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DEVELOPING E-PROCESSES FOR PATIENT RECRUITMENT

In the past decade, clinical-study patient recruitment has become increasingly challenging and complex, calling for more preplanning. As a result, many sponsors have come to rely on the help of patient recruitment experts who apply their knowledge of the clinical-research field along with sophisticated, time-tested principles and practices of marketing science. These include various metrics for selecting sites, projecting enrollment, monitoring project plans, redeploying efforts, and retaining participants. Today, recruitment is recognized as the most significant cause of clinical study delay. And business leaders high on the chain of command at sponsor companies large and small are paying attention and requiring more control over this critical process.

TYPICAL ISSUES THAT HINDER RECRUITMENT

The following presents the most compelling recruitment challenges and then ways that Web-based recruitment solutions can provide an efficient choice for managing clinical study enrollment.

1. Inadequately anticipating, monitoring, and redeploying enrollment efforts. Many studies suffer from poor planning and inadequate project management. Sponsors lack the tools to spot problems and make midcourse adjustments to the plan.
2. Poor site selection or performance. Many sponsors rely on outdated methods of choosing sites, such as past experience with a site or its reputation, rather than on study-specific criteria and operational capabilities. The result can be underperforming sites and under-enrollment.
3. Inadequate recruitment outreach. The most effective patient-recruitment outreach is created using the principles of marketing and most sponsors simply aren't equipped to manage this without the assistance of professionals.
4. Losing time through inefficient development and approval of recruitment materials. Time is a precious commodity in a clinical study, but it is often lost due to lack of control over the materials development/editing process and the institutional review board or ethics committee approval process.
5. Losing study participants or not keeping them compliant with the protocol. Study teams can often overlook patient retention, thinking it will take care of itself. The truth is, relationship building is an important part of keeping patients engaged in a study.
6. Losing time due to inadequate training of and communication among investigators, site staff, study monitors, country managers, and study teams. Relationships between study team members are important to overall study success, and one way to establish and improve them is via communication. Sponsors often forget to establish communication parameters and vehicles or to provide the necessary training.

A Web-based technology can be used to address these six issues. Through modules that can be individually selected based on key study challenges, sponsors can make initial study plans, measure progress, and create both top-level and detailed reports to spot trends and make key decisions. In addition, a patient-recruitment management system (PRMS) has the capability to optimize site selection using built-in metrics, manage patient enrollment data and site support, and track study materials and regulatory approvals.

Individual tools (functionality) within modules perform key tasks. One such tool uses essential information about a specific study to produce basic study enrollment projections and related insights for planning, implementation, and redeployment of recruitment efforts. This results in automatically calculated rates for optimal site initiation, patient screening, and randomization. The tool also allows users to adjust their data hypothetically, providing the means to compare different planning scenarios side by side.

One might ask: where do these data come from?

A Web-based system for patient recruitment is compatible with and can draw in data from other systems commonly used by the clinical study community. Although systems such as clinical trial management systems (CTMS), electronic data capture (EDC), and interactive voice response systems (IVRS) primarily capture data that are used to support an FDA submission, there are specific data points within those data sets that can be very useful to gauge and monitor recruitment. A PRMS can talk to other systems and "filter" those data as appropriate to populate and compute built-in recruitment algorithms, resulting in actionable information.

Additionally, a PRMS, designed for facilitating enrollment stands out among e-process solutions because it forms a reciprocal relationship with the user. As country study managers, monitors, clinical research coordinators, or other study community members experience the value of information and reports generated via existing data, they will be motivated to add other operational data points that will make enrollment more efficient.

Good planning and early planning is paramount. This forms the basis for successful patient recruitment. It is never adequate to rely on a static project plan. A PRMS provides effective systematization and management of recruitment processes, from planning and implementation through retention. Because it is Web-based, it is inherently flexible. What's more, with a modular structure, it is scalable. That means it can provide an instant recruitment infrastructure and continue to grow with a company as new study challenges arise.

Joan F. Bachenheimer is a Founding Principal of BBK Worldwide, Newton, Mass., which is committed to innovation and education to improve industry practices and awareness, and TCN e-Systems LLC, which comprises licensable e-business patient recruitment solutions. For more information, visit bbkworldwide.com.

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