

HOW TO GROW YOUR INVESTIGATIVE SITE

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ABSTRACT: *Growing an investigative site is challenging but rewarding. This article covers common pitfalls in growth and solutions to those pitfalls, how to retain study coordinators and staff, tips on site location and equipment, departmentalization for growth, expanding capacity with networks or new sites, and selecting investigators.*

Common Pitfalls to Growth

When my site started growing, we faced many pitfalls. I had a friend who worked at Clinical Studies, which had sites nationwide. Clinical Studies opened a site near my area by hiring coordinators instead of following the usual model of using a doctor's office. My friend told me, "if you build a site they will come." I rented space, hired experienced coordinators, and started.

We got a study for a new medication for schizophrenia. The budget was \$800,000 and I thought my ship had come in. I had already lined up psychiatrists as investigators. The company gave us a lot of money up front for expenses. We bought fax machines for the psychiatrists' offices and took the psychiatrists to lunch. Then we started recruiting. We had promises of many patients with schizophrenia, but we did not see one for several months. Meanwhile, the company was breathing down our backs. We learned that it is not easy to take working medication away from a schizophrenic, and that informed consent is really difficult.

Finally, we found a patient who looked like he fit the study criteria. We brought him in for an evaluation, and the psychiatrist who was his doctor performed the battery of tests for the study. When he finished the assessment, the psychiatrist found out that the patient did not fit the description for schizophrenia.

We realized that we could not do the study. We had to borrow money to return the money that we already spent to the company. We learned about one of the most common pitfalls: there is a reason why companies pay you a lot of money to do a study.

Another common pitfall is not reading the protocol, or not reading it well enough. Often, the more sophisticated monitors sit with the principal investigator and make him/her read the protocol. They do this because they have had so many bad experiences. Also, make sure you have the patients before you start the study.

TABLE 1
Goals for a Good Site

Study volunteer safety
Clean data
Quality
Qualified personnel
Continuous training

Preparing for Growth

Table 1 outlines goals for a good site. Patient safety is foremost. With all of the stuff in the news, there is more and more emphasis on this. Set the site up so that it provides patient safety and good quality research. You cannot set up good quality research unless you have good people working at your site. When the Food and Drug Administration (FDA) audits a site, inspectors want to make sure that you are not harming anybody or doing anything bad. Set everything up to reflect this.

Be willing to take risk and live on the edge, and expect many sleepless nights. Growing your site is scary because you will go through a period with no revenue coming in. Even when you have money coming in, you will not get it quickly. You also need to make a commitment of your time and to travel.

If you are doing studies out of a doctor's office, do not see regular patients as well as study patients. This is a common mistake. I started a freestanding research site, but I also tried to have a research site at my office. I almost lost some of my nurses because they became overwhelmed. Seeing a study patient takes one to two hours. If you see your regular patients too, your staff begins to resent you and gets mad at the coordinator because they have to spend a lot of time on the paperwork.

Consider how serious you are about doing clinical trials. Factors to consider that indicate it might be time to grow are: lack of storage space, having more than one monitor on-site on the same day, investigators who are busier, doing studies that are profitable, and limitations on the number of studies you can do due to staffing constraints. If you want to start doing a lot of studies, get the staff in place and train them before you start building your center. If you do a bad job on a study, that company will not come back to you.

Growing an Investigative Site

You can grow an investigative site by increasing the capacity of experienced sites, building broader networks, or finding alternative principal investigators. Critical factors that you must put in place are: primary and sub-investigators, coordinators, a quality assurance program, a regulatory department, administrative staff, equipment and

software, and physical space. It is expensive to run a large site, and you must always be working on a decent number of studies. You are limited by your space.

Adding investigators is a double-edged sword. You will train investigators who will then go out and start their own companies or work for other companies. There is no way to avoid that.

Organizational Structure

The larger your site is, the less profit you will make. You need an organizational structure that is flat, with staff members who are cross-trained, back-up coordinators, a screening and recruitment department, and a coordinator for the support staff. Many sites use a director of clinical operations to manage the coordinators (an ex-monitor or a strict coordinator), an office manager, and a marketing and recruitment department to continually bring in studies. We have three full-time marketing people and four or five recruiters to keep patients coming in, plus an office manager who handles the minutia of running the office.

