

Internet Study Finds Clinical Trial Data Lagging

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NEW YORK — When questions were raised about possible concealment of clinical trial data, two pharmaceutical companies agreed last year to set up Web sites where such data would be posted.

It appeared at that time that others in the industry would follow suit, “but as it turns out, very little has happened,” Norman Sussman, M.D., said at a meeting on psychopharmacology sponsored by New York University.

According to Dr. Sussman, an Internet search performed in early March, followed by inquiries to the companies themselves, found that information was for the most part incomplete, difficult to use, or entirely absent.

“This says something about the goodwill of the companies,” commented Dr. Sussman, professor of psychiatry at the university.

In June 2004, New York State Attorney General Eliot Spitzer filed suit against GlaxoSmithKline Inc., charging that the company’s selective release of clinical trial

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data on the use of paroxetine (Paxil) in children constituted consumer fraud. As part of a settlement of the lawsuit at the end of August, the company agreed to post the clinical trial results for all GSK drugs on its corporate Web site.

An inquiry that had been conducted by the New York State Attorney General’s Office into data relating to the off-label use of drugs manufactured by Forest Laboratories Inc. led to a similar agreement with that company.

Dr. Sussman’s Internet investigation found that one pharmaceutical company has done what was promised; however, it was neither of those originally involved. The company was Eli Lilly. Its Web site (www.lillytrials.com) supplies clinical trial data on all its psychotropic drugs, broken down into “completed” and “initiated” trials.

For completed trials, the site supplies PDF files of basic information—“not everything you want to know, but a sense of how the study was designed, the method, and outcomes,” he said.

For the most part, the information given consists of raw data: “If you were expecting something simple, it’s not here. You have to have an understanding of research methodology to evaluate these,” Dr. Sussman said.

The “initiated trials” section lists phase 2, 3, and 4 studies that were begun since July 2004, most of which are still recruiting patients. “The idea is that once you do this, you can no longer hide the results of the study,” Dr. Sussman said.

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complete clinical trial data on its Web site “tells you that any company that wanted to could do it tomorrow. They all have internal documents that summarize studies,” he said.

The GlaxoSmithKline registry (<http://ctr.gsk.co.uk/welcome.asp>) is “a little more restricted,” he said. The site only posts results of studies done after Glaxo and SmithKline merged—which excludes most of those involving Paxil and children, Dr. Sussman said.

The GSK presentation includes less narrative discussion of study findings than the Lilly site. “It’s mostly numbers. ... You have to look into the statistics and form your own conclusion. It’s not intended for the average practitioner,” he said.

The other company that agreed to post clinical trial data, Forest Laboratories, has set up a registry (www.forestclinicaltrials.com), but although completed trials are listed, there are as yet no data from ongoing studies.

“If you call Forest, they send you from one department to another,” Dr. Sussman said.

An industry association, the Pharmaceutical Research and Manufacturers of America maintains a Web site of its own (www.clinicalstudyresults.org), but clinical trial data, supplied by pharmaceutical companies, are fragmentary.

A government site (www.clinicaltrials.gov) lists some ongoing trials but no results, he said. ■

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