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Power of Site

**ePRO providers have developed
a third puzzle piece** to help

pharmaceutical, biotechnology and

medical device companies enable true
eClinical trials worldwide.

Two down, one to go. Electronic patient reported outcome (ePRO) solutions and electronic data capture (EDC) systems have replaced untrustworthy paper processes for data collection at patients' homes and clinical sites, respectively. Most questionnaire data, however, remain paper-based and are therefore unreliable. That is, until now.

Study sponsors who abandoned paper for ePRO have experienced significant returns on their investments with improved data quality and more efficient trial management.

These ePRO solutions are normally deployed on handheld devices, called eDiaries, which are distributed to patients for use outside of the site. These eDiary devices transcend the rigid limits of paper methods with timestamps, branching logic, calculations, edit checks, reminder alarms, measurement device integration, cognitive assessments, and other advanced features. All data are complete, logical, legible, and available for real-time remote review. Data from eDiaries are often integrated into EDC systems, which sites use to clarify and create a consolidated and centralized stream.

Addressing the Missing Link

The missing piece is site-based ePRO. Industry research indicates 50% to 60% of trials capture health-related quality of life (HRQL) and other questionnaire data. This figure is expected to rise significantly considering the FDA's PRO Draft Guidance and its emphasis on involving the patient perspective. Therapeutic areas and indications such as oncology, Alzheimer's, disorders of the CNS (e.g. pain, insomnia, depression), respiratory, and immunology are particularly strong candidates to benefit from these data. Large multi-center trials such as Phase IV, registry, and marketing studies also make frequent use of this information.

Consider oncology, for example. According to 2003 Mayo clinic proceedings, because the optimal treatment for different types of cancer remains uncertain: "HRQL can provide unique information that leads to the choice of effective treatments, rejection of interventions, and clarifies the tradeoffs between management strategies."

Moving Beyond Paper Bias

So why are these critical data most often captured on paper, especially when the sponsor is already using ePRO and/or EDC?

PHT CORPORATION, Boston, is a provider of electronic patient reported outcome (ePRO) solutions used in more than 350 clinical trials around the world. For more information, visit phtcorp.com.

Good question. One of the key benefits of eSource technologies is the ability to shorten the time to database lock and data analysis. Collecting questionnaire data on paper negates this advantage by acting as a bottleneck due to double data entry, queries, and other costly delays. Further, paper processes add to site burden as they require study coordinators to remember which questionnaires should be administered during each visit. (And while we are discussing the ills of paper, we would be remiss in not mentioning the environmental impact of printing so many volumes of surveys that then have to be managed and stored in over-crowded site offices.)

Unfortunately, viable solutions had not been previously available. For years potential customers have acknowledged the importance of capturing unfiltered and unbiased PRO responses directly from patients rather than relying on investigators to try to explain how patients feel, but high-quality devices have not been available, thus forcing them to work with other solutions and even revert to paper.

Fortunately, forward-thinking eClinical technology providers already have begun to address this need by delivering innovative solutions created specifically for site-based ePRO. Today, mobile devices with large screens stay at the site, as opposed to going home with each subject. When a patient comes in for a clinic visit, the study coordinator is automatically presented with the appropriate questionnaires for the subject to complete. These solutions typically support hundreds of patients at each site on a single device.

Branching logic, edit checks, and structured response options reduce respondent burden — especially if the device is intuitive and easy to use for patients of all ages and abilities. Responses are timestamped, which removes any doubt of when they were entered, and all data are sent to a central server where they are immediately made available for online review. Meanwhile, automatic calculations and efficient tools for subject and visit management make it easy for sites to spend their time focused on caring for their patients.

Clinical research sponsors leveraging ePRO at the site eliminate the problems and suspicions of paper-based data. In return, they exclusively receive complete, timely, and logical health-related quality of life and questionnaire data from every subject and site in the study.

In this way, ePRO providers have developed a third puzzle piece to help pharmaceutical, biotechnology and medical device companies enable true eClinical trials worldwide. ■



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