There is a lot of aggravation in growing. You must realize that. But there are a lot of rewards in growing. It is nice to have a big site and have sponsors come to you. When things work well, they work really well.

You want to cross train everybody, especially if only a few people work at your site. If somebody is sick, you do not want to have a major disaster.

Coordinators are the backbone of the site. When I first started doing this, I learned a great lesson. First, I tried to make my office nurse a coordinator. She was a great office nurse, but not a great coordinator. Then, I took people who had just finished college and were interested

in going into research and trained them. That worked really well because we had enthusiastic young people, but I soon became the training ground for monitors for the industry. The easiest way to find coordinators is to hire experienced coordinators, people who have already been monitors or have experience. If you put a lot of time and effort into training them, you want to make sure they do not like to travel because they will leave you. No matter what you pay them, a drug company with \$80 billion will pay them a lot more.

Retaining Coordinators and Staff

To grow, you need an experienced coordinator. Even if you hire inexperienced coordinators, you want a lead coordinator who can teach and mold the other coordinators.

Establish a formal retention program. When the monitors or people from the sponsor or contract research organization (CRO) visit your site, they want to see the same people and have relationships with them. We try to make our site such a good place to work that coordinators do not want to leave. We have 401K plans, profit sharing, and dental and eyeglass benefits. Once you get a good coordinator, do not let him/her go. It disrupts everything and you have to start all over.

Recognizing coordinators as professionals is more important than pay or benefits. Often, this is lacking. You must realize that coordinators are special. Maximizing time flexibility, patient contact, and a professional work environment are also important.

Quality Assurance

Over the last couple of years, the FDA has been finding all kinds of problems during audits. Most are related to not following the

protocol or not doing informed consent properly. Investigative sites are under a microscope. If the FDA finds something wrong, you must put procedures in place so that what you did wrong will not happen again. Do not wait until this happens. Start each study from day one as if the FDA will audit you and keep everything in order.

A quality assurance program is crucial. This will keep the site out of trouble. It is also a good marketing tool because sponsors and CROs love to see that sites have a quality assurance program. A quality assurance program could be as simple as one coordinator conducting quality assurance over the other coordinators. If you make a mistake in the study, you usually make it on the first few patients. If you do not have a quality assurance program, it is really important to have the monitor come in after you enroll the first patients and check things. Compliance is a major issue. Responsibilities of quality assurance include:

- Compliance with Good Clinical Practice
- Compliance with FDA regulations
- Compliance with protocol requirements
- Review informed consent forms
- Review consent verification logs
- Review source documents

Quality assurance has many other responsibilities as well.

The primary responsibility for our quality assurance person is managing the consent forms. We have a study where the consent form changes every few months. If the FDA comes in, auditors want to make sure that the participant signed the right consent form for that day. This gets complicated, especially if you have enrolled hundreds of people in a study. We have very strict standard

operating procedures (SOPs) for our consenting process. We always send potential participants home with the consent information or have them read it before they come in.

A Regulatory Department

As you grow, a regulatory department becomes crucial to compliance. The FDA's favorite documentation is the regulatory binder, which will show any problems with the study. An incredible amount of paperwork goes through your site. The regulatory department handles complete regulatory submission to institutional review boards (IRBs), sponsors, and CROs; maintains the regulatory binder; obtains IRB approval for patient recruitment initiatives; and partners with quality assurance to prepare for FDA and sponsor audits. It is also an important marketing tool. If you can get your regulatory documents in very quickly, say within 24 hours, this is a powerful marketing tool. This shows the sponsor or CRO that you are a "can do" site. We have two full-time people in our regulatory department.

Recruiting and Retaining Administrative Staff

Administration staff includes data management, research assistants, and administrative personnel. You want to maximize the coordinators' time with the patients to maximize your profits. The coordinator should do clinical, not administrative, work. He/she should not make copies or transcribe the source documents to the case report forms (CRFs). Data management staff transfers information from source documents to CRFs, under the oversight of the coordinator.

At our site, each coordinator has a research assistant and a back-up coordinator who knows the study. Research assistants do the minutia for the coordinators. They handle copying, obtaining source documents,

and maximizing the amount of time the coordinator spends with study volunteers. We also have data people to maximize efficiency.

