

How Clinical Research Can Grow a Medical Practice

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Clinical research investigators can use many different tools available to them through their practice and the study sponsor to ensure that they are active enrolling clinical research sites, such as study-specific Web sites, dedicated information lines, and educational sessions. If these tools are approved by the study sponsor and used properly through outreach in conjunction with proper processes and internal controls, a clinical research study will facilitate growth within a medical practice while ensuring that the investigators become or continue to be key opinion leaders within their specialty.

KEY WORDS: Clinical research investigator; clinical research coordinator; patient recruitment; marketing; clinical research study.

The National Institutes of Health defines a clinical research study as a scientific study of how a new medicine or treatment works in people. The very nature of clinical research seems to require and facilitate an investigator to grow his or her medical practice, but a study investigator in any research study can be at either a passive enrolling clinical research study site or an active enrolling clinical research study site.

A passive enrolling research study site is one that relies solely on its current patient population to find qualified subjects for the research study. These sites do not attempt to engage in the recruitment of qualified study patients. A patient at a passive enrolling study site may only be aware that his or her doctor is an investigator in a study that the patient may qualify for and benefit from if the investigator remembers to mention the study to the patient during the patient's visit.

Passive study sites often do not have processes in place to ensure the practice is screening all possible candidates for the study. The lack of processes and outreach could be the reason that some sites have very low enrollment over the course of a couple of years. For example, in a medical device study that requires 400 total patients, a passive research site may enroll only three or four patients total over a two- to three-year period of open enrollment. During that same time period, an active enrolling study site may enroll 45 to 60 patients.

Both types of sites may have investigators that are passionate about research, both sites may have a dedicated research staff, and both investigators may be top in their

field, so what is separating the low-enrolling passive sites and the high-enrolling active sites? The active research site uses several different recruiting options concurrently to actively search for patients in its community that meet the inclusion and exclusion criteria set forth in the clinical research protocol.

The active enrolling study site is using the clinical research study as a vehicle to grow its practice.

In turn, the active enrolling study site is able to use the clinical research study as a vehicle to grow its practice through community outreach and education about new treatments and technologies. These research sites also engage the entire practice in the execution of potential study subject screening and enrollment. Community outreach and education and the proper internal controls and process are how a clinical research study can grow a medical practice.

There are several ways to participate in outreach for clinical research studies. A study site must receive approval from the study sponsor before initiating any recruiting or study marketing for two reasons: (1) to keep the practice and study investigator out of trouble with the Food and Drug Administration (FDA) by ensuring the outreach is well within the regulations that surround advertising and marketing an unapproved medical device or drug; and (2) the practice may be able to receive budgetary or staff support from the sponsor.

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Clinical research sponsors (the group, organization, or company that is funding the clinical research) invest in tools that help study sites recruit patients for their study. Fast enrollment is critical to most research studies. The faster a study meets its enrollment needs, the faster the data can be collected and then presented to the FDA. Depending upon the scope of the study, by completing enrollment early or on time, a study sponsor could save over a million dollars and be to market with a treatment earlier than forecast. Therefore, facilitating fast enrollment among study sites is a priority for a study sponsor.

A study investigator has many things within his or her control that have a direct impact on the site's study enrollment rate. The easiest and simplest form of outreach is to communicate to colleagues and current patients that the practice is participating in cutting-edge research. It is innovative—they want to know.

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Start the outreach within the practice. Create an expectation through a process. The expectation is that each member of the practice is aware of the criteria of the studies that are enrolling within the practice. The process that ensures this expectation is being met is the requirement that clinical research is discussed at every meeting. The investigator and clinical research coordinator for each actively enrolling study must report the status of the study to the staff. This will lead to a greater understanding of the studies and to more study-specific referrals within the practice.

For example, there are orthopedic practices that are composed of spine specialists and knee specialists, so if a research study protocol identifies patients with back pain as the patient population, ensure the entire practice is aware that the spine specialists are enrolling patients with back pain for a research study. This way if a patient is being seen for a symptom related to his or her knees and during the office visit the patient mentions he or she is also experiencing severe back pain, the patient can be referred to the spine specialist that is enrolling patients into the research study. This keeps patients within the practice instead of the patient seeking a spine specialist outside the practice.

