

## Electronic Alerts Advance Safety

James Rogers

**T**he recent spate of adverse publicity surrounding Vioxx and other blockbuster drugs has intensified the U.S. Food and Drug Administration's scrutiny of novel therapeutics in the pipeline. While this reaction is understandable, it comes at an unfortunate time. The industry has been making great strides in moving toward a more streamlined approach for conducting clinical trials, with the goal of shortening the time to market for drugs and medical devices in development.

Public opinion notwithstanding, patient safety is of utmost concern to all parties involved in a clinical trial, as evidenced by the number of safety reviews conducted during any clinical program that are reported to an array of safety monitoring bodies, ranging from Institutional Review Boards to the FDA. Although the recent focus is on postapproval pharmacovigilance, enhancements in trial safety systems could improve the monitoring of a product's safety before the new treatment reaches the market. This achievement may rest on the shoulders of a new clinical trial methodology being made possible by Web-based electronic data capture (EDC): electronic safety alert messaging.

### An electronic evolution

The next evolutionary step in the safety process, automatic electronic messaging gives sponsors and other key personnel notification of potential adverse safety trends during ongoing studies. Notification can be pushed through any number of devices, ranging from cell phones and desktop PCs to PDAs and pagers. This form of immediacy in a clinical trial is further improved when it can be achieved through safety monitoring and messaging conducted in real-time—one of the key reasons for using a Web-based EDC system.

Biopharmaceutical companies are historically slow to adopt new technology due to the complex regulatory and risk-adverse environment in which they operate. However, the pharmaceutical industry is now acknowledging the value of improved information technology solutions for clinical trials, which represent the most expensive phase of drug development. Industry analyst firm IDC issued a Life Sciences report last year stating that, "while the market for clinical trial management systems and EDC is still immature, it is expected to grow exponentially through 2008." It also pinpointed the areas of most concern to pharmaceutical and biotechnology companies when selecting an informational system. These concerns



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include the ability to track enrollment and study progress across multiple test sites, as well as functionality for identifying and managing potential study delays (including safety issues) before they become severe. It's no coincidence that these are also primary factors for selecting an EDC system.

### The need for speed

Today, sponsors understand that they can no longer afford to wait weeks or months to extract and compare data derived from clinical studies being conducted at multiple sites. There are a number of products on the market that can streamline clinical trial data management. However, a Web-based methodology is best suited to provide the framework for the

rapid assimilation of data across multiple sites and collapse it into an analyzable format that automatically generates safety alerts when pre-established safety thresholds are exceeded.

Real-time automatic safety alerts have several human and financial advantages, including the following:

- Patient safety is assessed on an ongoing basis and is not restricted to annual or biannual Data Safety Monitoring Board meetings.
- Safety data between treatment groups can be analyzed by the EDC system without breaking the study blind; alerts do not reveal study data and are sent only to key personnel.
- When multiple studies are stored in the same EDC system, safety data can be compared across all the studies.
- Safety alert triggers can be specific to an adverse event (e.g., myocardial infarction) or they can be more broadly defined (e.g., all cardiovascular events).
- Minimization of patient risk, including early termination of a clinical trial when the data shows safety concerns.
- Minimization of financial risk to the sponsor through the early detection of unsafe products; early detection allows the company to terminate a program and reassign resources to more promising candidates.
- Potential to ease regulatory concerns for a clinical trial by providing an aggressive safety monitoring plan.

There's no question that an automatic electronic safety notification process will save time, money, and potentially the lives of study participants in clinical trials. It may only be a matter of time before regulatory agencies require it to be part of the clinical trial process, adding further protection for the people who bravely participate in the research process. □



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