



Marketing Strategies for Clinical Trial Recruitment and Patient Retention

Behind every new medicine are the volunteers who take part in clinical research studies; however, the number of people who participate in clinical trials is quite small. This article details how product managers can help to build clinical trial awareness.



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Every year, several million people participate in clinical trials to support new drug applications (NDAs) submitted to the FDA. This level of participation represents less than 10% of the more than 60 million people who have severe, chronic, and life-threatening illnesses in the United States, according to data from the Pharmaceutical Research and Manufacturers of America, Washington, DC.

Advances in treatment and care for patients with serious diseases are a direct result of clinical trial findings; however, recruiting a sufficient patient pool for a trial in a timely manner has become increasingly difficult. According to CenterWatch (Boston), patient recruitment accounts for a quarter of the time spent conducting a typical clinical trial.

Moreover, the research-and-development (R&D) and clinical trial processes required to bring a drug to market are becoming more time consuming and expensive. According to a 2001 report from the Tufts Center for the Study of Drug Development, Boston, the average R&D cost of an approved medicine was \$802 million, representing a 250% increase in drug development costs in just over a decade. This indicates that new, innovative drugs require further research and longer, more complex clinical trials before they are approved. Meeting the challenge of improving patient recruitment can help clinical trials proceed more efficiently, potentially saving millions of dollars in R&D expenses.

Barriers to Recruitment and Retention

A survey conducted by the Coalition of National Cancer Cooperative Groups (Philadelphia) in 2000, along with research from CenterWatch identified the most frequent barriers to clinical trial participation cited by patients: inability to find a trial, study center is too far away, insufficient information, fear of reduction in quality of life, fear of receiving a

placebo in place of actual treatment, concern about potential side effects, fear of being treated like a "guinea pig," physician reluctance to refer patients to clinical trials, lack of information about clinical trial benefits, and concern that insurance will not cover treatment.

Patient retention is just as important as patient recruitment. On average, nearly 25% of volunteers drop out before completing the study. Maintaining study volunteers is often linked to how valued patients feel and how they are treated during the process (from their first phone screen to regular visits throughout the trial). Patients welcome good customer service; hence, the best way to keep patients enrolled in a clinical trial is to treat them as indispensable customers.

Patient Recruitment Strategies

Discovering eligible patients for clinical trial participation usually begins with an examination of available patient databases and physician referrals. Whereas this step is sometimes enough to meet recruitment targets, other strategies must often be examined. Furthermore, mass media and other marketing strategies are frequently used as productive recruitment methods. Pharmaceutical companies are now beginning to understand the need for procedures to support patient recruitment initiatives, and are investing resources into the development of staff and programs internally to provide recruitment services (Figure).

The first step to deciding which marketing strategies will work best for a specific trial is to determine the target audience. Defining the target audience's needs and motivations will aid in the development of an effective message and recruitment strategy. As with any tactical plan, budgets will dictate which strategies will be most appropriate.

Clinical Trial Branding. A common strategy to build clinical trial awareness among patients is developing a recognizable acronym for the clinical study that will resonate with patients and investigators. Some example clinical trial names include PACCE (Panitumumab Advanced Colorectal Cancer Evaluation), a nationwide research study sponsored by Amgen (Thousand Oaks, CA) and Abgenix (Fremont, CA) of an investigational colorectal cancer drug; TORCH

(Towards a Revolution in COPD Health), a three-year, multi-center, randomized, double-blind, parallel group, placebo-controlled study of a drug for chronic obstructive pulmonary disease sponsored by GlaxoSmithKline (Philadelphia); and TARGET (Therapeutic Arthritis Research & Gastrointestinal Event Trial of Lumiracoxib), a gastrointestinal safety outcomes study sponsored by Novartis (East Hanover, NJ).

Successful branding of a clinical trial often includes the development of a logo and approved colors for all materials and on-line content. These visual elements should include the trial acronym or the name of the study. They must never make any claims about the compound being researched, or they will be seen as promotional and therefore in violation of institutional review board (IRB) regulations.

Advertising and Media Buying. Clinical trial recruitment advertisements that appear in newspapers, or on public transportation, radio, television, and the Web, are an effective means of reaching patients. In 2002, an estimated \$500 million was spent on mass media promotion of clinical trials, up from \$400 million in 2000, according to CenterWatch data.

In many therapeutic areas, publications are devoted to informing, educating, and supporting patients who have that disease or condition. These magazines provide consumer-friendly information to those suffering from such chronic diseases as cancer, Parkinson's disease, multiple sclerosis, and asthma that are ideal for ads of this nature.

Once IRB approval is received for the ads, study sites must begin to obtain media buying information, including advertisement availability. Depending on budget and geographic area, some prime-time television ads can be purchased within a package. Featuring a site's physician names and office location the ads can add credibility and trust.

Media Relations. Conducting local market media outreach at specific study sites encourages patients to enroll in clinical studies. When conducting media relations, it is important to identify how many and which study sites will be the focus of one's efforts. It is also important to identify an investigator from each target center who is willing to serve as a local spokesperson for the trial. When working with individual study sites, public affairs representatives at the selected institutions should be contacted and informed about media relations plans. These market contacts can be instrumental in identifying key media with whom they have ongoing relationships, working with their local investigators, and securing media coverage in their market. Once the physician who will act as the clinical expert speaking on behalf of the study is identified, media and message training is encouraged to ensure effective delivery of key messages and compliance with FDA and IRB regulations.

