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Delivering Above and Beyond Expectations, PRC Clinical™ is providing Trial-Management Solutions for Development Milestones and Reducing the Cost of Bringing New Products to the Life Science Market

Healthcare CRO

PRC Clinical™ 1111 Bayhill Drive #408 San Bruno, CA 94066 877-519-6001 www.prcclinical.com



Tony Taricco CFO + COO

BIO:

Tony is responsible for the general business operations and finance activities, as well as human resources and clinical payment services.

Prior to PRC Clinical, Tony spent nearly two decades in Workers Compensation Insurance, starting as a Claims Adjustor for a small company of 25 employees and growing with that company to the position of Vice President and a staff of nearly 300. Tony's business degree and extensive practical experience in business growth brings together the unique perspective of understanding the values and challenges of a small busi-

ness and molding those into a strong foundation for long term expansion.

A Cum Laude graduate of San Francisco State University, Tony received a Bachelor's Degree in Business Administration with concentrations in Finance and Banking, and previously held a California Real Estate Salespersons license. Personal interests include real estate remodeling and architectural restoration, and indigenous landscape design.

About PRC Clinical:

PRC Clinical™, based in the SF Bay Area, provides trial-management solutions that advance the completion of development milestones, increase the efficiency, and reduce the cost of bringing new products to life science markets. For more than 10 years the SF Bay Area company has served sponsors in Phase I-IV clinical studies from orphan drug trials to large clinical registries in the U.S., Canada, and Europe. Its service offerings span protocol development, project management, regional monitoring to clinical data management and payment services for diverse disease indications and therapies.

Interview conducted by: Lynn Fosse, Senior Editor CEOCFO Magazine

CEOCFO: Mr. Taricco, would you give us a little background on PRC? **Mr. Taricco:** Curtis Head and I started PRC in 2003 as a small monitoring group which grew out of Curtis' work as an industry consultant. Over time we began providing additional services such as in-house clinical staff-

ing for our sponsor clients, site management, study management and CRO services particularly focused in phase II activities. That is how we got started and the growth continued steadily until late in 2008. In 2009 we felt the economic downturn like most small businesses and our growth stalled for a while. During this time we focused on our business plan, managed our expenses, paving attention to our current clients and where our business was coming from. It ultimately resulted in us developing much deeper loyalty with our current clients and helped us define our niche - which is to focus on personalized service and shared study goals. In contrast to larger CROs where you have a lot of contacts, so maybe you get the B team. You always get the A team with PRC. All of our CRAs and project managers set the goals and timelines with our sponsors. We work closely with them and there is a lot of communication. We are not a 9 to 5 company so many of our sponsors are communicating with us outside of office hours and that is perfectly normal for us.

CEOCFO: Who are your typical clients and could you walk us through an instance where that personal touch made a difference?

Mr. Taricco: We describe our typical clients as small to mid-sized pharmaceutical and biotech companies. When we say small to mid-size we are not referring to the size of the company per se, but the size of the clinical departments and in some cases the lack of a clinical department. Many, sponsor companies, particularly biotech startups do not fully

support a staff of clinical people, and clinical trial management is not their core business. They are developing the compound. When it comes time to develop the clinical trial sometimes they just need to augment their clinical group with experienced project managers who have conducted clinical trials to NDA or with specific indication experience. It is the attention to detail and the understanding of the personnel needs of the sponsor that sets us apart. It is not unusual for the clinical director or the sponsor to leave a meeting with new priorities. We do not need to wait for a change order - we just need a telephone call to talk about how we are going to address the new priorities of the study. Most clinical trials really follow a steady course from point A to point Z. There are always exceptions along the way and you just need to see the exceptions as routine and not as impediments.

CEOCFO: Do you primarily work with companies in your geo-

graphic area?

Mr. Taricco: One of our strongest advantages right now is with our local clients because we really are there

in person. We will attend meetings on their premises or provide space for them here. Some virtual companies will come in and meet with us and do the work or meet in our office. That is a huge advantage to the local clients. We do not really consider geography to be any impediment to the type of service. We found that being there in person makes a big difference and we try to do that as often as possible, but when that is not practical we still keep our personal contact as a priority.

