Do Clinical Trials Fit in a Private Medical Practice?

Ronald Nahass
ID Care, Hillsborough, New Jersey

Although traditionally thought to be the purview of academic health centers, clinical trials to evaluate new drugs, tests, and devices are being done more and more in private medical practices or in healthcare organizations with little or no academic affiliation. There are many reasons for this observation.

First, the sheer number of new medications and devices which are in development that need large numbers of patients to evaluate their effectiveness or readiness for clinical care requires a large number of study sites. There simply are not enough sites in academic settings to get the work done. One estimate puts the number of new products being studied at 37,000 [1]. Clearly, to enroll enough patients to study this number of products requires sites outside the academic environment.

Second, the pace of development and the importance of rapid enrollment to keep costs down to improve the return on investment for the sponsoring company pushes many companies to seek sites in nontraditional locations. Slow recruitment is costly for many reasons including the obvious delays in getting a product to market but also in the delay of cancelling development of a nonviable product that maybe even more costly.

Third, participation by nonacademic study sites provides the opportunity for them to offer treatments or devices for their patients before their general availability. This process tends to create an additional level of credibility for the site because they are now working closely with well known academic locations to help develop new treatments for disease. This activity can be used to promote an image of innovation and knowledge that creates more prestige and patient volume.

Fourth, a well developed clinical trial program can improve the finances of a practice or healthcare facility by providing an income stream not directly related to traditional patient care activities. Because this income stream comes through a contract with a for-profit company and not from a government program or healthcare insurance company, it provides a diversification for the revenue of the entity.

So, given these observations, is the addition of a clinical trials program as part of a private medical practice something you should pursue? The answer as always is that it depends.

The first and probably most important point to be answered is whether doing clinical research is something the clinicians in your organization or practice are willing to take responsibility to do. There are great responsibilities that come with such a program to protect patient rights in a setting in which experimentation will be done. The oversight of patient participation in a clinical trial has liability implications, rule of law implications, and ethics concerns. Not everyone is comfortable with these issues. Furthermore, there is greater and greater scrutiny being placed on clinicians who assume the role of principal investigator (PI) in regard to conflicts of interest and oversight responsibilities for monitoring progress of the study and patient safety for which you need to have a committed group of clinicians comfortable with this scrutiny. An additional concern in this regard is the “Sunshine Act” of the US Food and Drug Administration, which requires any sponsor of a clinical trial to post the income a PI receives on a publically available website even though much of that revenue will be used to support the infrastructure needed to run a clinical trial.

A second and almost as important question to ask is whether there are clinicians with an intellectual interest in performing this type of work. Clinical trials are scientific inquiries designed to answer questions about new drugs and products. Do they work? Are they safe? What is the right dose? How do they interact with other medications? Furthermore, the treatments or devices maybe implemented as part of a randomization process that takes the assignment of treatment or testing modality out of the hands of the investigator. For a clinical trial program to be successful, the clinicians performing such work will need to be comfortable with these issues and others that characterize clinical experimentation. Otherwise, it will be difficult to successfully enroll and retain patients.
because of uncertainty or discomfort by the clinician with this process.

Once the responsibility and intellectual hurdles are cleared, you then need to create a business case or model to allow the program to be successful. Most important to this model is the recruitment of dedicated staff to provide support for the activities that will be performed. It is also necessary to have certain equipment and space, both of which vary depending on the nature of the clinical trial. It is not uncommon to find small programs that try to perform such activities by adding the new responsibilities of clinical trials to old responsibilities of clinical care. This practice is not a good formula for the business success of the new venture. The requirements for management of data, regulatory and institutional review board concerns, marketing, patient recruitment, and documentation of clinical visits are different for clinical trials compared with clinical care. Having dedicated staff that is familiar these issues will improve performance and efficiency and are an important key to success.

The other critical aspect of the business model for making a clinical trials program work in any setting is great attention to budgeting, contracting, and bill collection. Again, this function is distinct from the traditional mechanism for tracking clinical care and the billing and collections for it. Clinical and administrative staff dedicated and familiar with these 2 different aspects will be necessary to make the program work. In a small program, overlaps of responsibilities will be possible as long as the staff is dedicated to the clinical trials program. However, the program is far more likely to achieve financial viability once a certain size is achieved to allow dedicated staff for the administrative and the clinical functions because you will gain efficiency and greater patient throughput via this development.

The development of a clinical trials program can be personally, intellectually, and financially rewarding if it is developed properly. You will not only provide your patients and community with care they may not otherwise receive, but you will also keep yourself on the leading edge of change and development in your field. You may even get the opportunity to publish or present some of the work.

Reference