

managing the margin

...strategies for generating new revenue and controlling costs

JANUARY 2003

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Clinical Research Trials: Creating Competitive and Financial Advantages

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As providers seek approaches for leveraging competitive advantage in an increasingly unstable and unpredictable healthcare market, clinical research trials can provide a unique opportunity to distinguish an organization from its competitors and increase revenue. By gaining access to new patient populations and enhancing an organization's image as a state-of-the-art provider, healthcare organizations can leverage clinical research trials into a strategic initiative with multiple benefits. Two key developments make trial participation an attractive option for a wide range of providers: growth in funding from pharmaceutical companies and the movement of research out of mostly academic circles.

Growth in the Pharmaceutical Industry

Growth in the pharmaceutical industry has reached unprecedented levels in recent years, with scientific advances expected to drive continued growth in

research and development funding. Estimates indicate that in 2001, at least \$50 billion was spent on pharmaceutical research by private funds (e.g., pharmaceutical companies) and public sources (e.g., the National Institutes of Health [NIH] or National Cancer Institute). During the same year, more than \$30 billion was invested in research and development by pharmaceutical companies, according to the Pharmaceutical Research and Manufacturers of America's 2002 Pharmaceutical Industry Profile. This estimate is 16.6 percent higher than investments made in 2000, and three times the investment made in 1990.

Clinical development, as a portion of global research and development dollars spent, has doubled since 1996. In 1996, \$14.5 billion was spent on clinical development. In 2002, the most current year studied, experts estimated the amount spent would be \$28.4 billion, excluding NIH figures.

As a result of these scientific advances, clinical research trials are on the rise. According to CenterWatch, a web-based clinical trials

listing service, an estimated 4,000 drugs were being investigated in 1994. By 2000, the number increased to 7,000.^a The number of medical personnel conducting trials, or investigators, increased from 14,000 in 1994 to 46,000 in 2000. Because of anticipated growth in trials, this number is projected to reach 56,000 by 2005.^b

Shift Away from Academia

Private funding sources are seeking more nonacademic providers to conduct research, which is creating enormous opportunities for hospitals, physicians, and outpatient providers. Twenty years ago, 80 percent of clinical research trials were conducted through academic medical centers. In 1998, estimates indicated the number of academic medical centers as investigator sites had dropped to less than half. These days, investigator sites are more commonly

community and teaching hospitals, physician offices, and other outpatient settings.

One significant reason for this shift is the amount of time it takes to gain protocol approval in academic settings. The window for funding sponsors to initiate the trials needs to be narrow to allow as much time as possible for the actual testing. The initial approval process prior to initiation of the study can take from two to six months in an academic medical center, compared with one to two months in a private hospital or less than one month in a physician's practice.^c

Why Participate in Clinical Research Trials?

Healthcare providers who participate in clinical research trials realize numerous advantages. Participation in clinical research trials enables healthcare organizations to provide premier medical care to existing patients as

a. Demattia, Robin F., "Testing the Waters," *Modern Physician*, February 2000, page 4.

b. Mettera, Marianne Dekker, "On Trials," *Medical Economics*, July 12, 2002, page 79.

c. Stark, N. J., "The Clinical Research Industry: New Options for Medical Device Manufacturers," *Medical Device and Diagnostic Industry*, January 1997.

Case Study: Research Activities at Christiana Care Health System

For an example of a successful research program initiative, consider the case of Christiana Care Health System in Wilmington, Del.

Christiana Care is recognized as one of the leading non-academic-based research institutes on the East Coast. Currently, Christiana Care has 750 open protocols for research. These protocols are either funded (supported through private or public grants and awards) or unfunded (undertaken as a resident- or mission-based value).

Christiana Care has been quite successful in administering clinical research trials; 80 to 90 percent of funding is repeat business from pharmaceutical companies. Christiana Care is in an excellent position because it is approached by pharmaceutical companies to participate in studies, and it has a wide selection of protocols from which it can choose to participate.

The foundation of Christiana Care's success appears to be threefold: the ability to attract patients for participation, a comprehensive due-diligence process for each protocol, and the ability to gain approval from the Internal Review Board quickly to initiate a protocol.

The director of the board believes that Christiana Care's ability to attract the necessary number of potential research participants and, ultimately, study subjects is a result of the following:

- Volume of the overall facility;
- Private practice physicians

who are interested in clinical research to provide enhanced care for their patients;

- Qualified and competent research support; and
- A reputation of providing cutting-edge care.

The due diligence required for each protocol is fairly compre-

tasks, and impact on and role of other support areas (e.g., laboratory medical records, etc.).

- **Given these resources, will the protocol's timeline be met?** It is important to weigh the demands on staff time from competing interests.

project is forwarded to the Christiana Care Institutional Review Board (IRB) for final approval. As a result of the feasibility process, a two- to three-week window is the typical time frame from IRB review of the protocol until the protocol is approved.

