Engaging Clinical Trial Sites: The Role of the Clinical Trial Liaison

Key Customers in Clinical Research

The ability to engage customers is a primary driver of business success because fully engaged customers tend to purchase more and are overall more profitable than those who are less engaged (Dasu & Chase, 2013).

Enrollment in clinical trials is heavily dependent on two very important customers: the research subject and the clinical trial investigator. Research subjects are highly valuable since it is obviously impossible to complete a clinical trial without a willing group of participants. There are many groups and even entire companies that specialize in engaging potential subjects and connecting them to clinical trials (Centerwatch 2004). A variety of “direct-to-patient” strategies are used to engage potential subjects, including traditional media advertising (TV, radio, newspaper), Web-based strategies (including social media), and community outreach among others.
The effectiveness of these strategies depends on two key factors: the ability to reach potential trial subjects directly and the ability to easily communicate the benefit of trial participation to potential participants. For some types of studies, direct-to-patient strategies are highly effective and may be all that are needed to ensure that enrollment goes smoothly. For many other trials, however, the effectiveness of direct-to-patient approaches is lower, as the condition being studied may be less common or the trial may be complex in its goals or design.

In these situations, the clinical trial investigator (and by extension the entire clinical trial site) becomes a much more important customer. Clearly, our recruitment strategies need to target the right customer.

Figure 1 below represents a guide to deciding which strategies to employ when there is a need to accelerate recruitment for a clinical trial.

Figure 1: Potential Recruitment Strategies
THE CLINICAL TRIAL SITE AS A CUSTOMER

The clinical trial “site” is composed of many different customers, most importantly investigators and research staff. Engaging each customer requires an individualized approach.

Clinical Investigators

A quality protocol that addresses a relevant clinical question is the first need of clinical trial investigators. The protocol must be well written and provide clear and appropriate eligibility criteria, a succinct and accurate description of study procedures and accessible dosage modification criteria. Provision of easily followed guidelines for managing the drug’s side effects is extremely helpful. Investigators also need the detailed information contained in the Investigator’s Brochure to further assist with understanding the trial rationale and help assess toxicities that may be experienced by individual patients.

In addition, when investigators are engaged on a scientific level, they are able to take ownership of the success of the study. While comprehensive training on the scientific background often occurs at the site initiation visit and investigator meeting, ongoing reinforcement of the trial’s key messages and showing sincere appreciation for the investigator’s efforts should occur throughout the course of the trial. Where possible, this reinforcement and recognition should come from a sponsor or a CRO personnel who has the skills to discuss patient care and science at the level of the physician.

Beyond reinforcement and recognition, specific needs may differ depending on the investigator, and using a tailored approach is critical. For example, academic physicians will very likely be interested in the latest developments in the science of the disease and study drug and will often spend the time to have in-depth discussions on these topics. They may additionally have interest in conducting investigator-initiated clinical studies and/or translational research that may further the goals of the trial’s sponsor, thus creating a mutually beneficial collaboration. The busy practitioner, on the other hand, is generally incorporating research into his or her daily practice. These physicians generally appreciate succinct messages that reinforce the trial’s goals and allow them to easily convey the benefits of trial participation to potential subjects. Time is in extremely short supply for these physicians, and activities that require only small amounts of time will be more effective for this group.
Research Staff

Having effective research staff at each site is critical to enrollment performance. The ability of the research staff to interact with both potential subjects and investigators creates an environment in which the site can perform to its fullest potential. Their key duties include:

- Establishing an effective pre-screening strategy to recruit or identify potential subjects within the site
- Communicating the benefits of clinical trial enrollment to both patients and physicians
- Training of all site staff, including data managers and research assistants
- Interacting with sponsors and CROs
- Maintenance of complete study records
- Timely data entry and response to queries

Because both the number of duties that fall on the research staff and the complexity of those duties are high, keeping these tasks as simple and easy to perform as possible should be a primary goal. In this effort, sponsors and CROs should strive to make the staff’s lives as easy as possible and to demonstrate that they genuinely care about keeping their lives simple. Both of these are critical to building trust, which is a cornerstone of developing and maintaining engagement. In addition, a balance must be maintained in the relationship, as there are needs of the study that at times may require the research staff to “go the extra mile” to meet a deadline, such as a data sweep prior to a data management committee meeting or database lock.