Another media relations tactic involves developing a comprehensive turn-key kit of materials for selected clinical study sites, which can comprise template press releases,



Figure. Patient recruitment strategies.

disease fact sheets and backgrounders, public service announcement scripts, and advertisements, as well as local market media lists and questions and answers for use when speaking to the media. These turn-key kits empower local public affairs individuals and study site investigators to conduct their own media relations. All materials that are developed for distribution to the media, including briefs, fact sheets, and press releases, must be IRB approved before dissemination (Table).

Patient-Advocacy Relations. Patient-advocacy organizations communicate using electronic and printed newsletters, websites, teleconferences, and annual meetings. Many patient advocacy organizations list and discuss enrolling clinical trials within these patient communications. Checking with these organizations to determine requirements for inclusion of information about clinical trials in their communications materials is an effective way to have key messages reach a motivated target audience. On average, patient advocacy websites garner thousands of "unique visitors" per month. Patients who are involved with advocacy groups are usually highly motivated to learn as much as they can and take action in managing their disease. All materials distributed to patient advocacy groups (nonmedical personnel) must be approved by the IRB before dissemination.

Site-Specific Support Programs. Site-specific support programs involve tactics designed to encourage local public affairs contacts and the physicians at each enrolling clinical study site to continue seeking to enroll more patients in the clinical study. For example, a sponsoring pharmaceutical company's medical affairs department could distribute a

TABLE: A GUIDE TO INSTITUTIONAL REVIEW BOARD APPROVAL REQUIREMENTS

Materials	Approval Required	Approval not Required
Press Release	✓	
Fact Sheets and Backgrounders For Use With Media	✓	
Fact Sheet/Fact Card for Distribution to Physicians		✓
Print, Radio, and Web Advertising	✓	
Company-Sponsored Clinical Trial Website	✓	
Turn-Key Local Market Media Kits	✓	
Media Training Materials	✓	
Patient Advocacy Communications (not addressed to medical affairs)	✓	
Patient Advocacy Communications (addressed to medical affairs)		✓
Web Postings Through Clinical Trial Matching Services		✓
Web Postings Through Patient Advocacy Organizations	✓	
Investigator Newsletters		✓

newsletter or hold a conference call for all investigators every two to three months to highlight the sites that have accrued the most patients, remind investigators of enrollment targets, provide information about the study, and offer recruitment tips. Not only can these tactics build momentum and give investigators something to work toward, but they also act as a refresher on the study's protocol. Many clinical study investigators enroll patients for several clinical trials at the same time, so any detailed information to help them stay informed about a particular trial is helpful.

Collateral materials designed to promote the clinical study internally at clinical research centers are also helpful. For example, study sponsors can provide the enrolling sites with IRB-approved physician-to-patient letters, posters, flyers, and brochures for distribution to patients.

Web Strategies. A branded clinical trial website allows patients who are either enrolled or interested in enrolling in the clinical study to learn more about the trial. In addition, disease-specific nonbranded websites can act as databases for patients seeking clinical trial information, called clinical trial listing services. CenterWatch provides a listing of clinical trials, searchable by keyword, disease, condition, or location. Patients who opt to be notified of new trials or newly approved drugs when new trials are added to the website receive E-mails about these. They can also submit questions or request additional information by E-mail.

Metrics

The effectiveness of patient recruitment programs can and should be measured. Useful approaches to measuring the

return on investment for these efforts include tracking media coverage and reporting the number of impressions in each target market, tracking the number of visitors to branded websites and patient advocacy sites, assigning each advertisement a distinct telephone number to track where calls come from and how patients heard about the study, comparing the number of telephone calls received before rolling-out recruitment strategies to the number received during and after, and conducting patient surveys to evaluate quality of life during the study.

According to Praxis, a clinical services provider based in Jacksonville, Florida, a campaign consisting of an educational brochure, a website, an Internet banner ad, and a PR campaign helped them surpass enrollment goals set for a female sexual dysfunction study. D. Anderson & Co., Dallas, reduced the patient drop-out rate by 50% for a diabetes clinical study that was initially losing approximately 18 patients per month. Effective tactics included a comprehensive patient retention and site-support program designed to reduce available participant drop-out rates energizing sites to be proactive about anticipating patient attrition issues, and creatively managing retention issues.

Conclusion

As R&D costs continue to increase, finding more effective ways to complete clinical trials must be pursued by the companies and institutions conducting these trials. Presently, nearly 86% of clinical trials conducted in the United States fail to enroll subjects within the contract period. This failure rate is up from 80% of trials in the late 1990s. If this trend continues, companies sponsoring important trials will need to continue investing more money to complete them. In addition, the longer it takes for clinical trials to be completed, the longer it will take for potential treatments to reach those patients who need them most.

By executing tactics designed to effectively raise awareness of clinical trials among physicians, patients and their families, friends, and caregivers, and encouraging more patients to participate in the research of potential new treatments, pharmaceutical companies can have a tremendous positive effect on people's lives. ■

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