

Business Development for Clinical Trial Sites

By Terence L. Webb

Sites Need Studies

Investigative research sites, whether for-profit or non-profit, need clients (study sponsors and contract research organizations (CROs)) to provide clinical studies that generate revenue. The process of finding and securing studies is called "business development" (BD), also known as "sales." A systematic business development program increases the probability of securing the studies needed to keep a site in business and even growing.

In some industries, business development is conducted mostly by specialists, but in clinical research, principal investigators, site managers, study coordinators, marketing managers, BD managers, and external consultants can all contribute.

Experienced sites know that many, if not most, study opportunities are unsuitable for their site (or any site). Unsuitable studies may be difficult to enroll, have inadequate budgets, be scientifically questionable, or have a host of other potential problems. A given site may not have the necessary patient population, expertise or equipment for an otherwise excellent study. An active business development process increases the odds of finding the right studies.

Understand the Opportunity

Clients may have access to thousands of sites. Their challenge is to find the best sites for their studies. The site's challenge is thus to provide the information the client needs to make site selection decisions. To do so, the site must understand three important things:

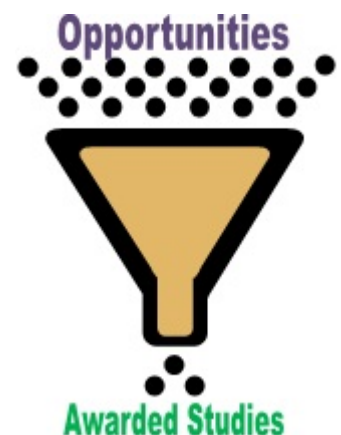
- **The site's business.** The site must know its capabilities (strengths), challenges (weaknesses), and track record (proof) in order to screen potential studies and explain to a potential client that this is the right relationship. In other words: "What do we have to offer?"
- **The client's business.** The site should understand how sponsors and CROs operate and the methods and metrics they use to identify potential investigators. In other words: "What information do *you* need and how do *you* want us to communicate it?"
- **The relationship between the two.** Finally, the site must know the value it brings to the client for the study at hand compared to the value other sites might bring. In other words: "Why should you hire *us* instead of another site?"

The Business Development Funnel

Business development is like drug development. It takes many study opportunities to generate a few suitable studies. The ratio could be 2:1, 5:1, 10:1, or greater. In other words, if 10 studies go into the top of the funnel, only one may emerge from the bottom.

There are four steps to moving opportunities through the funnel:

1. Generate leads (possible clients and studies)
2. Qualify prospects (likely clients and studies)



3. Evaluate study feasibility
4. Make the sale
5. Build the relationship

By balancing the BD effort across all four steps, potential new studies move smoothly through the funnel. In contrast, if the resources become unbalanced, bottlenecks will emerge, follow-up will take too long, and potential clients will drift away. When suitable studies get trapped in the funnel, a site may be tempted to take on unsuitable studies, with potentially dire consequences.

Generate Leads

Study opportunities can arrive at various stages in their development:

- **Planning.** The study is expected to start enrolling subjects more than six months in the future. There is plenty of time to identify the right people at the sponsor or CRO, but the people might change or the study might be delayed or cancelled. Since no site selection decisions are being made, it is not possible to “close the sale.” Even if the sponsor has verbally committed to using the site, the protocol could undergo revisions that render it infeasible. Under the best of circumstances, it will take a long time to generate revenue.
- **Currently Recruiting Sites.** The sponsor or CRO is actively recruited for a study that will start in one to six months. If it is a suitable study and the site is selected, revenue will arrive in the near future. Securing these studies should be a high priority.
- **Rescue.** The study is underway, but needs more sites to meet the enrollment objectives. The sponsor or CRO is relatively flexible on site qualifications, the budget, and contract terms, but time is of the essence since enrollment may end before the site can recover its startup costs. If a study is in rescue mode, it is vital to understand why. Are the eligibility criteria too restrictive? Are potential subjects scared off by the procedures? Has a competitive drug entered the market? Was the first CRO replaced?

Marketing vs. Sales Approaches to Lead Generation

The marketing approach to lead generation is like retail marketing. Shampoo, car and insurance companies run television ads and then passively wait for customers to come into a store or call on the phone. The sales approach to lead generation is like door-to-door sales, in which the salesperson actively approaches potential customers. Most business development programs employ a mix of both marketing and sales.

Established sites learn of study opportunities by passively receiving faxed or emailed inquiry questionnaires. Potential clients maintain databases of sites, but the process of determining which sites get which inquiries can be haphazard. It is easy to get lost in the shuffle. Also, the less attractive the opportunity, the more inquiries go out.

