

Industry Performance on Postmarketing Commitments

By Norman M. Goldfarb

The FDA publishes an annual report in the Federal Register on postmarketing commitment studies for drugs and biologics.^{1,2} In general, postmarketing commitment studies are studies that pharmaceutical and biotech companies agree to conduct when they obtain approval from the FDA to market products.

An article last year described the limited progress that pharmaceutical and biotech companies have made in reducing their backlog of commitments.³ In the three years from September 30, 2002 through September 30 2005, the number of open commitments increased slightly, from 1,316 to 1,321. After concluding 401 studies in 2002, industry concluded an average of 193 studies per year from 2003 through 2005. At this rate, assuming no new commitments, it will take over seven years to work off the backlog.

Has the current high level of attention on drug safety had an impact on the industry behavior? Apparently not: From September 30, 2005 through September 30 2006, the number of open studies in the combined pending, ongoing and delayed categories increased 10%, from 1,280 to 1,409. The number of ongoing studies decreased from 284 to 274 (-4%), while the number of delayed studies increased from 81 to 109 (35%).

Clearly, publishing study commitment information on the Internet has not motivated industry to reduce its backlog of postmarketing commitment studies.⁴ To get industry's attention, it may be necessary for the FDA to exercise its never-used authority to withdraw marketing approval for a delinquent drug.

References

1. Federal Register, Vol 71, No 42, March 3, 2006, Notices, pg 10978
2. Federal Register, Vol 72, No 22, February 2, 2007, Notices, pg 5069
3. "Is There Any Commitment in Commitment Studies?", Norman M. Goldfarb, Journal of Clinical Research Best Practices, June 2006
4. "Postmarketing Study Commitments: Introduction", FDA, last accessed 5/12/06 at <http://www.fda.gov/cder/pmc/default.htm>

Author

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.