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ClinDatrix, Inc. Collaborates with its Biotechnology, Pharmaceutical and Medical Device Clients Globally to Advance New Products Through the Rigorous Development and Approval Process

Healthcare
CRO

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Louise M. Murphy, PhD, MBA, CQA
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BIO:
Louise M. Murphy, PhD, MBA, CQA is President and CEO of ClinDatrix, Inc. Dr. Murphy has more than 25 years experience in research, 20 of these being in the pharmaceutical /biotechnology/CRO industry. Before co-founding ClinDatrix in 2002, Dr. Murphy was Vice President, Clinical Informatics at ICON Clinical Research. There she was responsible for the startup of the Irvine office and for US data management services. Prior to joining ICON, Dr. Murphy served as Vice President, Clinical Informatics at CoCensys, Inc., a biotechnology company. At CoCensys, she was responsible for biostatistics, clinical programming, medical writing, and drug safety. Previously she held positions with CRO firms and was responsible for the functions of data management, programming and biostatistics. Prior to her association with these CROs, Dr. Murphy held the position of Acting Director, Biostatistics at Allergan, Inc. Most recently, between 2006 and 2009, Dr. Murphy held the position of Senior Vice President, Global Clinical Research at Allergan Medical. In addition to serving as a Director of the Society for Clinical Data Management, Dr. Murphy has held various positions within the PMA Clinical Data Management focus and has conducted courses in Clinical Data Management internationally. She holds Masters and Doctorate Degrees in Experimental Medicine from McGill University, Montreal, Canada. While at McGill, she conducted research in cardiovascular mechanics and in respiratory physiology. Dr. Murphy also obtained an executive MBA from the University of California, Irvine, and recently earned her Certified Quality Auditor certification through the American Society for Quality.

About ClinDatrix, Inc:
ClinDatrix is committed to providing world class, full service clinical research capabilities to the biotechnology, medical device, and pharmaceutical industries. Partnering with its clients, ClinDatrix uses a personalized approach to apply knowledge and experience to the goals of managing, monitoring, collecting, validating, analyzing, reporting, and delivering quality clinical data with efficiency and accuracy.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Murphy, what is the concept at ClinDatrix?
Dr. Murphy: ClinDatrix is a contract research organization or CRO. We provide the services biotechnology, pharmaceutical and medical device clients need to move their new products from preclinical development to market. We provide the services that enable them to make regulatory submissions that are in compliance and sufficient for approval. More simply stated, we guide our clients through the most critical stages of their product development process.

CEOCFO: There are many companies in your field. What is special about ClinDatrix and why should a company use your organization?
Dr. Murphy: ClinDatrix is a company that works, first of all, to high standards of quality. That was the founding value and requirement for our company. We are small enough that we are very responsive to our clients. We both manage their clinical development tasks and advise them in a consultative fashion. In addition, we specialize in working with small to mid-sized biomedical innovators. Many of our staff members have worked for start-up biopharmaceutical or medical device companies, and we fully appreciate the challenges of advancing a new product through the regulatory process. Our staff members are all very deep in experience and have expertise that crosses over many areas. We are extremely flexible and work with each of our clients

from preclinical development, if we are working on a drug or biological, right through to the submission. We have the large electronic data capture (EDC), data management, medical safety and other systems like the large CROs. However, we do not have the large prices like the large CROs. We offer more value for our clients' money through our responsiveness and focused expertise.

CEOCFO: Would you give us an example of where that personal service, where that consultative approach made a difference in what you were able to do for a client?

Dr. Murphy: We have tremendous expertise in protocol development and case report form design. In fact, for most of the clients that we work with, we design the case report forms. That sounds trivial, yet everything – clinical monitoring, data management, medical safety all the way through regulatory submissions – hinges on the clarity and ease-of-use of the case report forms. Because we pay attention to our clients, because we work closely with them throughout the study process, we are able to assist them with Institutional Review Board approval, site selection and monitoring, on through the maze of clinical study requirements and reviews. We are very efficient in the design of the data management database and collection of the data, so we help our clients move more efficiently from trial start-up to pre-approval meetings with the regulatory agencies. Again, our expertise is especially useful to small sponsors or device developers who may not be able to command the attention of the large CROs.

CEOCFO: How do you work with a client that is so proud of what they have developed that they cannot see the problems or take your advice?

Dr. Murphy: First of all, we fully appreciate our clients' passion for their products and the work, time, money and energy they have invested before they come to us. It's mind boggling, really. Their product embodies much more than potential profits for them; biomedical industry innovators are working to improve treatment options and patient outcomes. So our first step is to ensure them that we "get it." We understand all that is at stake. By listening to them and showing them that our advice is furthering their agendas, we begin to build confidence with the client. If a client is adamant about not following our advice, we explain to them what the unintended consequences of their approach will be. At the same time, we keep an open mind, too. If they propose an approach that is different than the one we would have taken, we study it closely to see its merits. If the outcome of their approach and our approach will be the same, we can work with theirs, and we continue to advise and guide them down the right path. As our relationship grows, our clients become more and more confident in our decisions and often then leave decisions to us. It is all about building that relationship; once the relationship is built, we get more and more responsibility for the decisions.

CEOCFO: Do you have a preference for projects on which to work?

