CEO CFO

Research Dynamics CONSULTING GROUP LTD.™

Issue:
August 26, 2013

CEOCFO Magazine - The Most Powerful Name In Corporate News and Information

Research Dynamics Consulting Group Ltd. is a Clinical Research Organization Providing High Quality, Cost Efficient and Flexible Clinical Research Services for Pharmaceutical, Biotech and Device Industries as well as Investigators

Healthcare
CRO

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Lorraine D. Ellis
CEO

BIO: Lorraine D. Ellis founded Research Dynamics in 1993 to provide specialty clinical research services to the industry. Her expertise and experience in pharmaceutical product development has become the foundation of the business.

During her 30 years experience in the pharmaceutical industry, she has worked in positions throughout the product development pathway from pre-clinical laboratories through Clinical Operations to Project Management. She has worked at several pharmaceutical companies in positions ranging from Associate Pharmacologist to Director, Medical Project Planning and Development. During her work in clinical operations, she has completed various clinical trial activities from protocol design and preparation, through monitoring to preparing FDA submissions. While she was Director, Clinical Operations, Ms. Ellis developed efficient workflow procedures and CTMS technology to integrate technology into the workflow for greater efficiency.

For the past 20 years she has developed and taught clinical research training programs to insure project quality and compliance to FDA/ICH standards to all types of professionals from monitors to CEOs and from Coordinators to Investigators. Realizing the impact technology can have on clinical trial methods, she was part of the team that designed and implemented one of the first CTMS systems over 15 years ago and it is still being used by dozens of companies. She continues to be an advisor to technology companies for clinical research systems.

Ms. Ellis has a BA (Biology) from Hofstra University, MS (Biology) from Adelphi University, and MBA from Rochester Institute of Technology. Having completed a minor in secondary education, she used the expertise to design and provide training programs. Continuing her work in education, she is an Adjunct Professor at RIT and on the RIT Clinical Advisory Board to develop a new Masters Degree in Clinical Research Management. She is also an Adjunct Assistant Professor for MGH IHP Graduate Program in Clinical Investigation.

She is active in professional organizations: Drug Information Association (DIA), Association of Clinical Research Professionals (ACRP), and Women President Organization (WPO). Her organizational volunteer work includes serving on several committees and advisory boards. She was a member of the ACRP board of directors for 5 years.

About Research Dynamics Consulting Group Ltd.:
Research Dynamics is a Clinical Research Organization (CRO) that provides high quality, flexible clinical research services (CRO services), training, and consulting to the pharmaceutical, biotech, device industries as well as to investigators and academic medical centers. We use innovative technologies, experienced research professionals, and a commitment to clients through product development to approval to ensure that patients benefit from novel therapies as soon as possible.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Ms. Ellis, what is the focus for Research Dynamics Consulting Group Ltd.?
Ms. Ellis: Research Dynamics is focused on providing high quality clinical research services at a very cost effi-

cient level. We use technology to increase the cost efficiency.

CEOCFO: Could you define high quality? What does that mean for you and how does it compare to some of the other offerings available?
Ms. Ellis: We have developed procedures and engineered our processes so that we deliver quality data the first time rather than cleaning it up by monitoring. We set up procedures so that we make sure the data entered at the site has continuous monitoring so that errors are not compounded but continually cleaned along the way and they are retrained as necessary. Many companies are going to do that in the future but I do not think many have done that yet using electronic data capture.

CEOCFO: How are you ahead of the curve? What is it about the nature of the company and yourself that allowed you to realize, when others have not, that this is an area where you can make a difference?
Ms. Ellis: I have been interested in the use of technology for about 25 years, and I see how it will improve clinical research processes for quality and speed. Twenty years ago I worked on a new CTMS system that is still available and what we learned was that the information could be gathered in one place and used in a relational database. It could be shared by all of the stakeholders. That is one of my philosophies- to make sure all of the information we generate is available to all of the stakeholders. We have a CTMS system that is open to our sponsors so that they can get 24/7 information. When electronic data capture came along, I saw that the advantage was real time data review rather than monitoring every four to six weeks. We re-engineered our processes five to six years ago when EDC was starting to gain some traction, and we have been providing those processes to our sponsors since then because it increases the data quality from the site.

CEOCFO: Are there particular types of trials that you work on or would prefer to handle?
Ms. Ellis: No, we work on drugs, biologics, medical devices, IVDs, and some over the counter products. We really work on all different products, and they are all interesting so we do not have a preference. I think our strength is more in drugs and medical devices rather than biologics.

CEOCFO: How do you reach potential customers?
Ms. Ellis: A variety of ways. We do sales as everybody else does, but we believe in content marketing. We do a lot of free webinars and we also do training webinars to train people how to do clinical research. We have a blog, we write white papers, and I do presentations so that the company gets known as CRO with a high level of expertise in clinical research.

