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Insider Insights:

DSP Clinical Research

CWWeekly's *semi-monthly company profile feature, Insider Insights, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with Darlene Panzitta, founder and chief executive officer of DSP Clinical Research.*

Q What led you to start your own self-named CRO, now in its 9th year, after launching a consulting business, all before turning 40 years old?

A I started it out of necessity. When I started the consulting business, I had a hard time getting a job in the industry I wanted to work in. No one would hire me because I didn't have experience. So I found a job as a consultant, getting a variety of different clients. The opportunity to expand and become a true CRO presented itself when a colleague was leaving the company we both worked at. Back then, I kept the consulting business dormant while I explored whether I wanted to be an employee.

But I was not happy as an employee. Luckily, this colleague was leaving to work for another small company with no infrastructure, but he needed somebody to run the company's CRO end. He needed help and that's when I saw the opportunity to build a business and have my first CRO client. And that company is still a client—a mid-sized pharma company that had 15 employees when I got there and now has about 200 employees.

Q Although based in the New York-New Jersey metropolitan area, your success in finding patients is largely in Florida, Texas, California and Pennsylvania. How did this strategy evolve, and is it a significant part in your recruitment efforts?

A We have investigators all over the country. When we get a study, we are selecting the doctors and they are the ones who enroll the patients. We help them with recruitment. But we are more successful in Texas, California and Florida—everybody is successful in those states. It just seems there are more patients willing to participate in clinical research in those areas.

The New York-New Jersey area is good for certain studies, but the majority of our studies are not successful in the Northeast. Why? Some patients in the Northeast shy away from doing research or have a negative attitude toward clinical trials. They hear the word "investigational" and they are not interested in pursuing that.

You go to Florida, people hear "investigational" and it doesn't seem to scare them away as much. We think that is the mentality of the patient. Maybe there is more insurance coverage in [the New York-New Jersey area] that we don't have as many patients who need free treatment.

When we are treating a chronic disease, like diabetes or hypertension, versus the one-time treatment, like infertility or pain, we get a better response in Kentucky compared to California. We also do pretty well in Pennsylvania. I can take 10 studies and say seven have done well and three have done poorly. It's the indication we are studying.

Other factors are insurance and the cost of their existing treatment. If it's a really expensive cancer treatment and patients don't have insurance, they are more willing to participate in the clinical study. In general, we always do well in Texas. It's a large state with a variety of different populations. People may not have as much insurance coverage; patients are more willing to participate in clinical research studies.

Q With a focus on small to medium-sized biopharmaceutical companies, what are the three biggest misconceptions these companies have in launching clinical trials?

A Cost is the first. A majority of companies I see overestimate it because they are relying on outside data and may not have conducted a study yet. With investor

Headquarters: Parsippany, N.J.
Year founded: 1999, first employees hired in 2003
Description: A CRO dedicated to the management and execution of phase I through IV clinical studies for small to mid-sized biopharmaceutical and device companies. Clinical research focus is on women's health, reproductive endocrinology (infertility), urology, gastrointestinal, pain and cardiovascular. Services include project, data and site management, statistics and medical writing. Honored by the 2012 Women President Organization as one of the fastest growing women-owned/led businesses.
Officers: Darlene Panzitta, founder and CEO
Leslie Humphries, MT, CCRA, senior manager, clinical monitoring
Craig A. Serra, PMP, CCDM, director, data management
Jenna Hasenei, senior manager, clinical operations
Offices: Parsippany, N.J., and San Francisco, Calif.
Employees: 40
Clinical trials: 85 trials since 2003, of which 50 to 60 were completed in the last three years. Currently managing 12 phase I and phase III studies in infertility, urology, gastroenterology, birth control and COPD.
Clients: An undisclosed number of mid-sized pharmaceutical and device companies and large CROs.
Web site: www.dspclinical.com

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money they often think it is going to cost them $10 million to do a project that may be only $5 million. They are getting information from larger companies or historical data that doesn't tell the whole story. The other end is companies that significantly underestimate costs. They have a limited amount of money and time and want to do a lot.

Underestimating the competition is second. Smaller companies tend to rely on the marketing data available on the patient population and don't really estimate properly that those patients may not come into a research study. They see that hypertension affects 30 million Americans and estimate, "Okay one percent of that we can get and 0.5 % of that total is in Kentucky or Tennessee." They don't realize that it won't matter because we have to target the place that will do investigational studies. Often these small biopharmas rely too much on the marketing data.

The third misconception is time lines, which affect everybody. We see it more often because small companies want to conduct trials more quickly and get on the market more quickly, so they really don't understand the amount of time it takes to get a project done. Everybody has that issue, but larger companies accept it. They are not looking to shave 12 months off a project. They know the time issues because they've been down that road before and don't want to waste time reaching for the stars, while a smaller company hasn't accepted that reality yet.

Q Recently some CRO leaders have acknowledged that the clinical trials industry is flourishing overseas. Since your career began as a CRA, what would you tell aspiring CRAs in the U.S. who might consider a different career path?

"Smaller companies tend to rely on the marketing data available on the patient population and don't really estimate properly that those patients may not come into a research study."

Darlene Panzitta, founder and CEO, DSP Clinical Research

A International clinical trials are definitely flourishing, but the U.S is still the top place conducting the most clinical research and it will stay that way until the insurance laws change. The industry is putting more focus on other countries because we are running out of patients. But anyone coming into a position in clinical research—especially the CRA—will have to learn the cultures and laws of these other countries, but it will not affect getting a job in the U.S.

When I started, I didn't have to know international regulations and international cultures, because it was all U.S. based. Are there a million opportunities for CRAs? Absolutely! That hasn't changed and it will be a great market for somebody trying to get into this industry. Clinical research is highly compensated, and if you want to make a six-figure salary within the first four or five years, you certainly can.

But I also see more CRO entrepreneurs than I did 10 years ago when I started the company. People said I was too young. They looked at me and kind of laughed, probably thinking, "You are not going to compete with these big CROs. You are 29 years old. What do you know?" That push back is what made me keep going forward.

Q As clinical trials increase in complexity and investigative sites are under increasing pressure to meet recruitment targets, how do you work with Principal Investigators and IRBs differently than some of your larger competitors?

A One of the things we do is keep the work simple and keep the work back on us. Investigators, more so than the IRBs, are inundated with paper work. They are spending 70% of their time on paperwork and 30% of their time finding and enrolling patients in studies.

What we do is try to take on as much of the paperwork for investigators as possible. We want them to focus on the recruitment so we do the extra paperwork. Keeping it simple and giving them that hand-held service is going to free up their time so they can focus on recruitment.

I think the larger companies forget that sometimes. They are so focused and have a very good structure. But they don't understand that the more work you give to the investigator that is paper based, they have to hire someone to deal with that, which cuts into their resources and, ultimately, investigators shy away from those studies.

Big pharmas want to go to a CRO with a huge amount of resources and financial stability. What they don't understand is that the larger CROs are not doing anything differently. If anything, we can do it better and give them service that big CROs can't, plus the hand-holding, which they don't get from a large company.

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