

Personalized Clinical CRO Model for Pharmaceutical, Biotech and Regenerative Medicine Developers



Curtis Head
Chief Executive Officer

PRC Clinical
www.prclinical.com

Contact:
Olivier Roth
(415) 216-6181
oroth@prclinical.com

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

"Our philosophy is to go above and beyond the expectations of our sponsors for every clinical trial."- Curtis Head

CEOCFO: Mr. Head, the tagline on your site is "Trial Management Specialists". Would you tell us about that?

Mr. Head: PRC Clinical has been in business for more than fifteen years. What that means to us today is around how we support clinical trials. How we do it is what sets us apart: We are more hands-on and committed to our customers than traditional large CROs. The focus, high touch communication style and experience of our team allows us to exceed the level of service offered by large CROs.

CEOCFO: Would you walk us through a typical engagement?

Mr. Head: Most of our clients are small to mid-sized biotechs and pharmaceutical companies. Some of them are "virtual". The support that we have discovered they need from CROs (Contract Research Organizations) is very specific, and quite intense. There is a lot of competition and what we call "big-box" CROs. Sometimes they are not able to be as nimble or as agile as we are. We know that our niche is going to be with a client that has a lot of needs. We can support those from the beginning of the trial all the way through study conduct.

CEOCFO: How do you work with your clients to temper expectations or to get them to understand the way they see what they have developed may not be the reality?

Mr. Head: That is something that we deal with, with almost every client, particularly the clients that have never done this before and are smaller organizations. This might be their first trial and might be their only drug that they have in development. It is high visibility for them and they are looking for the right partner. Our best chance of getting off on the right foot and being successful in running the trial is setting expectations early. It is just about having the face time with them to understand where they come from and what they are expecting from their CRO. Reciprocating with our experience and how we have seen this play out in the past is our best guidance for them going forward.

CEOCFO: What has changed in your approach over time and what have you learned over the years that allows you to provide a better service today?

Mr. Head: I think we learn something from every clinical trial we participate in or support. I would say over the years the market has changed and the clients have become more sophisticated and choosy. We have had to adapt to those changes.

CEOCFO: *Are there particular areas and types of projects, therapies, or branches of medicine of focus for PRC?*

Mr. Head: The regenerative medicine space is where we have been focused. Most of our business historically has been in the field of CNS (Central Nervous System) and neurology. It led to the natural progression into regenerative medicine. We feel that is the game changer. I am sure you know it is not about just treating the symptoms of the diseases but it is potentially offering a cure for a lot of the serious life threatening diseases. From that perspective, it is a game changer. We deal with stem cells, gene therapy, and tissue regeneration research which has put a new twist on a variety of therapies and indications. From a clinical research business perspective, having the experience we have allows us the ability to compete in areas where we may not have in the past because the regenerative space covers such a variety of therapeutic indications and diseases, we can now bring our stem cell experience to a lot of new indications where we may not have had the expertise in the past.

CEOCFO: *How do you stay on top of all the research, new techniques, and technologies that can come into play when you are working with a client?*

Mr. Head: That is a challenge. We have clinicians and a clinical operation team that is very engaged with our customers and the clinical trial community. We have a business development department that focuses in the area that we tend to focus on the business that we are pursuing so we know the latest of what is going on in those areas. From a technology perspective, we pride ourselves on leveraging and using the latest technologies and allowing our sponsors to leverage that technology.

CEOCFO: *How do you stay objective when you may be looking at something that is a real game changer and promising?*

Mr. Head: That's what research is all about. How someone might spin it when they pitch it to us, we have to interpret it for ourselves when we are considering a project and what it means for us to execute it. I think that is an interesting question and we are enthusiastic about all of the projects that come to us because we like what we do as a company. When we manage a clinical trial, the drug either works or not. That is not our problem or our focus. From our perspective as a CRO running the study, the process itself is always a strong endeavor and a successful team accomplishment. When we finish a clinical trial and whether it works or not and is approved or goes to market, it is a whole other question.

CEOCFO: *What is different about participants in trials today and are you working with people or are you doing other parts of clinical trials?*

Mr. Head: All of our research is in the clinical stage which means that it is in humans. Most of our research is early so we run the Phase I and Phase II study, and sometimes they are the first in-human trials. Where we do not actually participate in preclinical or other laboratory modeling, we are the next step. We realize that trial participants are also becoming more sophisticated and are able to research trials online and to do more research than ever before. We are always trying to consider what it will look like from the patients and subjects' perspective when we are helping them sponsor and design a trial.

CEOCFO: *Is it easier for you to get the right people because of your experience or does each engagement have its own challenges?*

Mr. Head: Each project has its own challenges but I believe that's where our experience running clinical studies pays off. It is easier for us to adapt because we know what we are doing and there are not many situations that we have not seen in the past.

CEOCFO: *What is your geographic reach?*

Mr. Head: The bulk of our customers are in the San Francisco Bay area, however we have clients on the east coast and run a growing number of international clinical trials.

CEOCFO: *How do you stand out to people who may be new in the industry?*

Mr. Head: We have an expanding business development department that reaches out and extends our network. We also started a community event called ClinPulse. We are hosting these events to engage the research industry and our community and promote a dialogue on relevant topics. This has been a successful marketing tool to connect with new people in a genuine and mutually beneficial manner.

CEOCFO: *What features of trials might you recognize are in need of change but the industry has not?*

Mr. Head: Our first ClinPulse event had a focus on the new patient experience. What we examined under that topic is the patient's experience in regards to new technologies available to patients, sponsors, CROs and research sites. We also organized an event about the role of millennials in clinical research and acknowledging that there is a new generation of

workforce that is among us and how it actually changes the conduct of a trial. We are trying to engage the community on those levels which has been very enriching for our team, partners, and customers.

CEOCFO: *Would you tell us your approach to security and regulations?*

Mr. Head: We have SOPs for the critical work that we do and anything that is under the regulation that we function under. From a QA perspective, we have individuals who are responsible for different parts in ensuring that. There are many safeguards in place from our IT department and they are generally flowed down from the regulatory compliance aspect. All of our systems are built around those securities.

CEOCFO: *What is the plan for the next year or so?*

Mr. Head: We are on a growth spurt. We are contemplating our third move based on accommodating our growing staff. We are trying to grow responsibly so we have training programs that everyone is on-boarded properly and trained accordingly.

CEOCFO: *What are the intangibles do you want in your people? How do you know if someone is the right fit?*

Mr. Head: I think the critical component of any employee that is going to be successful here is going to be their ability to be part of the team. We are a service provider to the sponsor, we don't develop drugs or molecules, we offer the services to support sponsors. That is our position in the relationship and our mission is to ensure that we give excellent service and that our sponsors are satisfied. That is why we value team work, communication, and quality above all.

CEOCFO: *Why choose PRC Clinical?*

Mr. Head: Customers choose us because of our high-touch team and how we approach the conduct of a trial. There is a lot of competition and CROs that potentially provide the same service and I think what sets us apart is how we provide that service. Our philosophy is to go above and beyond the expectations of our sponsors for every clinical trial.