Two additional processes followed by the clinical research manager of Christiana Care's Research Institute, which also contribute to its success, include the review process for studies that may not break even and the review process once the protocol is initiated. Once the budget is set and contract negotiation begins, if it is determined that the funds available will not meet the costs of the proposed project, the protocol is reviewed by an administrative team to determine whether the study will be pursued. Finally, during the study, the research team meets on a semiweekly basis to discuss progress. These meetings allow the team to discuss any issues that may arise and are used as a forum for identifying potential problems.

The true value of participation in clinical research trials is the opportunity to advance medical science and patient care. A healthcare provider that conducts clinical research trials in an efficient, cost-effective manner also will have the opportunity to increase its level of participation in future trials and solidify its reputation as a cutting-edge provider in the highly competitive healthcare market. ■

Christiana Care Health System

Service area:

Based in Wilmington, Del., Christiana Care Health System is one of the largest healthcare providers in the mid-Atlantic region, serving all of Delaware and portions of seven counties bordering the state in Pennsylvania, Maryland, and New Jersey.

Organizational Status:

Not-for-profit and privately owned

Hospitals:

Christiana Hospital, located on a suburban campus south of the city of Wilmington, and Wilmington Hospital, located in the downtown business district of Wilmington

Licensed Hospital Beds:

Nearly 1,100

Annual admissions:

45,000

hensive. Once a protocol is brought to the attention of the Christiana Care investigator and the investigator determines his or her level of interest, a feasibility process is initiated that will be completed prior to board approval. Essentially, the feasibility process answers three questions:

- **Can the resources available accommodate this protocol?** Resources to be considered include determining how patients will be identified and acquired, the quality and quantity of support staff required, necessary administrative

- **Will the funding cover all costs associated with the protocol?** It is important to determine the staffing and personnel costs incurred from prestudy activity (e.g., patient interviews) through study closure. Other considerations include supplies, equipment, and space needed for participation. By undertaking a thorough budgeting process, providers allow better contract negotiation and enhance the likelihood of being able to cover costs.

Once the due-diligence process is complete, the

Did you know?

Development of a new drug often can take 15 years from the time of laboratory testing to FDA approval. Phase III clinical trials, where anywhere from 1,000 to 5,000 patient volunteers are needed to

monitor adverse reaction to long-term use, do not begin until year nine or 10. Ideally, the amount of time from the completion of Phase III to final FDA review and approval should not exceed three years.

well as a new group of patients. Recognition as a state-of-the-art provider may enhance an organization's ability to expand its patient base and recruit physicians and residents. The provider may gain additional recognition through mentions in academic publications. Participation in research initiatives also may generate a "halo" effect on other programs and services in the form of referrals and increased awareness of service offerings.

Increased revenue for the healthcare organization is an additional potential benefit of drug trial participation. Most community and teaching hospitals are hesitant to provide specifics regarding what trial participation provides to the bottom line. Statistics for revenue generation within physician practices are more readily available. Clinical trial participation in a physician's office can contribute up to 3 percent of total practice revenue. According

to CenterWatch, an average study can bring in \$58,000 in revenue, with net income as high as 40 percent.^d

Despite such potential for revenue enhancement, it is important to weigh costs associated with participation, as well. For example, one small practice indicates that while revenue from trials is 10 percent of the total practice revenue, the costs associated with running the trial are 50 percent of total practice costs. Because the administrative requirements of clinical trials are re-source intensive, experienced physician practices suggest networking with numerous physicians to gain economies of scale. This approach also helps physicians attain the number of patients needed for completing the study.

d. Rollins, Gina, "Trying Their Patients: Practitioners Find Clinical Research Projects, Chosen Well, Can Create Extra Income and Widen Treatment Options," *Modern Physician*, August 1, 2002, page 16.

Critical Success Factors

Clinical research trials have the potential to be cost centers rather than revenue generators if they are characterized by poor planning and management.

When evaluating potential participation in clinical research trials, healthcare organizations should:

- **Conduct a comprehensive budget review.** Knowing the costs associated with running the study is extremely important. Cost estimates for all of the potential resources, such as staffing, supplies, and laboratory work must be determined.
- **Negotiate wisely.** Identifying the costs mentioned above facilitates the negotiation process. Funding sources are fairly flexible on the payment per patient, which varies greatly depending on the study.
- **Coordinate administrative functions.** Provide a centralized contact to be the liaison for the funding sources, principal investigators, and compliance officers. Coordinating these functions is particularly important when multiple studies are being conducted at once.
- **Keep overhead low.** A healthcare institution

with high indirect costs, such as graduate medical education, will find it more difficult to break even on research trials.

- **Participate in Phase III (premarket) trials.** Funding sources are willing to invest more money in Phase III trials. Be aware, however, that a patient base of up to 3,000 people is required for participation during this phase, which involves studying a drug's efficacy, further evaluating its safety, and studying side effects.
- **Coordinate clinical research trials with centers of excellence.** Examples include drug trials in a cancer or women's health center and device trials in a cardiology or orthopedics center.
- **Treat the trial as a business line.** Apply product line business practices to clinical research programs.

Signs of success include recognition for providing excellent care and generating repeat business from the funding sponsors. ■

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