

Profile: Clinical Research Organization

Clinlogix North Wales, PA.

An interview with JeanMarie Markham, president

Tell me about Clinlogix's background.

The company was originally called Markham and Associates, which was a company I founded in 1991 that offered monitoring services. What was different about the monitoring services we provided at that time was that we were all nurses. Sponsors then thought that having a nurse as a monitor was an interesting concept. We established a training program for new nurse CRAs that included a mentoring component. In 1997, while providing monitoring services to a client, we were having issues with identifying new quality investigators. One of the sponsor's biggest frustrations was that the sales and marketing arm would give clinical lists of physicians who they wanted to be able to participate in research. When we did a pre-study visit, we'd find that these physicians were inexperienced and had not done research before. So, there clearly became a need for someone to do investigator training and help guide some of these practices in the conduct of clinical research. At that time we started providing investigator and study coordinator training and support, which was relatively new then. We developed our Regional Research Manager Program as a result. We began to offer trial management and site management services and renamed the company—Clinlogix. In 2000, CRA America, became part of the Clinlogix family. This expanded our monitoring and site support services to over 850 contract monitors and regional research managers throughout the U.S. and Canada. Clinlogix evolved into a research service organization that is

capable of providing monitoring, site identification, site support services, investigator training, which translates into patient recruitment efforts, data management and project and vendor management.

What differentiates Clinlogix from other CROs?

We're a company that fully understands the clinical, and e-clinical, trial process from both from the sponsor and the site perspective. We can run a project from soup to nuts. What's different is that we don't have to take the whole trial. We could, but what we find is that most sponsors don't want that. They may just want the project management piece and the monitoring or they may just need data management. We offer a platform that's flexible, scalable and allows them to choose the services that they need. We build a project team and that team stays together for the life of the project for that client. Our CRAs have an average of seven years of monitoring and e-monitoring experience. We have very little turnover. Our clients will always get the "A team" for their projects. That's something else that defines us differently from other CROs. The experience and consistency of the team defines the quality of the work. That's very important to our clients and equally important to us and the people we put on that team.

Tell me about Clinlogix's alliances with other CROs.

Our core competencies are project management,

Year founded: 1991

Employees: 10 F-T

Independent contractors: 35+

Contract monitors: 850+

Active projects: 15

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monitoring, data and vendor management; we partner with other companies that complement our services here in North America and outside of the U.S. We make sure that we have the breadth and depth to fit our clients' projects. Because these people are not working for us all the time, we can provide a top-notch service at much better cost. We don't have to carry all that overhead. To give us a global reach for our clients, we have developed relationships with other CROs/SMOs such as OCT [Outsourced Clinical Trials] in Russia, SIPLAS in Latin America and ICRI [India Clinical Research Institute] in India. We have the opportunity to pick and choose whom we work with, so we choose the best of class. We are currently developing a presence in China.

What are your plans for future growth?

Our growth has always been solid and commensurate with the projects we're taking on. We've been growing conservatively about 20% to 25% a year. I don't anticipate much a change from that. Our business is dynamic and will continue to evolve to best fit the needs of our clients. We have been here for the last 15 years and are here for the long run.