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## **Third-Party Audit Firm Confirms Lilly Has Kept Its Promise to Disclose Clinical Trial Data**

### **Company has disclosed 100 percent of studies; more than 99 percent posted on schedule**

INDIANAPOLIS, July 20, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- An independent, third-party audit firm has confirmed that Eli Lilly and Company (NYSE: LLY) has followed through on its commitment to post clinical trial information on its website.

When Lilly launched its clinical trial registry, [www.lillytrials.com](http://www.lillytrials.com), in December 2004, it was one of the first pharmaceutical companies to voluntarily post a comprehensive registry of its clinical trial data. At that time, Lilly committed to a third-party audit of the site to ensure that Lilly disclosed all studies that met the standards set in its disclosure policy, and did so within the promised time frame.

Recognizing the public's skepticism toward the pharmaceutical industry, Lilly commissioned SEC Associates, Inc., a North Carolina-based firm with expertise in regulatory compliance, consulting and auditing for the life sciences and healthcare industries, to review the clinical trial registry process, audit the associated clinical trial information, and to publicly disclose the audit findings.

SEC's independent audit confirmed the findings of an internal audit Lilly conducted late last year: From December 2004 through December 2005, Lilly disclosed 100 percent of the studies it committed to in its policy on public data disclosure, which is noted on its registry website. In addition, more than 99 percent of the time the studies were posted on schedule. The audit also included a broader look at the accuracy and completeness of the data disclosed. A copy of the report was posted today at [www.lillytrials.com](http://www.lillytrials.com).

"The results demonstrate Lilly's commitment to be transparent in the disclosure of clinical trial information," said John McKenney, senior vice president, SEC Associates, Inc.

Results from Phase I through Phase IV clinical trials of Lilly's marketed products are posted to the Lilly registry as well as a registry supported by the Pharmaceutical Research and Manufacturers of America. Additionally, the registry includes information on the initiation of all Lilly-sponsored Phase II through Phase IV clinical trials; this is also posted on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), a service of the U.S. National Institutes of Health.

Through July 15, 2006, 152 summaries of study results as well as information on the initiation of 387 studies have been posted to the registry. Nearly half of the initiated studies are still enrolling patients; trial information and location enrollment status for enrolling studies are updated monthly. Each month, the site receives more than 10,000 visits.

"When we launched our registry, we sought to have the most comprehensive effort, by either a public or private entity, of publicly disclosing clinical trial information," said Alan Breier, M.D., Lilly's chief medical officer and vice president of medical. "We firmly believe that transparency of this information is absolutely essential to restoring the public's trust in our medical research."

Earlier this year, Lilly established a clinical trial registry office within its medical operations, which is supported by six full-time employees. The goal of the office is to ensure continued company compliance with its public disclosure commitments and monitoring of external clinical trial registration and results reporting obligations.

The registry is an extension of the company's Principles of Medical Research, which were adopted by Lilly in 2003. These principles are an outline of policies and codes for the conduct of medical research, disclosure of research results, and payment to investigators for services related to the conducting of clinical trials.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers -- through medicines and information -- for some of the world's most urgent medical needs. Additional information about Lilly is available at [www.lilly.com](http://www.lilly.com).

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