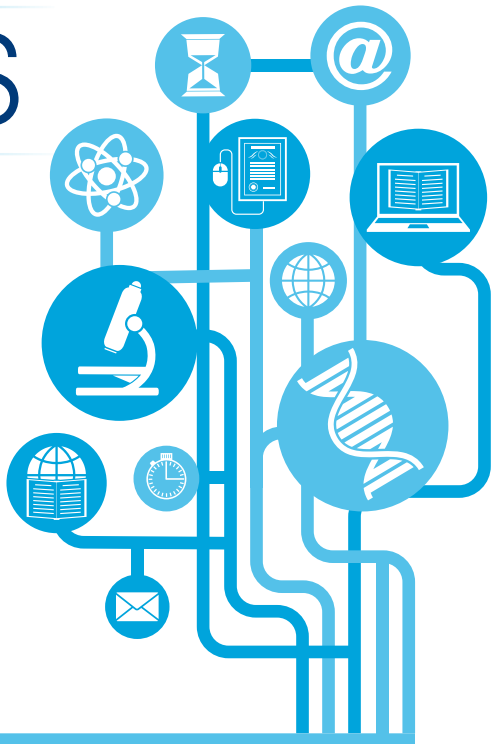
CLINICAL TRIALS



MARKETING YOUR PRACTICE FOR CLINICAL RESEARCH

The two most important parameters are the patient population and relevant research experience.

BY RYAN BOUCHARD

A clinical trial's success often depends on the collaborative efforts of the sites that participate. Proper site selection is fundamental to facilitating efficient, safe, informative, and timely clinical studies. If high-quality sites are selected (ie, they meet enrollment goals on time, implement the study protocol accurately, and are FDA audit-ready), then the trial will likely finish on time and on budget and provide the study's sponsor with viable clinical data. How can you be sure that your site is ready to participate in an upcoming study and that it is selected? This article covers some of the key characteristics you should consider when marketing your site to the clinical research community.

WHAT DO SPONSORS LOOK FOR IN A SITE?

Generally, the parties managing clinical trials look for sites with a proven track record in clinical research. This track record includes a familiarity with, a thorough understanding of, and adherence to good clinical practice-International Conference on Harmonisation (also known as GCP-ICH) guidelines. It also consists of an ability to enroll patients, complete study procedures, and maintain adequate and accurate study documentation, all to the highest standards of quality, ethics, and efficiency. Specific sponsors may have slightly different site selection requirements, depending on the specific needs of the clinical trial in question. At Ora, we evaluate sites involved in trials based on three top criteria: capabilities, experience, and patient populations. As you begin to think about your site for a clinical trial, it is important to remember that participation in a clinical trial demands a major commitment. You can expect to invest time, staff, and facilities.

HOW BEST TO POSITION YOUR SITE

To present your site's capabilities appropriately to potential study sponsors, you should know what is going to be required of your location and how to articulate that information effectively. More often than not, most contract research organizations and sponsors require completion of a feasibility or site qualification questionnaire or survey as an initial step to evaluate a site. Although the questionnaires may seem like a tedious or trivial task, especially when you need to repeat the exercise for various sponsors, they are often the only available tool for the sponsor to assess your site. If a site is slow to respond to the feasibility questionnaire, including it in a project may be difficult. Typical feasibility questionnaires include questions regarding satellite offices, doctors and investigators, common practice patterns, past and current clinical trials conducted by the investigators, and experience with certain equipment (eg, imaging tools such as optical coherence tomographers or wavefront aberrometers). Other important topics likely to be addressed might cover whether you use a central or local institutional review board, the approval timelines associated with the agency, and whether or not your site has recently been audited by the FDA or another regulatory agency.

Your practice's assets should be presented adequately. The two most important parameters are the patient population and relevant research experience. If you have an experienced research coordinator at your site, for example, be sure to mention that. If you have a great track record of hitting milestones on time, be sure to include this point in your comments.

AT A GLANCE

- Respond promptly to feasibility questionnaires. Sponsors and contracted research organizations value quick turnaround. It is often seen as an indicator of how responsive you will be during the course of the trial.
- When reviewing and determining your practice's potential recruitment rate, consider all the factors that will affect a patients' desire to participate in a study.
- Consider how technology plays a role in understanding your patients and available populations to identify.

Questionnaires may also be geared toward information on the volume and visit rate of patients relative to specific procedures. Access to local referral networks or patient communities may be of great value. Perhaps you have a radio or newspaper advertisement to attract new patients, or you have recently implemented a patient referral system. This type of information can only help the managing parties have confidence in your site and better understand your capabilities.

HOW IS THE DECISION MADE ABOUT WHICH SITES TO ENROLL?

The decision to take on an investigational site is not an easy one. Opening sites in a study is expensive and time-consuming, and the sponsor looks for sites that will help to guarantee successful and timely project execution. A careful review of the questionnaire as well as site visits and follow-up teleconferences form the backbone of the decision to include a site in a clinical trial. The best combination of infrastructure, capabilities, experience, recruitment prowess, and passion for excellence in clinical research is the matrix we use to select sites for different research programs. You will also likely need to disclose your commitments to other studies so that the sponsor can assess the amount of time and effort that can be reasonably dedicated to the study at hand.

CONCLUSION

Do not be afraid to contact the contract research organization or sponsor with any questions that you may have. After all, once your site gains qualification for participation in the trial, it is truly in your best interest to maintain the qualities you have proven during the site qualification process throughout the trial. Not only does this ensure timeliness and accuracy in clinical trial results, but it also increases the likelihood of your site's being selected to participate in future studies. ■

Section Editor Ryan Bouchard
■ director of medical devices at Ora
■ (978) 332-9574; rbouchard@oraclinical.com