Phase IV Trials — Improving Product Life After Approval Through Technology

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It can be theorized that some of the most important research on pharmaceutical products begins after approval. Increasing the commercial applications of an already approved drug is just one of the many desirable outcomes from generating more data. But it is also because of the ability — and need — to test among a larger number of patients that the real learning about all the potential benefits, and safety cautions, of a particular pharmaceutical takes place.

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Employing Technologies for Phase IV Efficiencies

The sources for Phase IV data often shift from trained clinical investigators to participant physicians, who are the gatekeepers to the end users. This shift enables research to evaluate additional, yet extremely important, quality-of-life outcomes that often are not adequately covered in a controlled Phase III clinical-trial environment and assessment of effectiveness may rest with simpler, often more subjective, parameters.

To introduce efficiencies and ease of data collection, electronic data capture (EDC) may be the best method to employ. These systems, with their built-in parameters and automatic checks and balances, are often the best way to give pharmaceutical company sponsors the important information they need without unduly burdening physicians with an increased workload that they often are not prepared to handle.

The ability to adapt to new outcomes discovered in the course of data collection and consistent monitoring using EDC is likely to become an even more important factor in Phase IV.

Any EDC diary scenario, when applied to the general marketplace in Phase IV studies, has been shown to be far superior to paper diaries in gathering reliable data, with a substantial reduction in costs associated with cleaning up inconsistencies.

Yet to maximize this advantage, EDC scenarios must be flexible and easy to use. Clinical researchers and other trial managers must be able to access relevant technologies to make the data as reliable as possible.

Indeed, the competitive advantage of an EDC technology is maximized by the flexible application of Web-based, interactive voice response (IVR) and paper-based fax scanning systems — often used simultaneously or interchangeably in response to the needs of the research sites' capabilities.

In addition to the fact that the "investigator" in Phase III studies has often been substituted with a working physician in Phase IV, there is an ongoing need to make the technology for the end user as easy to use as possible. This is obviously a heightened need when capitalizing on the increased sample bases available in large population areas such as India, as well as the long-term commitment of patients that Phase IV studies may sometimes require. Simply put: EDC systems must be adapted for the end-user in each global region or the competitive advantages of using these systems will not be maximized.

Going Global

As a greater percentage of Phase IV studies go global and involve multiple languages and cultural norms, the challenges to keep data centralized, yet at the same time relevant to individual geographic data subsets, will increase.

Harmonization of protocols, while allowing for language and cultural differences will be a key element in allowing Phase IV studies to maximize their harvest of information cost-effectively.

Outsourcing for Results

While many pharmaceutical companies have previously perceived the need to manage Phase IV research in-house to guard marketing data, it is gratifying to learn that the trend is toward greater outsourcing of Phase IV studies.

Apparently with the need for the additional patient sources to meet agency-mandated conditions of approval, data are more easily gathered by CROs that are already set up to provide such data from key regions of the globe. And with that, the continuity of committed personnel on project teams is of increasing advantage to a greater number of pharmaceutical manufacturers. ■

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