CEOCFO: Are you doing the whole process, soup to nuts, or are there segments of the process that you work on more often than others?

"What sets us apart is the fact that we can provide cost effective services with a high level of staff expertise."
- Lorraine D. Ellis

Ms. Ellis: We really concentrate on the area from protocol development to data management. That is our main focus, but we have partners that also do statistics and clinical study reports. We also have partners in areas outside of the United States, and we have partners who help us provide regulatory support as well. Our main focus is the protocol development to the delivery of a clean database.

CEOCFO: Could you tell us a little about the training that you do?
Ms. Ellis: We provide training to everybody; sponsors, investigators, investigative site staff, and IRBs, on exactly how to do clinical research according to the regulations. We also provide training on developing standard operating procedures, re-engineering your processes, and everything under the umbrella of clinical research. We either provide it by a webinar, or we go to a company if they want us to develop an in-house program for them. We would develop it and provide the training for them.

CEOCFO: Is there a common area where most companies fall short in understanding?
Ms. Ellis: Inexperienced companies, being sponsors or investigator sites, do not really understand the impact of the regulations. They will read the regulations and not realize how that applies to their day to day activities. Part of my training class is to explain that you have to do procedures because the regulations say that, and to help them make the connection.

CEOCFO: What is your geographic reach?
Ms. Ellis: Right now we are able to do North America and Europe, but we are partnering with some people in Asia and Latin America so we are moving into those other areas.

CEOCFO: Why is this the time to make that push?
Ms. Ellis: Many of our sponsors and customers are moving into those areas, so we follow what our sponsors need.

CEOCFO: How do you find the right people for your company, and what are the intangibles that you look for over and above the technical expertise?
Ms. Ellis: Our number one trait we are looking for is customer focus. We try to understand where the customer is coming from, what they need, and how we can provide it. We also provide 24/7 support, which I think is somewhat unique in the industry, so our first trait is customer focus. The second element is the quality aspect- that everything is done to the highest level and it is not just to check a box but it is to make sure it is done to the client or the sponsor's specifications. The third item is that they need to have the clinical research expertise.

CEOCFO: Are you able to ramp up quickly if a large number of products come your way?
Ms. Ellis: That is actually part of our model- that we can ramp up quickly. We are not a large CRO where we have 500 people sitting there waiting there for the next project. The way I designed the company was that we have a core group, and then for pro-

jects we either pull from the core group, but if it is not sufficient we have databases of experienced staff that fit our criteria and we contact them to do field monitoring or some unique expertise that we need for a particular project. We are able to ramp up in some cases within two weeks.

CEOCFO: How is business these days?
Ms. Ellis: Business is going well. I think the companies are just starting to reinvest in research. There was a drought there for a while in 2008 to 2009, but they are starting to reinvest in research and realizing that is where their future revenue is going to come from.

CEOCFO: Research Dynamics Consulting stared in 1993. What has surprised you over the years as the company has grown and developed?
Ms. Ellis: The changes in clinical research in twenty years. The changes include the use of technology. In 1993 there was not a viable EDC system - EDC was just getting started- and there were not many CTMS and IVRS and other technology available. The application of technology in clinical research surprised me, but on the other hand, what also surprised me was the slow adoption of the use of technology.

CEOCFO: Do you see a shift in larger and smaller companies outsourcing their services as well or outsourcing to use your services? On the other hand, has that remained pretty steady over the last few years?
Ms. Ellis: I see it continuing to grow. I think more companies and even the larger companies are starting to realize that they can no longer support large staff. I see everybody doing more and more outsourcing, and then the new startup companies obviously do not have the staff, so they need to start to outsource as well.

CEOCFO: Working with smaller companies can often be a challenge. What can you bring to the table to help first-timers or people who are not as familiar with the whole system?
Ms. Ellis: We specialize in working with a lot of small to mid-sized companies or just a founder type company, and we try to help them understand a few things. One is that it is going to cost a lot more money than you think it is going to cost to get the FDA to approve or clear your product, we help them understand that there is a great deal of expertise and time that is needed to complete all of the FDA requirements, and we help them to understand the whole process of how you have to follow the regulations to get it through FDA.

CEOCFO: Do you find that many companies do not go forward when they realize the challenge, or by the time they have gotten to the point of talking to you are most people going to move ahead no matter what?
Ms. Ellis: I find both. Some of them will stop dead in their tracks and realize they do not have the path forward financially. I have others who are going to try and circumvent the system and they are going to try and do it their way without all of this work. Some of them try to find another way around the cost of the clinical trials and approval.

CEOCFO: Why pay attention to Research Dynamics Consulting Group Ltd.?
Ms. Ellis: What sets us apart is the fact that we can provide cost effective services with a high level of staff expertise. The larger companies are a bit more expensive, and some of the smaller companies just do not have the expertise, so that is what sets us apart.

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