,4).

Information obtained in clinical studies and drug trials, especially regarding adverse effects, belongs in the public domain, as it can benefit healthcare professionals and patients alike. It is ethically unacceptable to withhold public access to this vital information.

Investigators could take the first step toward lifting this veil of secrecy by refusing to sign confidentiality agreements with drug companies.

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Selected references from Prescrire's literature search.

1- Prescrire Editorial Staff "Clinical trials in France: too many unpublished results" *Prescrire Int* 2006; **15** (85): 197.

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3- Jack A "Call to release human drug trial data" *Financial Times* 8 August 2006. www.ft.com accessed 26 August 2009: 1 page.

4- Prescrire Editorial Staff "Clinical trial registries: towards improved access to therapeutic data" *Prescrire Int* 2008; **17** (98): 256-259.

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