To maximize the odds of receiving inquiries for suitable studies, sites should make their interests and capabilities known to as many potential clients as possible. Many study sponsors and CROs maintain websites where sites can enter and update their information. Others will email or fax a form on request. Sites can then complete and return the form, hoping the information finds its way to the right people.

Some potential clients search for sites on websites that list sites. The three most popular such websites are CenterWatch (www.centerwatch.com), Research Investigator’s Source (www.clinicalinvestigators.com), and GoBalto (www.gobalto.com).

The sales approach to lead generation requires creativity, persistence and detective work to find someone directly involved in site selection. When study sponsors contract with CROs, either or both parties may be responsible for site selection. Sponsors often tell CROs which sites to use. At the opposite extreme, they might rely entirely on the CRO's site relationships. Sponsors are more likely to rely on the CRO's site relationships if the sponsor does not have existing site relationships because it is new to clinical research, a specific therapeutic area, or a geographical region.

The marketing approach to lead generation is like a shotgun blast, while the sales approach is like a rifle shot. The sales approach is labor intensive, so it is essential to first determine which therapeutic areas and types of studies deserve the effort. For example, a new site is more likely to obtain and succeed with Phase IV studies, while an established site can go after Phase II studies, which are more challenging but potentially more lucrative.

A good first step is to identify pharmaceutical, biotech and device companies that are developing new products in the therapeutic area of interest. There are three primary sources for this information:

- The website www.clinicaltrials.gov lists most industry-sponsored studies.
- The Physician's Desk Reference (PDR) lists most drugs currently marketed in the U.S. The manufacturers of these drugs are often developing new drugs in the same therapeutic areas.
- A comprehensive directory of clinical research sponsors can be found at www.firstclinical.com/directories/sponsors.html.

Once a company is identified, it is usually possible to find information about its clinical development programs on its website. If not, further detective work is required. A few Internet searches or a telephone call to the company will probably reveal basic information about products in development. If not, you can either proceed on the assumption that there is a product in development, or move on to less secretive companies.

There is a comprehensive directory of CROs at www.firstclinical.com/directories/suppliers.html. The ten largest (and always changing) CROs dominate the market and are certainly worth attention, but some of the hundreds of other CROs might specialize in the right therapeutic area or geographical region.

Numerous free web-based publications provide updates on various aspects of drug development. When a company announces that a drug has completed one phase of development, it may be actively looking for sites for the next phase of development. The following publications are some of those that cover such events:

- FDA News (www.fdanews.com)
- BioWorld Perspectives (www.bioworld.com)
- FierceBiotech (www.fiercebiotech.com)
- FiercePharma (www.fiercepharma.com)
- PharmaLive Therapeutics Daily (www.therapeuticsdaily.com)
- Food & Drug Law Institute SmartBrief (<http://www.smartbrief.com/fdli>)
- FirstWord (www.firstwordplus.com/home.do)
- Scrip100 (<http://www.scrip100.com>)

A comprehensive directory of publications that cover clinical research is available at www.firstclinical.com/directories/publications.html.

Clinical research and therapeutic area conferences (Table 1) provide opportunities to collect up-to-date information and meet with employees of potential clients. However, attending conferences costs time and money, and it can be difficult to meet the right people.

Study brokers, site and trial management organizations, and other intermediaries can facilitate the client/site matchmaking process. These intermediaries may charge a fee per study obtained or a set amount per month.

The most efficient way to identify potential studies (and pertinent contacts) is probably to develop a referral network of friends at other sites. Of course, referring inappropriate or tactless sites to sponsors and CROs will not help those relationships if they learn the source of the referral.

Table 1. Conferences for Business Development

Type	Examples	Features	
		Attendance	Cost
Clinical Research Conferences	DIA (Drug Information Association)	++++++	\$\$\$
	Partnerships in Clinical Trials	+++++	\$\$\$\$\$
	ACRP	++++	\$\$\$\$
	MAGI	+++	\$\$\$
	Site Solutions Summit	++	\$\$\$
Therapeutic Area Conferences	NCDEU	Psychiatry	
	ADA Scientific Sessions	Diabetes	
	ICAAC	Infectious Diseases	
	AHA Scientific Sessions	Cardiology	
	ASCO	Oncology	
	ATS/CHEST	Respiratory	

Qualify Prospects

The process of screening and converting a lead (possible client) into a prospect (likely client) is called "lead conversion" or "prospecting." Because the next step in the process, making the sale, is resource intensive, "qualified prospects" should be open to moving forward in the process of making a purchase decision. You do not want to spend an hour persuading someone to purchase your services and then hear, "This is very interesting, but we already have two sites in Memphis."

