Strategies in Patient Recruitment

Patient recruitment used to be an ad hoc affair, where sites were personally selected by a sponsor and given a few hundred dollars to create local awareness for a clinical trial. The sponsor's hope was that the investigator grants would be competitive enough to keep sites motivated, but unsurprisingly this approach resulted in numerous trials failing to recruit sufficient patients or meet deadlines. Although troublesome and costly, the industry learned from its mistakes. Today's clinical trials emerged from the past with finer tuned processes and now employ a more systematic approach of centralized patient recruitment and retention.

In essence, centralized recruitment programs are designed to provide the optimal choice of strategies for reaching potential subjects. By using a call center, a centralized program allows potential subjects to respond to a series of questions about their health/current medical treatment. This method increases the funnel of potential new patients while simultaneously targeting more pre-qualified patients for a first visit to the investigative site. While this process seems simple, it requires a top-down leadership approach where the study's core management uses a holistic and unified strategy.

The centralized recruitment method works best when the overall study team has access to one centrally controlled budget, rather than individual sites with their own allocations. This approach leads to more uniform strategic decisions across sites and provides a critical mass of funds to use for a variety of purposes. When executed correctly, this system still enables individual sites to refine the centralized strategies, which are frequently developed by specialized firms. Centralized patient recruitment programs are particularly relevant for clinical studies requiring populations in highly competitive areas (e.g. Alzheimer's) and in areas with challenging demographics such as pediatric patients or those patients with rare diseases.

Dedicated Functions and Departments

Some pharma and biopharmaceutical companies have been centralizing the decision-making process and outsourcing patient recruitment for several years. Companies are recognizing the need to create centralized functions and are setting up dedicated departments to focus on patient recruitment planning and decisions. These groups focus on study feasibility, which includes sampling a number of sites to make realistic estimates of patient accrual rates. This is achieved by a questionnaire or interviewing a site's staff on the historical data of patient visits and referral patterns at sites. An in-person interview is preferred since a site's staff may be able to provide information on competitive trials.

During this period of increased centralization of decision-making, more patient recruitment vendors have been marketing their services with a variety of models to identify and recruit – as well as retain – clinical trial participants. Estimates for the centralized patient recruitment market are approaching $500 to $600 million by the end of 2014 (CenterWatch). Given the enormous costs of study delays, the return on investment for a recruitment expert to ensure that weeks and months are not lost during enrollment is easily justified.

Finding and Attracting Patients

Pharma and biotech companies are turning, or in some cases returning, to a variety of countries to find clinical trial participants, including Russia, Central America and once 'abandoned' (over recruited) European Union countries. While effective for specific disease types, these locales do not provide all of the necessary participants for a clinical trial, especially where regulatory bodies insist that datasets must include patients from specific populations.

With thousands of clinical trials now conducted each year, many in competitive indications, traditional patient recruitment approaches are unlikely to meet targets. The fact remains that most potential subjects simply do not receive the message about clinical trials. According to one study by Harris Interactive, only 16 percent of the respondents have ever been asked to take part in a clinical trial, clearly illuminating there is room for improvement in awareness in the United States, as well as throughout the globe.

In the U.S., the Center for Information and Study on Clinical Research Participation (CISCRP) is a non-for-profit group dedicated to informing the public, patients and policy makers about clinical trial participation. Organizations like CISCRP use public service announcements, among many other tactics, to generate awareness of clinical trials and the importance of participation. They encourage sites to spread the word about clinical research, even if there is not a specific trial for their patient population.

Developing Supporting Technologies

Technology also has a role in improving patient recruitment processes. Patient data mining, which is still in its early days, uses anonymized health care or medical record data through legal agreements with healthcare entities or medical centers to identify potential subjects for a trial. The subject's physician would then be contacted to further evaluate the patient's fit for the trial and to seek agreement to participate.

The typical basis for the medical record data is the International Classification of Disease Code – 9th Edition or ICD-9 (the 10th Edition is available in October 2014). This is the standardized means of classifying medical conditions. Access to this information, even if anonymized, is a powerful tool based on actual diagnosis. Sophisticated patient data mining systems can even study concomitant medications used by patients to determine study eligibility defined by specific protocols which would greatly support pharmacogenomic aspects of clinical studies.

Establishing patient data mining requires a significant number of data agreements to be in place to have sufficient volume of patients and representation (such as ethnic, geographical, etc.). Few organizations commit to these agreements due to concerns about possible privacy breeches, difficult valuations, and public perception. Nonetheless, data mining is slowly growing with specific companies (Bio-IT World, 2014).

As a patient recruitment tool, patient data mining requires a 'communications and follow-up component' to provide follow-up with the referring physician and the potential subject. While identifying a patient is important, ensuring understanding of the clinical trial, its risks and benefits, and providing the link to next steps for potential informed consent, medical screen and randomization is of far greater value. If conducted appropriately, the combination of a patient data mining service and strong communication tool can be an effective approach to patient recruitment.

More tools will no doubt develop and currently social media is a great area of focus (EPC, September 2014, PharmaVoice). However, it remains to be seen how effective social media will be as a tool and what the full ramifications will be. Nonetheless, one can be assured that patient recruitment vendors are already looking at the 'next great tool' and how it can be used to optimize clinical trial participation. Even with advances on these tools, concern for the patient, their awareness of the right clinical trial, and a thorough informed consent process remain paramount.