CEOCFO: How do you reach potential clients and how do people find out about you?

Mr. Taricco: In the early days, the main reach to potential clients was by word-of-mouth. The industry is very tight-knit. In the 2009 slump, the larger CROs were starting to shop our market. We recognize now that small to mid-size biotech and pharma planning Phase II studies are our target market. We are constantly taking steps to make new connections and

provide insight to potential new clients that lend real value to sponsors. Many sponsors don't even know the problems they could face; we try to provide answers to issues before they happen. We are attending many industry trade shows and also have openings to expand our Business Development department to get greater exposure to new clients.

CEOCFO: What are some of the biggest challenges that you face as you are doing a project?

Mr. Taricco: One of the biggest challenges that we face is indication specific experience. Most companies will look for a CRO that specializes in the specific indication of the study. The most important factor in conducting the trial is having a CRO with experience to conduct a clinical trial and focus on enrollment as a primary objective when you get into study startup. We like to be involved in the protocol development, often at risk, to help identify pitfalls that might impair

"Our sponsors know that if we promise something it will be delivered above and beyond their expectations—it's what we do."

- Tony Taricco

participation or complications with sites or might cause a need for protocol amendments. When we meet with a client we offer our suggestions and really begin working with them from the very first meeting.

CEOCFO: Are there any trials that you have conducted over the course of time that stands out because of its potential?

Mr. Taricco: One of our early projects maybe five or six years ago ultimately went onto approval. We started out as an augmented clinical staff onsite with a sponsor. At each turn we expanded our services to meet the needs of the sponsor. They were on a very tight timeline for a large Phase III program and there were a couple of turning points where they wanted to add sites and they did not want to go back and renegotiate with the large CRO. We started to take on fragments of this study and it developed us as a CRO because our early job was to manage the CRO. As

we became more experienced in being the CRO we saw that other CROs are not our necessarily competition, often we can integrate with them just fine on behalf of the sponsor. We also provide site payment services and introduced this service on this project. We recognize the importance of the sites getting accurate and timely payments.

CEOCFO: Where does technology come into play in facilitating all that you are doing?

Mr. Taricco: The way we have expanded into a full-service CRO is not to bring in a bunch of departments that are not our core service but we have partnered with other experts that provide these services. Other companies that do something well such as data management/EDC and lab services. We have also in-licensed a proprietary Clinical Trial Management System (CTMS), which has really changed everything. Typically, CROs and CRAs have a plethora of individ-

ual trackers, Excel spreadsheets and Word documents. Version control is a problem. We implemented this CTMS late last year and it has streamlined the quality

and control of tracking information, contract negotiations, enrollment, monitoring visits, trip reports and the entire electronic copy of the Trial Master File. It integrates with our site payments and our CRAs are able to fill out their visit reports online so we cut down on having to email sensitive documents. To be able to integrate electronically with the EDC and the IWRS is crucial.

CEOCFO: What is ahead for PRC?

Mr. Taricco: We are excited about our recent growth and plan to continue! We have an excellent team of CRAs for any size North American study. Currently, we are conducting a 50 site 400 subject study in an orphan indication, which has become an important part of our niche. The current indication is an orphan and fast track indication in ALS, which has a crucial need for ALS treatments. We are very excited about this size study and we are looking forward to expanding our services and client base in 2013.

CEOCFO: Why should the business and investment community pay attention to PRC Clinical?

Mr. Taricco: In these current uncertain economic times, innovation is key, risky, but key. People should pay attention to PRC Clinical because we have been in business for ten years and we have a sustainable

business model to de-risk clinical studies with our expertise in Phase II clinical trials and our personalized focus on the smaller sponsors who don't get the A Team with a larger CRO. We have figured out how to manage our business expenses to stay in business through tough economic times. We can turn on a dime

and keep studies moving quickly-saving time and money. We have a lot of loyal employees and industry associates. Our sponsors know that if we promise something it will be delivered above and beyond their expectations—it's what we do.



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