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Clinical Research at Small Sites

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Clinical research sites range in size from sole-practitioner physician offices conducting an occasional study to academic medical centers conducting thousands of studies. How can a small site properly conduct research and compete with large sites with so many more resources?

For the purposes of this article, we will consider a hypothetical small site, Acme Research, which is part of Acme Medical, a multispecialty clinic employing 10 physicians. Acme Research has three employees conducting 25 outpatient Phase II and III studies, of which 12 are actively enrolling.

Resources, Specialization and Generalization

Large sites usually employ some degree of specialization to organize their substantial resources. A given employee might specialize in subject interactions (e.g., study visits), subject recruiting, data entry, regulatory, contracts, budgets, training or quality control. With only three employees, Acme Research needs people who can handle a broader range of responsibilities. There is a constant tension between specialization and generalization. On the one hand, specialization can be more efficient because a given person will have more interest and talent in a specific area and can develop focused expertise and relationships. On the other hand, generalization makes it easier to balance workloads as studies proceed through their life cycles and people take vacation or sick leave or depart the organization. The best approach for a small organization is probably to balance specialization and generalization by having each employee take the lead in certain areas and also serve as a backup in others. Cross-training on functional areas and studies is thus required. Part-time and temporary resources can be useful. Relationships with specialists outside the organization can provide expertise when especially obscure issues arise.

Staffing decisions must consider a potential employee's ability to work within this environment. They must also consider that there is little or no hierarchy to accommodate career paths based on promotions. In the absence of such career paths, management can encourage growth in expertise, rotate employees through specialties, assign special projects, and set challenging goals.

While Acme Research does not have the luxury of developing highly specialized employees, it can create a highly integrated, flexible team that shares expertise and adjusts rapidly to changing demands.

Small sites like Acme Research often stretch their resources — staff, space and equipment — to the limit…and beyond. The same can be said for many large sites. The difference is that resource issues at large sites are often a question of allocation — who gets the resources — while the issue at small sites is often that the resources simply do not exist. These limitations need to be considered in study selection.

The local institutional review board (IRB) is definitely a mixed blessing for large sites. While local IRBs can give institutions more control over human subject protection and can have expertise in their investigators, community attitudes, and organizational capabilities, they often take months to approve a study. Acme Research can submit a regulatory package to a central IRB and obtain approval in a few days.

Similarly, the contract and budget specialists at a large site can negotiate clinical trial contracts and budgets with favorable terms, but it can be a time-consuming process that discourages study sponsors from even offering studies to large sites. In contrast, at small sites, the research manager is often responsible for the negotiation and often agrees to sponsor proposals with little or no negotiation, accepting less favorable terms but getting a quick start on subject recruiting.

Management, Decision-Making and Communication

While Acme Research does not have the broad resources available at large sites, neither does it have to deal with a bureaucracy of distracted managers, time-consuming committees, and interminable levels of approval. People intimately familiar with the circumstances can make decisions very quickly. However, bureaucracies can ensure that managers with many years of collective experience can make decisions based on thorough analysis and deliberation. A large site might spend many hours analyzing the feasibility of a protocol, while a small site might make the decision in a few minutes.

The challenge for Acme Research is thus to give adequate attention to decisions without the pressure of bureaucratic requirements. On the other hand, sites that move quickly are very attractive to study sponsors. It is also a very useful trait when studies do not go according to plan, which happens roughly…always. While large sites might make better decisions in some cases, Acme Research can make decisions faster and then adapt more quickly than large sites.

Communication within large sites can be a major challenge. A specialist might not even know who possesses or needs a particular piece of information. The lines of communication with study sponsors can be unclear. In contrast, communication at Acme Research is almost automatic; everyone knows what is happening without much need for meetings or memorandums.

Costs

The substantial resources at a large site are costly, although they can be spread over a large number of studies. However, large sites have overhead costs for layers of management and departments that do not exist at small sites. Large sites also tend to occupy facilities like medical centers with high infrastructure costs. Large sites save money by buying in volume, but these savings have minimal impact in clinical research, where most site costs are for labor. However, large sites can employ low-cost employees who can efficiently perform certain tasks. At a small site with only a few people, a research nurse may also function as an expensive and inefficient data entry clerk.

Subject Recruiting

Large sites obviously have access to larger patient populations than small sites. However, Acme Medical's 10 physicians treat over 15,000 patients. While a large site might have thousands of patients with a given medical condition, Acme Research might have access to only dozens. Acme Research thus has to be very careful in choosing studies that fit its patient population.

Communicating with potential study subjects is challenging for all sites. Acme Research can search the database and contact patients about potential studies, but it works better when a patient's physician or nurse makes an initial face-to-face contact. The challenge is thus to obtain cooperation ("buy in") from the clinical staff. At Acme Medical, one physician is very active in clinical research, three are somewhat active, and the others prefer not to be

involved. The nurses and medical assistants are helpful in varying degrees. The situation is similar at large sites, although Acme Research has a relatively small facility to roam.

Large sites, because of their size and high degree of specialization, tend to feel impersonal and factory-like to patients. In contrast, a small facility like Acme Medical has a single waiting room. Its physicians are relative generalists and thus, over time, see a given patient more often. The net effect is a homier, more personal feel, which is conducive to clinical subject recruiting. On the other hand, patients at major medical centers are more likely to expect cutting-edge medical care, including clinical trials.

Training and Quality Management

Large sites can develop training materials and employ training specialists to educate their personnel. Small sites must rely more on external resources like conferences, magazines, books and online courses. They can also take advantage of internal expertise for cross-training.

It can be difficult for large sites to ensure quality work by research personnel spread through a large facility. Some large sites therefore employ internal monitors or auditors to check quality; however, these programs are often less than comprehensive.

Small sites have to take a different approach to quality management. To start with, personnel working in close proximity and sharing responsibilities should be relatively familiar with each other's work. The site manager or investigator should, at least, spot-check documentation. One study coordinator might periodically review the work of another study coordinator and vice versa.

Risk Management

Large sites have more study personnel, more studies, and more financial resources than small sites. It is thus easier for a large site to cope with the inevitable ups and downs of clinical research. A cancelled study or a sick study coordinator is only a minor crisis. A small site like Acme Research thus needs to choose its employees and studies very carefully. For example, a small biotechnology company might offer a study with an exciting new drug, but it also might run into cash flow problems that it has to share with its sites.

Conclusion

Small sites and large sites share similar challenges but address them in different ways because of their different strengths and weaknesses. A site of any size needs to determine its objectives (financial, patient care, physician interest, etc.), determine what, if any, clinical research is practical at the site, make a commitment, and then methodically leverage its strengths and mitigate its weaknesses to achieve success.

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