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Insider Insights:

Vince & Associates 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 Bradley Vince, DO, founder, president and medical director of Vince & Associates Clinical Research.

Q Providing such boutique hotel-like amenities as bedside touch screen entertainment units, a movie theatre, game room and internet café in your new 90-bed Clinical Pharmacology Center has led to an award nomination for clinical trial innovation in the 2nd annual Partnerships in Clinical Trials Awards. What led you to build it, and which types of patients will use it?

A Our previous early development unit was more institutional. It had a neutral color palette and a small recreation area. We began to measure metrics of retention and found that our special population trials did not have as strong retention rates as our normal, healthy volunteer studies, especially when longer confinement periods were required per the protocol. After putting together a focus group, we realized for our organization to be the leader in recruitment and retention of these special populations, we completely needed to rethink the environment in which these trials are conducted.

It became clear to us that we needed to provide a clinical pharmacology unit that focused on delivering purpose-built and upscale amenities to special patient populations for the clinical trials of tomorrow. These subjects are very different from the recruitment of healthy, normal volunteers. Thus, we designed 10 uniquely themed research suites to include 20-inch bedside touch-screen entertainment systems that allow study volunteers individual access to TV, hundreds of movies, the internet and a host of video games. Because we conduct clinical trials in a variety of therapeutic areas, the unit was built for the purpose of accommodating a wide variety of patient populations secondary to our diverse therapeutic experience in clinical trials. From pediatrics to elderly, all study volunteers will find the necessary accommodations to feel at home in this state-of-the-art research facility.

Specifically, our clients were engaging us to recruit special patient populations earlier and with greater frequency in the clinical trials process. I knew in order to be considered the leader in these types of clinical trials, I had to make a bold statement with this unit. While I knew it was a significant financial risk for our organization, it was necessary in order to differentiate our company from the rest of the field. The results have been above and beyond my expectations, as the feedback from both sponsors and study volunteers has been overwhelmingly positive. In the end, we have built a world-class research facility that can adapt easily to both the needs and demands of special populations and clients alike.

Q Patient retention for longer and more complex clinical trials remains

Headquarters: Overland Park, Kan.
Year founded: 2001
Description: A provider of comprehensive multi-specialty (phase I-III) clinical trial services to the global pharmaceutical and biotechnology industry. Its growth has been in early-phase clinical research services, particularly conducting early development trials from analgesia to Human Abuse Liability (HAL) studies. It specializes in sleep research, pharmaceuticals, central nervous system and therapeutic areas including women's health, vaccines, pulmonary, infectious diseases and metabolic disorders. Support services include clinical management, protocol design and writing, scientific and regulatory affairs, medical report writing and project and safety management. It has a database of more than 50,000 study volunteers.
Officers: Bradley Vince, DO, founder, president and medical director
Lorraine Rusch, Ph.D., vice president, business development
Chris Hardage, director, clinical operations
Michelle Neaderhiser, director, phase I CPU
Facilities: Clinical Pharmacology Unit and Sleep Research Center, Overland Park, Kan.
Clinical trials: Has conducted nearly 400 since its formation
Employees: 110
Web site: www.vinceandassociates.com

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a challenge for sponsors, CROs and investigative sites. What have you done differently in recent years to improve patient retention?

A Most importantly, we have made a significant and ongoing investment in the delivery of customer service. All of our employees are focused on meeting the needs and exceeding the expectations of each individual volunteer who participates in a clinical trial. We have found that this solution-focused approach to customer service directly translates into unsurpassed patient retention in the clinical trials conducted at our facility.

Our new, upscale early development unit also has positively contributed to our high retention rates. In the past year, we have had two clinical trials with over 30 nights of confinement in a row, in which we have had 100% retention. The feedback we have received from study volunteers is exceptionally positive. The female study volunteers really appreciate the spa-like atmosphere of the unit, especially the private tile and stone bathrooms all uniquely decorated. The men enjoy the arcade and recreation rooms, including a dedicated PlayStation 3 room. The safety and security features provide additional comfort to study volunteers participating in early development trials.

