

Hudson firm provides monitors for drug, medical device industry trials

By Bob Tremblay/Daily News staff *** GateHouse News Service *** Sun Aug 05, 2007



Looking at the bottom line, the importance of the role clinical research associates, or CRAs, play in the pharmaceutical and medical device industries becomes clear quickly.

CRAs monitor clinical trials and these trials don't come cheap.

For example, the average cost to put a new drug into the marketplace is more than \$800 million, according to the Tufts Center for the Study of Drug Development. The average length of time for a drug to go from discovery to market ranges from seven to 10 years.

The success rate isn't high either. Only one out of every 5,000 compounds synthesized ever gets tested on human subjects. Then, only one out of five compounds tested in human subjects reaches the market. Finally, only three out of 10 drugs reaching the market recaptures their development costs.

In this scenario, having a top-flight CRA, or monitor, is crucial, according to Terry Himmelmann, president and founder of Study Hall Inc. The Hudson company provides CRAs to pharmaceutical and medical device development companies, referred to as sponsors.

"We're graded on how well our CRAs function," says Himmelmann. "All it takes is one or two mistakes and that sponsor will not call you back again. They don't have time. Every day that a drug is in development, it's a very expensive process. If you delay that process, if you're the reason that process is delayed, that's not a good thing. (Sponsors) don't have time for people who don't know what they're doing."

And Study Hall Inc.'s CRAs know what they're doing, Himmelmann says.

"We understand the process and that's what separates us ... from some of the other staffing companies who really don't," she says. "Monitoring is just one other area they're in ... but this is all we do so we know the business."

"It's a small industry. Everybody knows everybody so reputation is everything. From a sponsor perspective, our ability to communicate with the sponsors and understand the process is a wonderful marketing tool. From a monitor perspective, when we speak to a monitor, they know that we know what we're doing so they agree to work with us."

Study Hall has a database of 245 CRAs from which to choose in North America. From that number, it has a core of about 25 CRAs the company has worked with for years. "We tend to go to them first," says Himmelmann.

These CRAs, who have the option of working as Study Hall employees or independent contractors, have been discovered through a variety of channels. Himmelmann, who has a background as a CRA, has worked with many of them. As a member of the Drug Industry Association, the Association of Clinical Research Professionals and the Society of Clinical Research Associates, she has also met many of them.

In addition, as a result of its reputation, Study Hall receives many referrals and gets plenty of repeat business, says Himmelmann.

The company, which has worked with major pharmaceutical, major medical device companies and small biotech firms, has 19 of its monitors currently working on 18 trials.

Himmelmann started Study Hall in 1996 after working in the clinical field for close to 15 years. A former physician assistant, she worked as a monitor on an oncology trial. "After I got it into the field, I saw it as a business opportunity," she says.

At first, Himmelmann, who has a bachelor's degree in medical science and a master's degree in education, did all the monitoring herself. Over time, the company added other CRAs to its work force. It now has one in-house CRA to go along with its independent contractors. It moved from its headquarters in Himmelmann's hometown of Stow to Hudson's Main Street in January. "We needed more space," she says.

While Study Hall serves many therapeutic areas, it focuses on the field of oncology. "Mostly because that's where I started," says Himmelmann.

In overseeing the progress of a clinical trial, its CRAs are responsible for ensuring that the trial is conducted, recorded and reported in accordance with standard operating procedures and applicable regulatory requirements.

The common scenario has a pharmaceutical company, a medical device company or a contract research organization contacting Study Hall looking for a monitor for a specific trial. She notes that contract research organizations can provide their own CRAs as can large scientific staffing companies. But none of them concentrates solely on CRAs, says Himmelmann.

Once a pharmaceutical company, for example, gets approval from the Federal Drug Administration to conduct a Phase I clinical trial - the process typically involves three phases before a drug enters the marketplace - the firm sets up a protocol for that trial.

Specific information the company is looking for is then placed in a case report form. What the CRA does primarily is making sure the information placed in that form is "real and accurate," according to Himmelmann. "The other job is making sure the institution is running this study according to federal regulations and is not deviating from the company's protocol."

Regulations for drug development are numerous. "This is a highly regulated industry, second only to the nuclear power industry," says Himmelmann.

With multiple duties and multiple regulations to contend with, a good CRA has to be a good multi-tasker, according to Himmelmann.

"CRAs have to be pretty unique people," she says. "They have to deal with very busy people ... and they have to have a tremendous attention to detail. Most come out of ... health fields, primarily nursing. There are also physician assistants, pharmacists and medical technologists. You have to be able to understand medical records."

A CRA can make from \$80,000 to \$130,000 a year depending on the experience, according to Himmelmann. Study Hall takes a percentage of what a CRA earns. That percentage wasn't revealed.

In addition to its CRA function, Study Hall provides continuing education for its monitors and has been certified to do so. Few staffing companies provide such an education facet. Plus, in two to three weeks, Study Hall will offer an online therapeutic area core competency training program.

"Rapid advances in medicine and the increasing complexities of clinical trials require CRAs to know more than ever," the company's Web site states.

The first program will focus on oncology, specifically lung cancer. The cost has yet to be determined.

On the news front, Study Hall was chosen last week to serve as project manager of a multi-center Phase II ischemic stroke trial in the United States and Canada.

STUDY HALL INC.

President and founder: Terry Himmelmann

Company background: Based in Hudson, Study Hall Inc. provides clinical research professionals to the drug and medical device development industry.

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