Effective Patient Recruitment Training Programs

A Model for Success

Ask any group of clinical research professionals whose job *patient recruitment* is, and you will get a variety of responses: the sponsor, the contract research organization (CRO), the site, the patient recruitment service provider (PRSP), or some combination of these entities. Ask the same group, whose job *patient recruitment training* is, and a clear pattern emerges: It's the site's responsibility! And although members of this group will readily admit that they have little in the way of formal training programs for patient recruitment in place, they are unanimous in their willingness to support patient recruitment training programs[1]. Figure 1 reflects the pulse of a diverse group of clinical research professionals recently polled on their willingness to invest in patient recruitment training.

Ask . . . whose job *patient recruitment training* is, and a clear pattern emerges: It's the site's responsibility!

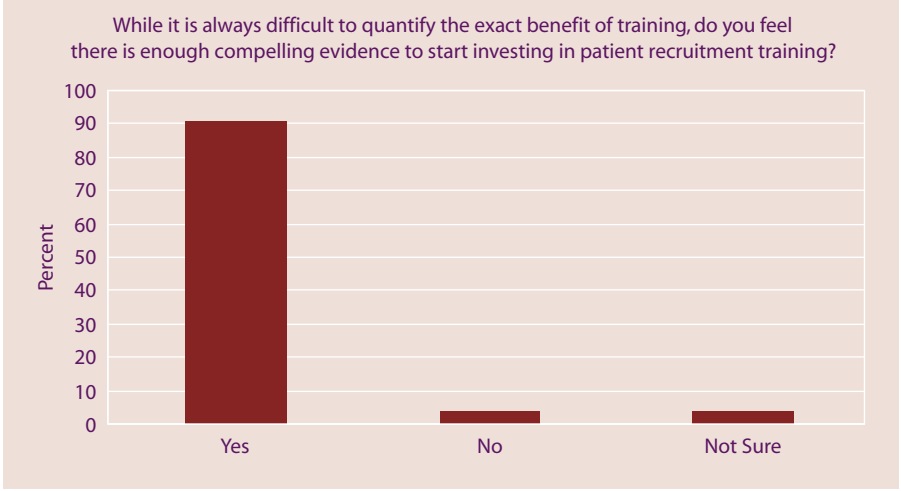
While investigative sites are typically the ones most directly engaged in recruiting study subjects, sponsors, CROs, sites, and PRSPs alike, all share the responsibility for successfully meeting enrollment targets and timelines. From a regulatory standpoint, both sponsors and investigators are obligated to ensure adequate training is in place. According to the Code of Federal Regulations, sponsors are responsible for providing investigators with the information they need to conduct the investigation properly.[2] Likewise, the International Conference on Harmonization (ICH) guidelines suggest that investigators should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial.[3]

From a practical standpoint, clearly both sponsors and sites have a lot to gain or lose if all study personnel are not properly trained in the protocol, study procedures, Good Clinical Practices (GCPs), or effective patient recruitment practices. Leaving the responsibility for patient recruitment and recruitment training to the site alone is a missed opportunity, particularly given the investment the sponsors are making to attract and encourage study participation. Recent industry statistics suggest that some $675 million dollars (USD) are being spent on recruitment activities, with the majority of spending still directly allocated to the investigative sites.[4] Sponsors who provide or offer comprehensive and study-specific recruitment training programs are able to gain a greater return on their recruitment investment by ensuring that all parties involved understand how best to utilize such funds. Likewise, sites that invest in training personnel in the core principles of patient recruitment, along with developing Standard Operating Procedures (SOPs) for patient recruitment, are able to maximize recruitment budgets, achieve efficiencies in recruitment practices, and secure additional studies.

An effective patient recruitment training program requires a basic understanding of the following:

- Patient recruitment is a complex process; it is not just about tactics and strategies.

Figure 1. Audience Responses to Polling Question at the 28th ACRP Annual North American Conference, May 2004.



Source: ePharmaLearning.

- Training is not the same as teaching or lecturing.
- Specific techniques and approaches are needed to reach the adult learner.

These core principles will drive the development and delivery of the training program. The complexities of the patient recruitment process provide vast opportunity to customize and tailor training programs to meet the needs of a specific investigative site or a given clinical trial. Many well-intentioned training efforts fail to achieve the desired outcomes because of a focus on one-way knowledge transfer versus interactive, practical, and activity-based learning exercises. Though the distinction may be minor, teaching is rooted in instructing, informing, and imparting of knowledge, whereas training involves an activity leading to a skilled behavior.[5] Training adults, in particular, requires problem-oriented instruction rich with relevant and readily useable information. Although a discussion of the principles of adult learning theory are beyond the scope of this article, there are many resources available that provide tips and techniques for teaching adults, such as the compilation of references developed by The Faculty Development Teaching Tips Index from the Honolulu Community College[6]. Instead, this article focuses on the contents and components for both site- and study-specific patient recruitment training programs.

