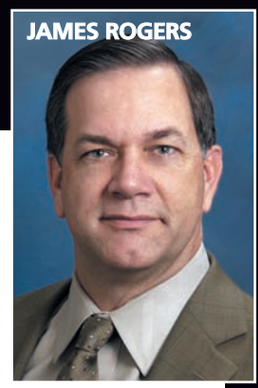
Contributed by James Rogers



MERGING CLINICAL-TRIALS SAFETY AND PHARMACOVIGILANCE

THE WINDS OF CHANGE IN SAFETY MONITORING

In November 2003, Mark B. McClellan, M.D., Ph.D., a former commissioner with the Food and Drug Administration, made the comment: "...there is no such thing as a completely safe medicine." In a speech before the Urban Institute, Dr. McClellan then went on to say the industry needed a better system to monitor the risks and benefits of new medical products, and he suggested that information technologies might play a pivotal role.

In 2004 and 2005, a working group of the Council for International Organizations of Medical Sciences (affiliated with the World Health Organization) studied the current safety practices and risk-management systems in place for clinical trials. The committee pointed out in its report, Management of Safety Information from Clinical Trials, that pharmacovigilance "has traditionally focused on detection and evaluation of signals in the postapproval environment."

The advisory group recommended that the industry extend pharmacovigilance to the clinical-trial setting, but it recognized that to achieve this goal, there needed to be new methodologies for managing safety information during the preapproval clinical-trial process.

Fast forward to March 2006. Laura Ramos, an analyst with Forrester Research, issued an industry report that predicts safety monitoring and e-clinical trial technology will merge so that clinical data can be used for both regulatory compliance and postmarketing surveillance. She describes automatic clinical safety reporting as the next frontier in the development of supportive data processes for the pharmaceutical industry.

While it's very clear that these and other industry pundits are talking about the commonalities between monitoring the safety of patients in clinical trials and monitoring the safety of drugs currently on the market, technology vendors have yet to jump on this bandwagon. To date, there is no clear leading product that has made the leap from monitoring the safety of novel treatments in development to postmarket pharmacovigilance.

PAPER TO ELECTRONIC — A SLOW PROCESS

For many pharmaceutical, biotechnology, and medical-device companies, it has been a slow process to move from paper-driven processes to electronic ones. For example, even with the availability of electronic alternatives, hand-written patient diaries are still in use with many clinical trials.

As a result, clinical trials are still hampered by lengthy delays between the time the data collection takes place and the availability of that data for sponsor review. This exacerbates the industry's ability to predict adverse safety trends and makes it almost impossible for sponsors to quickly compare data from multiple test sites.

This is not to say that the industry doesn't already have technology that could resolve these issues. For some time now, e-clinical products have been available that enable sponsors to set safety thresholds for investigational studies of biopharmaceuticals and medical devices and then monitor these thresholds in real time across multiple sites and multiple studies. An electronic alert or message can even be immediately transmitted to safety monitors when data trends point to a potential pattern of adverse events.

It's not too much of a stretch to envision this same technology being used for real-time, postmarketing pharmacovigilance. But first, it needs to be universally adopted as the standard for preapproval clinical research.

THE NEXT PHASE

Current practice already dictates the rapid reporting of safety trends in clinical trials to governing agencies. The next evolutionary step in the process is to tightly integrate a component of electronic safety messaging into the data collection and reporting platform so that sponsors are immediately notified, in real time, of potential adverse safety trends during ongoing studies. This real-time alert system will be made possible by an e-clinical product's ability to automatically code to MedDRA terms since any meaningful analysis of safety data requires that the events first be converted to standard terminology. The third phase will be to use this same system to monitor drugs once they have made it past the Food and Drug Administration's review process and into postmarketing studies.

The FDA's interest in, and advocacy of, technology solutions have laid the foundation for what industry researchers at IDC refer to as the development of "the pharmacovigilance continuum," or an end to the separation between clinical development and postmarketing activities for new therapeutics.

But until the life-sciences industry completes its initial revolution of conducting paperless clinical trials, and institutes as the standard the use of present-day e-clinical products and services for postmarketing, electronic pharmacovigilance will remain an elusive goal.

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