Identifying the Right People

Once a likely study is identified, finding the right people is often difficult, laborious and frustrating. However, remember that potential clients usually need more good sites for their studies, so they want the opportunity to consider your site.

Occasionally, contact information is available for one of the right people, be it the site selection specialist, study manager, project director, senior clinical research associate (CRA), director of clinical operations, or chief medical officer. (The list of possible titles goes on and on.) In most cases, one person has ultimate site selection authority. However, multiple people are usually involved, and talking to any one of them is, realistically, the best you can do. If a CRO is involved, determining who really selects the sites is often intentionally obscured, created an extra challenge.

Individual contact information can be found through friends, existing contacts at the company, social networking services (e.g., LinkedIn, Facebook), business directories (e.g., Jigsaw), general directories (e.g., Yahoo People Search, 411.com), and professional organization membership websites. An Internet search on "John Doe' email telephone" might yield contact information.

Communicating with the Right People

Once you know who to talk to, having an actual conversation with him or her is the next challenge. There are a few basic ways to make initial contact with a person: telephone, email, fax, letter or meeting. Meetings are best but unlikely except at conferences or with neighbors. Telephone calls are second best because they allow personal contact and do not take a lot of time. One good option is to leave a voice message and follow up with an email message, fax or letter providing more details. It may take five or more attempts to make contact. At some point, however, the persistent becomes the pest. Before that happens, stretch out contact attempts to monthly, quarterly or annually. It's not that they don't want to talk to you; it's just that you are one of 50 people who want something from them...on a good day.

If the person you want to contact does not return your calls, call the company's main telephone number and ask to talk to his or her administrative assistant. If such a person exists, he or she is likely to take your call, may schedule a time for a telephone conference, or might direct you to a better contact. In smaller companies, the switchboard may also be able to connect you to a better contact or at least a co-worker.

When trying to contact such people, saying you are looking for a study — any study — will not be as effective as saying, for example, that your investigator is very interested in participating in a study on a specific drug or device. The first person you contact at the company quite possibly knows who you should talk to, or can get you closer to one of the right people.

To help manage the process, keep a record of every contact or attempt. This record will also help avoid the embarrassment of introducing yourself to someone you spoke with a few days previously.

Each person has a different preferred method of communication, so when the conversation actually occurs, ask how he or she likes to communicate and how often.

The "Pitch"

Eventually, you will explain to the prospect why he or she should be interested in your services. Be prepared with presentations at three levels of detail:

- **The 1-minute elevator pitch.** An elevator pitch can be given on the phone, while in an elevator (literally), or in line for coffee at a research conference. What are the one to three things that will catch their interest and help them determine if they want to learn more? For example, it takes only 15 seconds to say: "We were the top enroller in three of our last five diabetes trials. Our medical director, Dr. Smith, has published over 50 journal articles. Our five study coordinators are all certified." Do not forget to ask if there might be an opportunity and how best to proceed.
- **The 5-minute coffee break profile.** In five minutes (or less), it is possible to provide a fairly complete profile of your research site. You can deliver your profile on the phone or during a coffee break at a research conference. It is a bit like speed dating, or so they say. In five or ten minutes, you also have time to further "qualify the prospect," i.e., learn about his or her role in the site selection process, how the process works, what studies are currently or soon to start recruiting sites, the site selection priorities, and who else you should contact.
- **The 20-minute capabilities presentation.** Capabilities presentations can be delivered face-to-face, by webinar, or over the phone. Most sites do not have enough useful information to fill 20 minutes, so most of the time will be spent in discussion and beginning to develop a relationship with the potential client.

Qualifying a prospect, whether or not it develops into an immediate study, is the beginning of a relationship. It might take months or years for the relationship to bear fruit, so do not abandon the individual just because today's opportunity does not work out. A year from now, he or she might open the door to a big opportunity.

Due Diligence

The BD process for a specific study often begins when the sponsor or CRO sends a synopsis of a study to the site, along with a confidential disclosure agreement (CDA) and a feasibility questionnaire (FQ). The synopsis should provide enough information for the site to complete the feasibility questionnaire. However, the full protocol is necessary to determine all the work to be done for the study and should be reviewed before signing a contract. For example, the protocol can reveal important details about subject eligibility criteria and who is qualified to perform assessments. The protocol's schedule of events may not list all study procedures, so a more complete reading is required. The investigator's brochure provides important information about the medical, scientific and safety aspects of the study. In some cases, the lab, pharmacy and other manuals include requirements that are not described in the protocol.