Options and Approaches for Study-Specific Patient Recruitment Training

Patient recruitment training can be offered via interactive workshops in conjunction with investigator meetings; live, on-line training via Web and teleconferences; self-paced Web training modules; one-on-one training at the investigative site; or some combination of these approaches. Each approach offers unique opportunities to enhance understanding of the patient recruitment process.

Clearly there are advantages and disadvantages associated with each approach. Face-to-face programs are most costly but maximize peer-to-peer learning and the exchange of successful practices. Such programs provide the ideal forum for applied learning in terms of case studies, simulations, and practical application of theoretical principles. When offering face-to-face training at investigator meetings, some sponsors prefer to have sites and clinical research associates (CRAs) complete pre-workshop activities, assignments, or theoretical learning modules to allow more focus and discussion on the most relevant topics during the interactive portion of the live training session.

Web-based live and archived sessions or computer-based training programs require less in terms of time and travel expenses and may allow for more self-paced learning. Although newer technologies facilitate the ability to conduct more interactive learning experiences via on-line training, they are still not a complete substitute for face-to-face programs. One-on-one training programs allow for maximum customization to the learners' needs, but may be impractical from a resource perspective.

Training can be offered at many intervals throughout the clinical research study as well. Training offered at the launch of a clinical trial may be supplemented by ongoing reinforcement of the core principles via Web conferences, teleconferences, and study newsletters. Discussions during monitoring visits also provide an effective continuum of learning throughout the enrollment period.

Components and Contents of a Patient Recruitment Training Program

Although there are a few formalized patient recruitment training programs and conferences available in the public domain, most sponsors are interested in training programs that are customized to the needs of a given clinical study. When planning a customized recruitment training program, ascertaining the needs and interests of the intended audience is paramount.

Conducting a pretraining needs assessment is a very effective means for identifying the topics of greatest relevance for the given audience and can be done via Web- or fax-based surveys or telephone interviews.

Training for investigators may cover more high-level concepts, whereas training for clinical research coordinators (CRCs) may involve more in-depth and practical information. For example, a discussion of the influence of the physician on patient participation in clinical trials and roles and responsibilities for patient identification and informed consent may be particularly important when training investigators. The "who, what, where, when, why, how, and how much" of implementing actual recruitment strategies and tactics are topics generally geared to audiences including site directors, CRCs, and recruitment specialists.

The nature of the training program will need to be adapted based on the level of research and recruitment experience of the audience. As more sponsors insist that CRAs take on greater responsibility and accountability for enrollment success, they find that CRAs must also be trained in the core principles of effective patient recruitment. Many sponsors are investing in training to help their CRAs learn how to validate site enrollment estimates, assess the recruitment needs, strengths, and weaknesses, and help sites develop and manage their recruitment plans. Training programs aimed at helping CRAs hone their site relationship, management, mentoring, and motivation skills are also gaining popularity.

The content will vary based not only on audience needs and experiences, but also on the therapeutic area involved, the specific nature of the study, its unique challenges, and the planned recruitment program. Training for effective patient recruitment in the emergency medicine setting may be quite different from that required for a study involving a chronic condition or rare disease. For some studies, the target population is readily identifiable, but the recruitment challenges may center more on patient education and the informed consent process. Other studies may face greater challenges in identifying the sources of patients and determining how best to raise awareness for the clinical trial. Thus, training should focus on the specific needs and challenges associated with the given study.

Training may encompass how to plan and budget effectively for a recruitment program, regulatory and ethical considerations, tactics and strategies, perfor-

Table 1. Topics for Study- and Site-Specific Patient Recruitment Training.

Recruitment Training Topics	Study-Specific Emphasis	Site-Specific Emphasis
Recruitment planning	• Enrollment expectations and timelines—calculating realistic enrollment rates • Dissecting the protocol: anticipated enrollment challenges and barriers along the patient participation continuum • Components of a recruitment implementation plan	• The recruitment process • Developing a patient recruitment budget • Resource planning for patient recruitment • Developing a recruitment plan and timeline
Understanding the target audience	• Motivators and obstacles to study participation • Patient sources and sources of influence • Patient and public attitudes towards clinical research	• Principles of market research • Developing effective messages and materials • Cultural sensitivity training—considerations for recruiting and interacting with diverse patient populations
Tactics and strategies	• Strategies and tactics to recruit patients from internal and external sources • Traditional and novel approaches to patient recruitment • Categorizing and prioritizing recruitment initiatives—which strategies are best for your study	• Developing a patient source map—where are the patients and how do they navigate through the healthcare system • Relationship building within the medical community and community at large; working with patient advocacy groups • Media buying and placement procedures • Developing effective public service announcements • Interacting effectively with the press
Study implementation activities	• Regulatory, ethical, and legal considerations in patient recruitment • Appropriate and ethical models for paying research subjects	• Effective patient scheduling and screening • Patient communication and customer service strategies • The informed consent process • Patient confidentiality and privacy considerations • Tools to optimize visit and medication compliance
Recruitment program management	• Evaluating the effectiveness of recruitment strategies—what should you measure and how should you measure it • Diagnosing and troubleshooting recruiting challenges—when and how should you change your recruitment approach • Contingency planning for program success	• Effectively using third party vendors • Recruitment tracking tools and expectations • Developing and implementing SOPs for patient recruitment • Principles of effective patient retention