Keep in mind, a study patient that signs an informed consent has agreed to return to the practice for regularly scheduled follow-up visits. In some cases, the patient is scheduled to return to the practice for follow-up for the next 10 years. A physician's practice is a business. As with all businesses, it is easier to keep customers, in this case patients, than it is to find new ones.

It is not just the other physicians within the practice that should have a complete understanding of the research that is being performed within the practice. Physician assistants, nurses, and even schedulers should know what studies are actively enrolling. A study site can request that small "cheat-sheet" tools that provide high-level information about the study be provided by the sponsor for all practice personnel. These cheat sheets will serve as a reminder of the study criteria and can be quickly referenced during a patient's examination.

Getting the word out in the community that a practice participates in clinical research gives, often accurately, the impression to potential patients that the practice is innovative and remains trained on the latest technologies available for the treatment of diseases and conditions from which the patient is suffering.

Neither an investigator, nor the sponsor of the study, is allowed to market the investigational device that is being studied; however, an investigator is allowed to market the fact he or she is screening for participants that fit a certain criteria to be in a clinical research study of a new treatment.

To again use a spine study as an example, a practice can run ads on the radio stating that it is looking for patients that are experiencing back pain to participate in a study of a new procedure that may treat that particular symptom. Investigators are also permitted to have a news story reported about the practice participating in a study that uses a new technology to treat a disease or condition.

Patients are now active consumers.

Participating in clinical research studies allows the practice to market itself as innovative. A practice that is participating in a clinical research study must have a dedicated practice Web site, and on the Web site the practice must keep information about actively enrolling studies updated with information about the type of patient the investigator is studying. Patients are now active consumers. A patient will spend many hours on the Internet researching his or her symptoms and all of the potential treatments. For this reason, a site that is participating in cutting-edge research must have accurate and up to date information on its Web site.

Many practices also have direct-to-patient marketing consisting of a quarterly newsletter sent via e-mail. This is another relatively inexpensive way to keep the practice on its patients' radar. The newsletter can be a simple one-page format that gives updates on the practice staff and simple health tips.

Outreach can also be accomplished through a more traditional educational format. An investigator can sponsor an informational session at the practice that addresses treatments for a particular disease or condition. During this session, patients will learn about approved and investigational

treatments for their symptoms or disease. After receiving permission from the study sponsor, the investigator may even present a few case studies to the audience.

Once a practice has decided to dedicate its valuable time and resources to recruiting study patients, it is imperative that processes and proper staffing are in place to take full advantage of the outreach efforts. Patients that do not qualify for the study do have symptoms that need to be treated, and these patients need to be captured within the system.

A study research site should have a dedicated telephone number and e-mail address that a potential study subject can use to reach a practice staff member who will provide information about the practice and screen the individual for the study. This person should be able to provide very basic information about the study. Whether or not the potential patient meets the study criteria, the practice staff member should have a script that rolls the patient over to a scheduler to set up an initial appointment.

An active study site has a greater likelihood of being one of the top enrolling sites. The top enrolling site often translates into being the investigator that is the lead author of publications related to the study's data set, which in turn

gives an investigator more time at the podium. Thus time spent on recruiting patients and developing processes to ensure patients that meet the study criteria are not missed can lead to more publications and more podium time, which will lead to being the investigator in more studies.

The new patient is a consumer-patient who has access to many different sources of information about his or her health. A practice can use the participation in clinical research studies in its marketing as proof that the practice and its doctors are innovative and have access to the newest technology available in the United States. Through community outreach and education, such as quarterly electronic newsletters and informational sessions for potential patients, and the proper practice internal controls and processes, a clinical research study investigator can remain an active high-enrolling research site. A study site that is a high-enrolling site has more opportunities for publication and to participate in future studies. There are many creative ways to recruit patients into a study. Before beginning any recruitment outreach campaign, get the research study sponsor and institutional review board's approval to ensure that your recruitment materials are in compliance with all FDA regulations. ■■