The following list provides a summary of factors that can help to maintain effective research staff engagement:

- Timely response by the sponsor/CRO during study start-up
- Provision of an easy to use study portal that houses all relevant documents
- Comprehensive and well-organized training at the beginning of the trial and at the time of any significant change in site personnel
- Provision of an easy-to-understand and easily explained informed consent document
- Immediate availability of study staff to answer questions
- Frequency and scheduling of calls that demonstrate a respect for the coordinator’s time
- An easy-to-use electronic data capture system
- Assistance with interpretation and resolution of queries
- Open and honest communication regarding study timelines
- Visible means of recognition for performance
The traditional medical science liaison (MSL) role has expanded since its inception in the late 1960s and today focuses on advancing standards of care and optimizing patient outcomes (2010; 91[3], 394-398). While in previous years this role was often part of sales and marketing, more recently in most pharmaceutical companies the MSLs are generally part of medical affairs. The primary duties of a typical pharmaceutical MSL include management of key opinion leaders (KOLs) as well as providing detailed information to healthcare providers on marketed products, including the background science, clinical trial results and post-marketing experience. In addition, MSLs frequently interact with pharmacists, pharmacy benefit managers or health insurers. Depending on the company, internal customers of the MSL may include sales, marketing, clinical development and medical information departments.

The clinical trial liaison (CTL) is a specialized role modeled after the MSL but is exclusively focused on engaging sites participating in clinical trials. The CTL works with all the sites on the trial to ensure that all investigators and study staff continue to be fully engaged throughout the course of the trial. In contrast to the clinical research associate (CRA), who usually is working on only a single study, the CTL serves as the consistent face of the sponsor or CRO across multiple trials. A longer term benefit of the CTL for the sponsor or CRO is the ability to select sites that are more likely to effectively perform on future clinical trials.

The interaction of the CTL with the site begins at the time of the site initiation visit. At this time, the CTL presents the scientific rationale for the study and discusses the eligibility criteria and study procedures in detail with the principal investigator (PI). Any feedback from the PI is provided back to the study team quickly. Once the trial is active and throughout the course of the trial, the CTL works with the PI to be certain that current information is available on the molecule’s development and to engage the PI in discussions on the study as well as on potential other areas for development. The degree of study awareness among sub-investigators is variable at most centers. The CTLs also meet with the site’s sub-investigators (including fellows, physician assistants and nurse practitioners where applicable) to help maintain focus on the study’s overall design, rationale and eligibility criteria. With research staff, the CTL works to ensure that appropriate pre-screening procedures are implemented so that all potentially eligible patients are considered for study participation. The CTL also provides supplemental training on more complex study procedures when required. In addition to working with each site independently, the CTL coordinates communication between sites in small group teleconferences and in small group meetings designed to maintain enthusiasm over the course of the trial.
The value proposition for clinical investigators and research site staff interacting with the CTL includes better understanding of the scientific background and clinical trial design, as well as the ability to have their site considered for future clinical trials that are of interest to, and will successfully enroll at, the site. The CTL also serves as a familiar point of contact for the site, responds to requests and serves at the point of contact between the trial medical monitor and the site when potential performance issues are identified.

CONCLUSION

The ability to engage investigative sites throughout the course of a clinical trial is a critical success factor for both enrollment and data quality. By building trust, respect and appreciation for the very difficult job of conducting clinical research, we can help to ensure the successful completion of our clinical trials. In doing so, it is important to realize that our sites are not a single customer, but a collection of customers with different desires and needs, and we must tailor our strategies to effectively engage them.

The CTL role has evolved to meet the needs for site engagement over the course of the trial and represents a new approach that has the potential to significantly impact enrollment. PRA has implemented a fully compliant CTL program to support our ongoing trials. The service is staffed by physicians in PRA’s Medical Affairs and Therapeutic Expertise groups and by PharmDs and PhDs who have clinical experience and can provide effective interactions with site personnel throughout the trial. All team activities will be managed by a program coordinator who will serve as the channel of communication between sites, internal project teams and the liaisons.

Bibliography


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