mance metrics and analysis, or diagnosing and troubleshooting recruitment challenges. The contents of a training program may vary for studies where a PRSP is involved vs. those studies where the sites are responsible for the development and implementation of the recruitment campaign.

Considerations for Site-Specific Patient Recruitment Training and SOP Development

While there are many universal principles of patient recruitment that can be applied to any therapeutic area, clinical trial, geographic region, country, or culture, each site is unique in its own operating procedures, research practices and institutional requirements. As such, site-specific training programs often involve a different emphasis, even though some of the core principles and approaches are still relevant.

Site-specific training often focuses on budgeting, resource planning, and the delineation of roles and responsibilities for the conduct of patient recruitment activities within the research setting. Identification and development of relationships with the primary patient sources in a given community should be included, along with institutional-specific processes pertaining to the approval and implementation of recruitment initiatives. Providing an opportunity for site personnel to hone their patient education, communication, and customer service skills is essential in any training program. Strong attention should also be placed on ensuring that the site staff develops a thorough understanding of patient protection measures. Table 1 provides a list of suggested topics to include in both study- and site-specific training programs.

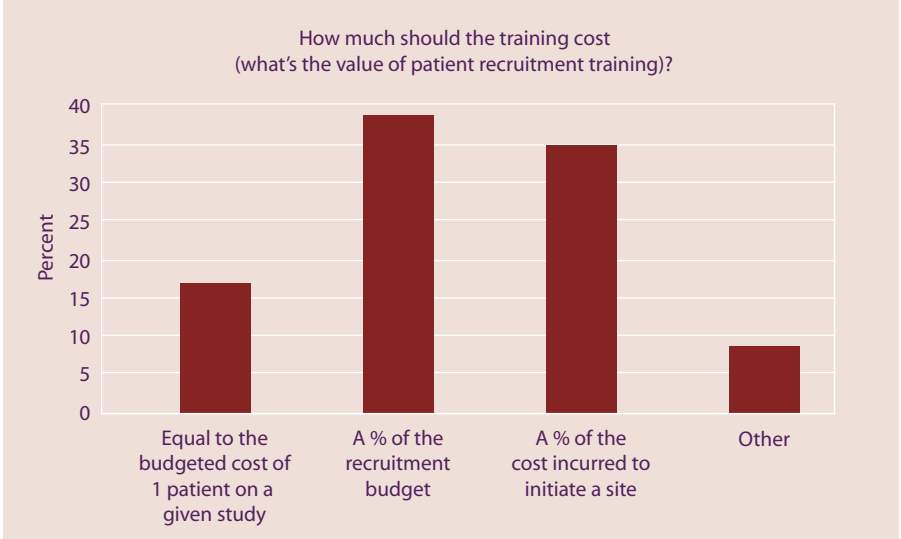
As . . . CRAs take on greater responsibility and accountability for enrollment success, . . . CRAs must also be trained in the core principles of effective patient recruitment.

As the clinical research process becomes more professionalized and roles are better defined, some sites are beginning to formalize not only their staff training programs, but also all of their processes and procedures. The development of standard operating procedures (SOPs) for patient recruitment and the emergence of good recruitment practices (GRPs) are gaining greater interest and momentum within the clinical research industry.[4]

No matter what the emphasis of the training is, site- or study-specific patient recruitment training programs require a significant investment of time, energy, and resources. However as the old adage goes: You get what you pay for. Reflections from the same group of clinical research professionals recently surveyed suggest that at least a portion of the recruitment budget or a percentage of the cost incurred to initiate a site should be invested in patient recruitment training (see Figure 2).[7]

What's the value of patient recruitment training? Perhaps this can best be put into context by asking what the financial, statistical, and human health implications are if clinical professionals are not adequately trained. In other words, can you afford *not* to train your sites, staff, and study teams in the principles and practices of effective patient recruitment? **ACRP**

Figure 2. Audience Responses re Budget Allocations.



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7. Harper and Hanges, How to train your sites, 2004.

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