Once you build your staff, you must retain them. Retention methods include recognition, benefits, a 401K retirement plan and profit sharing, medical and dental benefits, competitive salary, and an education program. Some sites have ice cream socials and give certificates for doing something well. We have weekly meetings where we try to empower people. We have boards where we list our goals; when we meet certain goals we have a luncheon.

Infrastructure for Growth

Infrastructure for growth includes SOPs, business equipment, network software, and ongoing staff training. Buy high-speed copiers, more fax machines, and a larger phone system. Improve productivity and efficiency with network software. Keep service logs on refrigerators and other equipment. Lock drug cabinets to the floor.

Training is very important. We have monthly training sessions and an annual training seminar with all coordinators and principal investigators. Keep training logs and communication logs (for communication between principal investigators and sub-investigators).

Your office systems and paper trails must be complementary. For example, your appointment book and sign-in sheet should match so that you can prove when the patient was there. We also have study logs where we make sure that visits are not on national holidays, and we write down the days when participants need procedures.

The Right Size for Growth

Size is important. As you grow, you need to increase your physical space,

parking, and accessibility. Plan your physical space. You need space for staff, storage, and monitors. Monitor space is directly proportional to your commitment to research. Store records on site, if possible. Use the doctor's office model.

We are close to a mall, so people can get to us by bus. Access to transportation is important, especially if you work with an elderly population. Think about what type of studies you will do when you choose a location. For example, Hispanic people have a higher concentration of diabetes, so if you do a lot of diabetes studies, locate where they live.

You must retain records according to regulations. For some international trials, you must keep records 15 years. When you budget, think about storage space. In the United States, you must retain records for two years after the study drug was approved, or five years after the date the study was submitted to FDA.

To really grow, you need a recruitment department and a marketing department. The recruitment department should include dedicated staff, phone screeners, an organized recruitment program, and a community outreach program. The recruiting people are the first line to potential volunteers. They should be good at establishing rapport with people over the phone. We do a lot of community outreach, such as speaking at events of the American Cancer Society and other organizations and participating in health fairs.

The marketing department job should be a full-time position. This person obtains research grants, networks with other sites, and does continuous marketing. Continuous marketing is key. Market to the monitors. If your site is good, they can pass the word and help you grow.

A formal training program is a good marketing tool. It should include weekly in-service, a mentor program, an annual conference, monthly principal investigator conferences, hospital CEU conferences, Internet programs, and a research library.

Keep the site fun. A motivation program could include bonuses, a point system, rewards for all contributors, team building, and recognition. You can reward people with certificates, days off, luncheons, and so forth. This builds camaraderie at the site.

Building a Network

To build a network, you put satellite sites in other areas. If you are doing pulmonary studies, rent space from a large pulmonary group practice, put a coordinator in, and start doing pulmonary studies. You can associate with other sites in other parts of the country and work out informal networks to exchange study leads, or you can sign papers and enter a formal network. You can also work with site management organizations (SMOs). SMOs own the network, and sites participate on a study-by-study basis. They provide different levels of services, such as budgeting, quality assurance, and regulatory.

Informal networks are good. If you find sites in other areas of the country that are not your direct competitors, you can share leads and information. This can help you reach the next level more quickly. You can meet with people from other sites at national meetings, such as the SoCRA Annual Conference. The rest of the time, you can e-mail and talk on the phone. This is an excellent model if site participation is consistent.

Training new sites is another way to grow, but it is tough because

it puts other sites in business. You can provide coordinators, regulatory services, or other expertise. However, if you send your coordinators out to other sites, those sites will try to hire your coordinators. Providing regulatory services reduces the burden of the study to a new site, helps maximize coordinator time, and is a marketable service. You can also provide expertise in budgeting, viable studies, and avoiding compliance problems.

Investigators are usually physicians, but they can also be nurse practitioners, PharmDs, physician assistants, or retired physicians. According to FDA regulations, the sponsor can tell you who qualifies as investigators for a study. It is easiest to use physicians as investigators because if there is a serious adverse event, an adverse event, or another problem, they can handle it more easily. Federal regulations require investigators to be qualified by training and to have appropriate experience to investigate the drug.

TABLE 2
Conclusions Equal Solutions

- Make volunteer safety the priority
- Establish a quality assurance program
- Expand present investigative sites
- Build a broader network of collaborative partners