Dr. Murphy: One of the joys of our work is the variety of projects we get to participate in. We are working with many small to mid-sized companies, and we enjoy that because all of these companies are developing leading-edge technologies or therapeutics, whether device or biological or small molecules. We are helping guide the first studies in first-line technologies, so we are very excited to be working with them. That said, we especially enjoy working with clients who bring us in early and invite us to give input to the protocol. For them, we begin to be part of the project from the beginning and they value our expertise. As we ask questions and give them suggestions, they become confident in us, so it [early involvement] sets a good stage at the beginning.

CEOCFO: You mentioned quality early on. What are some of the ways you ensure that quality that perhaps others are not doing?

Dr. Murphy: We define quality as preparing the deliverables to satisfy the regulatory requirements, whatever the project is. Quality is built in right from the beginning; it is not an add-on at the end but is used throughout. That quality is achieved in two ways, first there is a quality control and secondly there is a quality assurance. As for quality control, we have different techniques, such as peer review, such as doing the same type of activity twice. For example, if we do data entry, we do *double* data entry. Quality control also includes having managers review everything. It includes training, documentation, workflow instructions, working together with a buddy, working across departments and understanding what other departments do so all of that is built in the quality control. We have job descriptions and families of job training strategies so that people are trained and know what they have to do. We follow standard operating procedures, which are required by the regulatory organizations, and those SOPs are trained for all the staff. This is the way we keep and maintain the quality control. Then we have quality assurance. Once a department completes a deliverable, an auditor from outside of that department verifies that they did what they said they were going to do and that they followed procedures. We have a director of regulatory affairs and quality assurance, Ned Whittemore. Both Ned and I are Certified Quality Auditors through the American Society for Quality. When you are developing a new medical product, the quality of your data is paramount. Delivering an unimpeachable level of quality is how we best serve our clients and how we can compete in the marketplace of CROs. Our quality systems ensure that we deliver what we say we are going to, seamlessly and in accordance with our clients' needs.

"When you are developing a new medical product, the quality of your data is paramount. Delivering an unimpeachable level of quality is how we best serve our clients and how we can compete in the marketplace of CROs."- Louise M. Murphy, PhD, MBA, CQA

CEOCFO: Do you find that companies are gravitating more toward quality, particularly after some of the overseas experiments that have not worked so well?

Dr. Murphy: Quality is and always has been a very critical component of clinical trials. If you deliver a quality product, you will get repeat business, and if you do not do that, you will lose business. We have substantial repeat business. In fact, two of our larger clients came to us when they were putting together their first Phase I studies, and we are working with them now on pivotal Phase III trials. For both, those Phase III trials are being conducted in multiple countries. One is a very challenging study in head and neck cancer, where we are providing electronic data capture in 14 countries, including Russia. We are proving that you can conduct quality projects across all kinds of challenges. You choose your partners carefully and adhere to your SOPs and standards. It is more difficult, clearly, to conduct multinational studies but, at ClinDatrix, the quality is the fundamental and sustained ingredient.

CEOCFO: ClinDatrix has established affiliations with CROs in other countries. How do you ensure that you are working with the best of the best?

Dr. Murphy: We have affiliations with CROs in other countries because we believe that working with the sites and understanding the local regulations, understanding the culture and the language, is best served by somebody in that country rather than by us sending someone in. When we select new affiliates – whether a partner CRO or individual experts – we look to see how much they operate like we do. Do they have a quality system? Do they have a full suite of SOPs on which they are fully trained? Do they have experience in the indication our client is pursuing, and are they familiar with working with CROs in other countries and, especially, in the U.S.? We prefer small firms, such as ourselves, that have the necessary flexibility to deal with the time differences and other complicated logistics of multinational trials. Of course, the more global experience we gain, the more resources we identify and form relationships with, and the better able we are to secure additional global contracts.

CEOCFO: What has surprised you most as the business has developed and grown?

Dr. Murphy: We just celebrated our tenth anniversary, and the biggest surprise is how quickly the time went by. Otherwise, I do not feel there have been many surprises. We deliberately planned our business growth so that we would add on services in a logical and progressive fashion. We started with core strengths in clinical, data management and biostatistics and built out from there. That is, we added medical writing, and EDC [electronic data capture]. We established a regulatory affairs department and acquired the systems to enable electronic regulatory filings. Most recently, we added a core group of preclinical specialists to help clients move from the lab through their investigation new drug (IND) or investigational device exemption (IDE) or 510(k) submittals and into clinical testing. Now, at the beginning of our second decade, we have a full executive team, we offer the full range of services our targeted clients need, and we have electronic systems and services to rival those of the largest CROs.

CEOCFO: What is ahead?

Dr. Murphy: There has been and, I believe, will continue to be a lot of consolidation within the CRO industry. At the same time, the economy is regaining strength, which means drug and device developers may be more successful in raising capital to advance their product development. Both trends work to our advantage. That is, the medium-sized CROs are growing into or are being absorbed by the large CROs just as a new crop of small to mid-sized biomedical companies are looking for personal attention in moving their products to market. ClinDatrix intends to be the CRO of choice for those innovators. I cannot say that we planned it this way. On the other hand, we have been circumspect in our expansion, and I think we are on the verge of a real growth spurt right now.

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

Dr. Murphy: We have a proven track record and solid experience in the pharmaceutical, biotechnology *and* medical devices industries. We are offering high quality results with lower costs to the client. We are responsive and have the expertise to work in a number of indications, particularly in oncology where there are many studies going on currently. We have all the systems that clients need to do their work, and we have the deep experience of our staff to conduct the studies, manage the data and make submissions in an expedient fashion.

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