Scope of Business Development

Module 13 Topic 4

Business Development: What & Why???

- 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

Business Development: What & Why??? (contd)

- 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)

Business Development: What & Why???

- 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 of BD

- 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 client's business
  - The relationship between the two

Understand the Opportunity of BD (contd)

- 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?"

Understand the Opportunity of BD (contd)

- 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?"

Understand the Opportunity of BD (contd)

- 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

The Business Development Funnel

The Business Development Funnel (contd)

- By balancing the BD effort across all five 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

Steps of BD: 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

Steps of BD: Generate Leads (contd)

Study opportunities can arrive at various stages in their development:

- **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

Steps of BD: Generate Leads (contd)

Study opportunities can arrive at various stages in their development:

- **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

- 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

Marketing Approaches to Lead Generation

- 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

Lead Generation: Finding the client

- 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**

Lead Generation: Finding the client (contd)

- 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

Lead Generation: Finding the client (contd)

- 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

Lead Generation: Finding the client (contd)

- 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

Lead Generation: Finding the client (contd)

- 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)

Step 2: 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

Step 2: Qualify Prospects

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

Step 2: Qualify Prospects

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

Step 2: Qualify Prospects

- 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.

Step 2: Qualify Prospects

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- What are the one to three things that will catch their interest and help them determine if they want to learn more?
  - The 5-minute coffee break profile- In five minutes (or less), it is possible to provide a fairly complete profile of your research site
  - The 20-minute capabilities presentation- Capabilities presentations can be delivered face-to-face, by webinar, or over the phone

Step 3: Make the Sale

- If the feasibility questionnaire (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

Step 3: Make the Sale

- 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

Step 3: Make the Sale (contd)

- 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

Step 4: 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

Step 4: Build the Relationship

- 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

Step 4: Build the Relationship

- 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.

Job Responsibilities of Clinical Business Development Team

- Recognize and prepare clinical trial research plans with CRO's, pharmaceutical and biotech organizations
- Explore various pharmaceutical organization's pipelines to find out new and up coming clinical study possibilities with a focus on obtaining new therapeutic areas, new contacts, new pharmaceutical/biotech organizations and new CROs in the industry
- Make calls to targeted companies, seek out new contacts, finish all surveys, make follow-up calls and evaluate web sites to make sure that all possible studies are being analyzed

Job Responsibilities of Clinical Business Development Team

- Accountable for supporting with external advertising and provide support in enrollment of subjects for ongoing clinical research at study sites
- Recognition of new possibilities for pipeline molecules/ products
- Research of all new products/ideas coming to market and evaluate business viability
- Accomplish or exceed organizational goals that have been put in place by the organization
- Comply with all organization procedures, instructions and directives for the achievement of organization objectives and generate sales. Maintain an automated monitoring of all ongoing leads, sales and works in process

Job Responsibilities of Clinical Business Development Team

- Be aware to market research reports, competitive strategies/ studies and convey this information to management
- Analyse new business models, methodologies, and markets that would maximize revenue share of the organization
- Attend yearly industry conferences to enhance Clinical Research Benefits and to obtain further data on research that can help new business opportunities
- Support with determining and recruiting new doctors to work as researchers at trial sites

References

- T. L. Webb, Business Development for Clinical Trial Sites, J. Clin. Res. Best Practices, Vol. 7, No. 4, April 2011
- https://www.jliedu.com/blog/a-career-with-clinical-research-organizations-in-business-development-bd/

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