

# MILLENNIUM GROWTH STRATEGIES

## for Health Care

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### Over \$26 Billion Spent on Pharmaceutical R&D in 2000

As the medical industry develops new drugs and medical devices that improve diagnostic and treatment capabilities, advances in drug therapies and medical technology continually change how hospitals and physicians provide care. Funding for clinical and device research trials comes from a cadre of sources, including the National Institute of Health, pharmaceutical and equipment companies, and private funding sources. And in September 2000, the Health Care Financing Administration ruled that Medicare will cover routine costs for qualifying trials.

The pharmaceutical industry estimates that over \$26 billion was spent on research and development in 2000, an increase of over \$2 billion from 1999 and \$11 billion from 1995. In 2000, 34 percent (\$9 billion) of research funding was slated for clinical drug trials that are increasingly awarded to community-based, nonacademic providers.

### Growth and Revenue Opportunities: Clinical Research Trials

As health care organizations seek new opportunities to better position themselves in an uncertain health care environment, participating in clinical research trials is an attractive option for consideration. Advancing the science of medicine and providing state-of-the-art care that attracts patients and leading physicians to the organization and generates a "halo" effect for other programs and services are among the many benefits of participation in research initiatives.

Recent growth in clinical research programs has been unprecedented. For example, industry-sponsored research at an urban, teaching hospital in the northeastern United States has increased from \$1.3 million in 1997 to \$7 million in 2000.

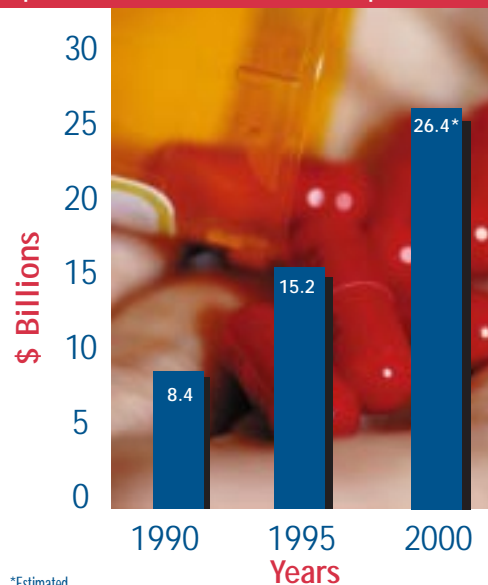
Successful models for offering clinical research trials include a central coordinating function in the hospital, such as an office of clinical research. A coordinated effort reduces administrative costs for the clinical department or group of affiliated physicians participating in a study. The central office is the primary interface between the pharmaceutical/device company and the provider, and therefore is responsible for negotiating the

agreement and budget, managing the funds, and possibly providing the dedicated research nurses and support staff. An internal review board (IRB), a requirement of the FDA, comprised of physicians, hospital department chiefs, an administrator, and community residents, is also supported through the central office. The IRB is responsible for the review, approval, and monitoring of research.

A typical provider's experience indicates that after two years of operation, a program will not only break even, but may also post a positive margin. To achieve a positive operating margin, experienced providers suggest these guidelines.

- **Participate in Phase III (pre-market) trials.** A large patient base of up to 3,000 patients is required to study a drug's efficacy, further evaluate its safety, and study side effects in a Phase III trial. In addition, funding sources are willing to invest more money in Phase III trials.
- **Negotiate wisely.** Do your homework on the actual costs associated with providing a study, including staff, medical supplies,

#### r&d investments by research-based pharmaceutical companies



\*Estimated  
Source: PhRMA Annual Survey, 2000.

lab work, etc. Funding sources are fairly flexible on payment per patient, which varies greatly depending on the study.

- **Keep overhead low.** A health care institution with high taxes or other costs, such as graduate medical education, will find it

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more difficult to break even on research trials.

- **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.

Elliott Kulakowski, Ph.D., president of the Society for Research Administrators International, advocates clinical research trial participation as a tremendous opportunity for the advancement of medical science. He cites three reasons that investigators become involved in studies: advancement of science, for the good of the patient, and for the revenue. Dr. Kulakowski recommends that programs decline finders' fees or signing bonuses from pharmaceutical companies to avoid attracting researchers who may focus purely on revenue potential.

Participation in clinical drug and device trials is a valuable opportunity for providers to demonstrate a visible commitment to outstanding patient care and excellence in medicine while potentially adding to the bottom line.



For more information on clinical research trials and other growth and revenue enhancement opportunities, please contact one of our directors:

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