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NEWS

Faculty of Pharmaceutical Medicine backs greater transparency in clinical trials

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Members of the UK Faculty of Pharmaceutical Medicine have expressed backing for greater transparency in clinical trials in their first survey on the topic.[1] They showed clear support for registration of all clinical trials, earlier publication of the summary results, and increased access to trial data.

Last year the charity Sense About Science, *The BMJ*, and other supporters of transparency in research established the AllTrials initiative (alltrials.net), which calls for registration of all clinical trials and for full study results and reports to be made publicly available.[2] Earlier this year members of the European parliament voted overwhelmingly to introduce new legal measures to increase the transparency of clinical trials in Europe.[3]

Of the faculty's 1550 members, almost a quarter (379) responded to the survey, which was published on 28 August.

Some 89% of respondents said increased publication of clinical trial results (including negative results) would ultimately lead to better drugs and better healthcare for patients.

An overwhelming majority (95%) believed all clinical trials should be registered, and 87% believed that overall increased scrutiny of clinical trial data would result in a stronger science base and would enhance medical research.

A minority of respondents (18%) believed that increased access to clinical trial data would harm the commercial environment in which companies operate.

In a report on the findings the faculty said it was understandable that employees of commercial institutions—especially those dealing with highly commercially sensitive data from early phase clinical trials—would be "reticent" to share all data related to a clinical trial.[1]

But it said only 5% of respondents agreed with the statement that companies should not be required to release clinical trial data.

The faculty said almost all respondents agreed that some kind of "gatekeeper" was required to manage the release of data, with 61% believing that either current regulatory organisations or a newly established independent body should assume that role.

Keith Bragman, president of the faculty, said, "It is very gratifying to note that, as doctors practising pharmaceutical medicine, we see the world of publication of clinical trial results and access to data in a common light. Namely, we have a responsibility to patients.

"The faculty has previously advocated increased transparency but has also been supportive of the need to identify and implement remedies which protect the privacy and rights of patients and research subjects and the interests of all stakeholders."

Bragman added, "We cannot write evidence based guidelines unless all trials are registered and the results published within a reasonable time frame upon completion of the trial. We cannot satisfactorily answer questions unless we have access to results and data, whether positive or negative. There must be protection of the anonymity of people who participate in research. We cannot educate those who are unaware unless we are first prepared to reveal, in a timely manner, the results of clinical trials."

1 Faculty of Pharmaceutical Medicine survey of members on transparency in clinical trials. Analysis report. 28 Aug 2014. www.fpm.org.uk/policypublications/clintrialsurveyreport.
2 Kmietowicz Z. Patients are urged to boycott trials that do not guarantee publication. *BMJ* 2013;346:f106.
3 Kmietowicz Z. Transparency campaigners welcome new rules for clinical trials in Europe. *BMJ* 2014;348:g2579.

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