Q Using special patient populations in phase I research has been more common in the past few years. Has this strategy altered the way your firm conducts clinical research?

A Yes. We saw the complexities of managing the medical needs of these unique populations. In an effort to provide the highest level of subject safety, we created and implemented The Physician Research Model, in which our full-time dedicated research physicians oversee all aspects of the clinical trials conducted at Vince & Associates.

Our Principal Investigators ensure that the proper medical and technical procedures are completed from subject recruitment to subject discharge. Overall, these unique trials require more physician oversight, secondary to the enrollment of study volunteers who have complex medical histories and are taking multiple concomitant therapies.

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Bradley Vince, DO, founder, president and medical director, Vince & Associates Clinical Research

Furthermore, there is an increasing trend in the use of monoclonal antibodies in special populations involving first-in-human research. This requires a heightened physician presence on the unit, as well as the support of experienced safety officers when conducting these types of studies. The complexity of monoclonal antibodies combined with the potential of a long half-life has necessitated a quality-before-quantity approach to the medical management of these challenging populations.

Q At a September conference with clinical pharmacologists, you spoke about how adaptive clinical trial designs can provide early signs of drug safety along with potential efficacy in a targeted therapeutic area. How important is this for the industry, which is still grappling with a variety of concerns about the challenges in implementing these often complex trial designs?

A It is very important, as these adaptive design trials can save the industry a significant amount of time and money. My discussion focused on Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) trials combined with Proof of Concept (POC) and patient cohorts. This adaptive trial design allows for greater flexibility, by incorporating patient arms for which the drug is intended, and provides data more quickly to support early termination for programs that do not produce efficacy. Not only does it save the industry and the FDA time and money, it also allows those funds to be redirected into other potentially promising clinical programs.

However, a SAD/MAD POC trial is not recommended if a) your drug has a narrow tox margin, b) it is in a challenging therapeutic area like epilepsy or c) when complex endpoints are present. Our organization has conducted multiple adaptive trial designs in the past year. For example, we have conducted several in the area of hepatitis C. This type of population has been successful in an adaptive model because of the presence of clear quantitative endpoints including the presence of biomarkers. These features are critical when deciding if a SAD/MAD POC trial is an appropriate clinical trial design. This efficient process ultimately provides better control of timelines and saves money in the race to bring new treatments to market.

Q As clinical trials increase in complexity and investigative sites are under increasing pressure to meet recruitment targets, how has your work as a Principal Investigator changed in the last three to five years?

A All Principal Investigators have seen a significant increase in the complexity of clinical trials over the last five years.

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The number of inclusion/exclusion criteria has substantially increased and thus has made the recruitment of eligible study volunteers more challenging. In addition to managing the daily safety and healthcare needs of special population volunteers, the micromanagement of the recruitment milestones and study timelines is now a full-time job for today's Principal Investigator. This necessitates the need to have a seasoned group of clinical research staff that is both full time and highly experienced.

Another challenge to the clinical trials industry has been the lack of experienced clinical trial investigators. Unfortunately, while many physicians are interested in gaining additional experience and income by conducting a clinical trial, often their first foray is not a positive one. Many of these physicians do not have the clinical trial management systems or experienced clinical and administrative site staff necessary to efficiently conduct studies.

Because the start-up costs including the training of site staff can be a significant burden for a small research company, many investigators find themselves actually losing money while conducting a clinical trial. Furthermore, because of the increasing complexity of clinical studies and the need for experienced staff to support the investigator, conducting clinical trials for many physicians is no longer a financially viable option.

Enrollment is often limited as pharmaceutical companies take a more conservative approach to recruitment by utilizing an increased number of sites. To quickly and reliably meet our recruitment targets, Vince & Associates maintains an on-site recruitment center. Accommodating study volunteers with evening call center hours is imperative. More importantly, having scheduling flexibility, to include both evening and weekend appointments, is essential to accommodate their busy schedules.

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