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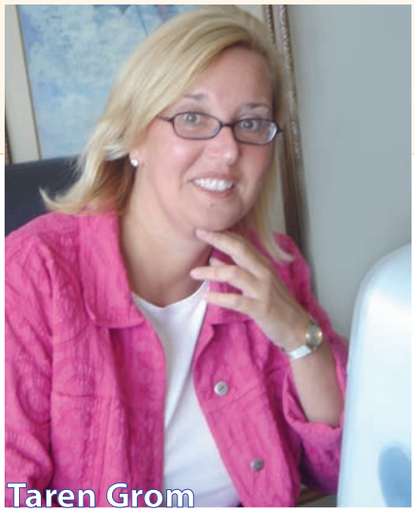
Real-world outcomes



As of September 2005, there were hundreds of U.S.-based postmarketing studies being conducted. The goal: to generate real-world safety and effectiveness information to better treat patients.

Phase IV studies appear to be the hottest thing in clinical research. More and more companies are fulfilling their regulatory commitments, more CROs are benefitting from the outsourced programs, and physicians have additional avenues for bolstering their resumes.

But what about the patients — you, me, and the guy down the street? We're already on a medication, and it's even reimbursed by our insurance companies. Why should I — or anybody else — go through the hassle of a clinical study? What's in it for us?

Improved outcomes, better risk management, and more complete safety assessments, that's what. But for postmarketing or Phase IV studies, or patient registries for that matter, to achieve a level of significance to have a meaningful impact, the pharmaceutical industry has to do a better job educating physicians and patients as to why these studies are important.

PharmaVOICE's Managing Editor Denise Myshko interviewed industry leaders from the major pharmaceutical companies, as well as leaders in the outsourcing and provider arenas, to discuss the value of Phase IV and postmarketing research for this month's Forum.

The consensus among these thought leaders is that there is an increasing need for more information about a prescription drug and about the characteristics of patients once a drug becomes available in the marketplace. With the safety of prescription drugs on everyone's minds, there is much more emphasis on — and more postmarketing requirements for — Phase IV studies, especially to learn more about the real-world effects of drugs in patient populations much larger than those studied in clinical trials.

Those within pharmaceutical companies stress that while there has been more focus on the safety of prescription drugs post approval, these studies are done to answer important medical questions and not as a marketing tactic.

For another perspective on the value of postmarketing studies, see page 58. Timothy Pratt, Ph.D., of MedNet Solutions argues that postmarketing research can move market share, and these studies are valuable and profitable mechanisms for meeting the needs of customers as well as the needs of corporations.

The promotional benefits are often secondary for pharmaceutical leaders. They stress the need to provide the healthcare community with real-world information so they can better treat patients.

"These studies are done to answer important medical questions," says Donald Therasse, M.D., VP, global medical affairs, at Eli Lilly and Co. "What's good for patients is good for business. The results of a good Phase IV trial, just like a good Phase III trial, could be used to help in the market positioning of the products only because we are trying to advance healthcare."

Industry leaders also say there is more continuity between the clinical phases of development and Phase IV/postmarketing research. They say silos are coming down and Phase IV research is becoming part of life-cycle management.

Others say there needs to be more focus on credibility and standardization of Phase IV studies.

"We see the evolution of standards in this arena happening very quickly," says Richard Gliklich, M.D., CEO of Outcome.

As Phase IV trials continue to increase in importance, you never know, you might be part of that clinical-study group yet. Let us know how it goes!

Taren Grom
Editor