Feasibility questionnaires come in many shapes and sizes. The basic information includes questions about the following:

- Site personnel, credentials, experience and contact information
- Site facilities and equipment
- Patient availability and estimate of enrollment capability

The site sends the completed FQ and signed CDA to the sponsor. Sponsors and CROs use the timeliness of FQ submission as an indicator of the site's efficiency and interest in the study. The fundamental question in completing the questionnaire is how many subjects the site can enroll. In particular, should the estimate be realistic, conservative or optimistic? A conservative or realistic estimate will make it easier for the site to deliver the subjects (the age-old adage of "under-promise and over-deliver"). However, an optimistic — but not too optimistic — estimate is more likely to generate sponsor and CRO interest in the site. Many sponsors and CROs expect optimistic estimates, so automatically adjust the numbers down. Even if the site gets the study, it may be allowed to enroll only three subjects.

At some point in the process, the site should perform its own detailed, internal analysis of the study's feasibility and desirability. The earlier the site can reach a go/no-go decision, the less time it will waste on infeasible studies. Just because the site *can* do the study, does not automatically mean it *should* do the study. For example, does the site really want to conduct a study with questionable clinical significance? It might very well if, for example, study subjects will benefit. A basic recruitment plan should be developed, although not necessarily in writing. The site should evaluate such dimensions as:

- Existing or desired relationship with the CRO or sponsor
- Duration and intensity of the project (resource requirements, commitment of the investigator)
- Clinical significance and scientific merit
- Likelihood of IRB approval
- Complexity of the protocol
- Benefits, if any, to study subjects
- Appeal to potential subjects and likelihood of retention and adherence
- Safety of test article
- Financial aspects (fees, costs, payment schedule, etc.)

After submitting the questionnaire, the site may not hear from the sponsor or CRO for months, so reach out every few weeks to confirm your interest and find out about site selection status.

Make the Sale

If the FQ meets the sponsor's and/or CRO's criteria, the next step is a site selection visit (SSV), also called a site qualification visit (SQV) or pre-study site visit (PSSV). SSVs are expensive for sponsors, so most SSVs are based on the premise that the site will be selected unless the monitor finds a reason not to select the site. At this visit, the site can do a lot to secure the study:

- Ensure that all participating site personnel, especially the investigator, are familiar with the protocol, or at least the part relevant to their responsibilities.
- Prepare questions ahead of time to clarify ambiguities and demonstrate serious interest in the study. If the questions might require research, send them to the monitor in advance. The SSV will go better if the visitor has previously monitored your site or is familiar with the protocol.
- Ensure that the study coordinator(s), investigator(s) and other pertinent staff attend punctually and for the time needed. Nothing shows lack of interest more than a cameo appearance or no-show by the investigator.
- Prior to the visit, send the visitor a welcome email or letter with information about driving routes, parking, lodging, restaurants, etc.
- Prepare a recruitment plan (preferably written) that demonstrates you know where to find the subjects.
- Ask the visitor for a specific timeline for follow-up to any questions and issues raised during the visit.
- Most importantly, at the conclusion of the visit, ask for the business! Ask the visitor if he or she will recommend your site. If not, or if the recommendation will be qualified, ask for feedback to help win the next study.

The sponsor and/or CRO will, sooner or later, decide whether to invite the site to participate in the study. The invitation may come in the form of a letter or a package of study documents. The decision may be delayed while other sites are evaluated, the test article is packaged, etc., so keep in touch with the sponsor or CRO. If the sponsor or CRO does not select your site, it may or may not inform you.

Once both parties have agreed to work together in principle, regulatory documents, IRB approval, and the clinical trial agreement and budget must be finalized before the sale is closed.

Build the Relationship

Good performance generates repeat business from long-term clients. It is much easier to secure new studies from satisfied clients...and much harder from dissatisfied clients. It is therefore essential to take on only suitable studies and then conduct them successfully. Note that repeat business is more likely from financially stable clients with robust drug development pipelines.

Sponsors and CROs are not always keen on rocking the boat with negative comments, so periodically ask for objective feedback. After the study is finished, ask for a "report card" and advice on how to improve performance.

Remember that the clinical research enterprise is built on relationships, and relationships require nurturing. Do not forget to thank all the people who participated in the business development process. Stay in touch with the ones who might be helpful in the future. Use calls, emails, holiday and birthday cards, newsletters, etc., to foster the relationship and ensure that your site will be considered for the next study. Personnel at potential clients are always changing, and potential clients know that sites are always changing, so it is essential to maintain contact.

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