

A CenterWatch Publication

Profile: Phase I/IIa Unit/Phase II-IV Contract Research Organization

Dedicated Phase I (DPI)/Dedicated Clinical Research (DCR), Phoenix, Ariz.

An interview with Jason Bonanza, CEO, Dedicated Phase I, and Suzanne Bonanza, CEO, Dedicated Clinical Research

How and why were DPI and DCR founded?

JB: Both Suzanne and I worked as contract monitors at various sites throughout the U.S. and Canada. As monitors, we identified myriad problems facing the industry at the site level regarding subject recruitment, retention and data integrity. Based upon our experience, we knew that we could make a difference by operating our own dedicated sites. In 2004, DCR, our phase II-IV arm, was created by partnering with a group of 19 neurologists. Our philosophy was: The longer it takes us, the longer the patients wait.

SB: The driving factor behind both companies is our passion for clinical research. The formation of the companies was appealing to sponsors from inception, which, I think, was due to the principles that Jason and I set in place from the beginning, as well as commitments from local multispecialty physicians and community outreach clinics. Our goal was pretty simplistic: Complete studies quicker by addressing the basic problems associated with recruitment, retention and data integrity. Within our first two years, DCR became a preferred vendor and clinical trial hub to five major pharma-

ceutical companies and was recognized as the first site worldwide to screen a patient in an Alzheimer's study and also the first in the world to randomize five patients—four days ahead of the sponsor's timeline—in a smoking cessation study.

JB: Dedicated Phase I grew from sponsor requests for us to establish an early phase unit to conduct trials with the same integrity that they recognized in our II-IV sites. So, in 2006, DPI was founded—a 22,000-square-foot, 80-bed facility that specializes in special patient populations.

In March of this year, we established another new site at the John C. Lincoln Hospital campus located in Central Phoenix, giving us access to a large urban population. Our CNS [central nervous system] division is also growing. Dr. Judith Engelman, a well-known psychiatrist and research advocate has cemented our partnership with Southwest Behavioral Health, Arizona's largest mental health provider with 16 outpatient clinics and more than 60 providers. This partnership allows us to conduct inpatient psychiatric studies utilizing Southwest's lock-down facility and trained research staff.

In 2008, DPI was recognized by AZBIO as the most significant new biotech company established in Arizona since 2006.

DCR founded: 2004
DPI founded: 2006
Employees: 52
Dedicated PIs: 18
CRCs: 13
Patients in database: 545,000 +
Beds: 80
USB 797-compliant clean room pharmacy: Yes
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What differentiates DPI and DCR from other CROs?

SB: We are a recruiting powerhouse. Our unique provider network of 150 multispecialty physicians are all connected to our research sites by a shared EMR [electronic medical record] system. We use the power of technology to identify and validate potential patient populations instantly. Having a shared system allows us access to complete patient medical records and also to alert our providers that their patient is enrolled in a clinical study. This ensures the best possible care. Our database has more than 565,000 patients' electronic medical records. We've developed a number of tools to

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maximize recruitment. Our private practices utilize closed-circuit TV monitors for educational information about research participation and also to announce new studies. Staff members wear an "Ask me about clinical research" button, and our PIs [principal investigators] and sub-Is [sub-investigators] meet twice weekly to discuss current and upcoming trials.

We view each patient as a new relationship and count community events and therapeutic not-for-profit group involvement as keys to our success. From top to bottom inside our organization we get involved and educate others.

JB: DPI's biggest differentiator is therapeutic early development. I'm not aware of another phase I unit that has the muscle we do in recruitment for these special populations. We conduct many first-in-human trials in both healthy and special populations.

State-of-the-art technology is another differentiator. One of the first things we implemented from an IT perspective when we founded DPI was the Mortara Central Surveyor System, which is a telemetry and ECG system that allows us to do QTC and thorough ECG trials. Beyond that, it allows us to do intense ECG trials. We were the second site in the country to have this system implemented, validated and calibrated with the capability of being a core ECG lab.

SB: The Mortara telemetry system allows the sponsor to dial in and receive real-time ECG data as we're collecting it. We program the entire protocol into the system, and the study managers instruct the patients to lie still for five minutes while the Mortara system automatically takes triplicate ECGs. Sponsors never lose ECG data this way. So many times in these types of trials, sites are working off the Holter system, where they have to send in their data on discs. Often, the discs are blank or there's too much static in the lines and data are unreadable. With our system, if there's a problem with a loose lead or static, we know it immediately and can make the proper adjustment—which translates into never having to rerun a trial and an enormous cost savings to our sponsors.

What changes in the clinical research industry have you noticed?

JB: In phase I, we have seen drastic changes in early development moving from large healthy trials to smaller, more detailed special population trials. Early development trials have become intense and complex, with therapeutic populations that require special procedures and testing. DPI is able to fulfill these requirements, in large part, due to our experienced staff. We have specialized teams in place to conduct complex trials including our large medial

board of physician specialists. Many of the first-in-human trials we have conducted include type 2 diabetes, lupus, oncology, rheumatoid arthritis and Alzheimer's.

We are also seeing a change in trials that originally initiated in India and Eastern Europe then come back to us due to regulatory and recruitment problems. We are conducting more global trials in early development; we are up and running months in advance of the international sites and able to recruit these populations at a faster rate than other units. Often, we find that, by the time international sites are up and running, we have already completed the trial.

What are your plans for growth?

SB: Our biggest challenge is managing our growth and implementing our strategic business plan. A big part of that plan is advancing our phase II-IV operations throughout the nation. We want to maintain ourselves as a full-service CRO with a very strong backbone in recruitment, so these expanded operations will need to carry over our culture and our capabilities to ensure success for every new venture. Part of this challenge is obtaining and managing new equity to fulfill the goals of our expansion plan. We view challenges as part of the energy we have and the passion to make a difference.