An Interview with Lorraine Ellis, MS, MBA

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This month we profile the distinguished career of Lorraine Ellis, MS, MBA, founder, CEO, and president of Research Dynamics, a contract research organization (CRO) based in Rochester, N.Y. Lorraine's clinical research career has spanned more than 30 years. From bench scientist and animal researcher to leader of her own company, Lorraine Ellis has left her mark on the field through her unending commitment to educating and mentoring many clinical research professionals.

Q Lorraine, how did you first become interested in clinical research, and can you describe a little bit about the path you took to get involved in your clinical research career?

A I became interested in research when I worked as a summer intern in the preclinical lab of a major pharmaceutical company. When I graduated from college, I looked for a preclinical lab position and worked as an associate pharmacologist for more than six years. My work involved screening new compounds on animals. Then, one of my colleagues left the lab to take a job as a clinical research associate (CRA). This was in the late 1970s, when few people, including me, had even heard about CRAs. It sounded interesting, but I didn't leave the lab until I became allergic to the animals. So I looked for a CRA job and found my first CRA position in a small company in Massachusetts. And as they say, the rest is history . . . .

Q You've held many roles in your career. Can you tell us a bit more about where you started and the different types of roles you've held?

A As I mentioned, when I became allergic to the animals and completed my master's degree, I looked for a CRA job because it was still research, it sounded like an interesting job, and I loved to travel! I worked as a CRA for four years before becoming a manager. I continued in clinical research, moving from clinical research manager to director of clinical operations and project management. As a director of clinical operations (DCO), I was managing many CRAs and projects. The exciting part was training new CRAs and getting them started on their new career. It is rewarding that many of them have continued in clinical research and are doing well in their careers as managers and directors in clinical research.

After 10 years going from CRA to DCO, I finished my MBA and decided to start my own company, Research Dynamics. We started as a training and consulting company and now, 20 years later, we are still doing that as well as being a full-service CRO. I am also one of the principal consultants, using my 30 years of clinical trial experience to help companies develop standards, processes, and procedures as well as

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training programs. Using my MBA, I also consult in organizational changes (such as integrating new technology into the clinical research process) and due diligence activities.

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In my "spare" time, and using my training experience, I consulted with a local university, Rochester Institute of Technology, to develop a master's degree program in clinical research management. I am also one of the adjunct professors who teach the courses in the program.

Q You and I worked together while we both served on the Association Board of Trustees for ACRP. Tell us more about your involvement in ACRP. When did you first get involved, and what type of benefits have you reaped from being a member?

A I have been involved with ACRP since the mid-1980s. I joined because it was one of the few professional organizations for CRAs and clinical research professionals. It provided training programs and conferences, so I could increase my clinical trial knowledge and keep current with the regulations and good clinical practices (GCPs). It was also a great networking group, as we all had similar experiences to share and learn from and the people were great.

I worked on several committees in ACRP over the years, including the Certification Committee and Education Committee. I was part of the Training Committee that developed the first preparation courses for the CRA and clinical research coordinator (CRC) certification exams. After we developed the prep courses, we also traveled across the U.S. and Canada, providing the prep course in person to dozens of clinical researchers who were eager to get certified.

I was elected to the ACRP Board of Trustees and enjoyed my experience on the board for five years. I worked with many great people in the organization, and had the opportunity to bring many changes and benefits to the organization that are still enjoyed by members today. During this time, forums were established, chapters were getting started, and more education programs were established. We even had a name change during that time from the Associates of Clinical Pharmacology to the Association of Clinical Research Professionals.

I have received many benefits from my membership in ACRP. Most of the benefits were from joining committees, working with other groups such as forums, and working on the board. It was fun work, and I worked with some of the best people in the industry with whom I still keep in contact. I also still use them as a resource for difficult GCP situations.

Q Since your career has spanned many years and you have no doubt seen many changes, what is the most significant change (or top changes) you have seen? How has this affected the industry, either positively or negatively?

A The most significant changes for me were the evolution and standardization of the CRC and the CRA roles. Another top change is the technology that we can now use, such as electronic data capture (EDC), imaging, biomarkers, etc. These changes improved the quality of clinical research conduct and the quality of data.

When I started in the industry, CRCs did not exist as a formally recognized position or role. Usually, someone in the physician investigator's office assisted with the trial paperwork without any training or support. In fact, many physicians directly completed the case report forms (CRFs)! Over the 1980s, the CRC position became more prevalent, as the regular office staff did not have the time or the training to complete all the clinical trial CRFs and documentation. In the 1990s, the role was formalized, and ACRP developed the certification program that solidified the CRC as a critical role in clinical research. Can you imagine doing a study now, or ever, without a CRC?

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The role of the CRA or monitor also changed over the years. Protocols and CRFs were much simpler 20 to 30 years ago, and CRFs were all paper forms to carry back to the office. If you didn't visit for several weeks, errors would just continue and multiply, since no one knew anyone was making errors. Although protocols and CRFs are more complicated now, the use of EDC and remote monitoring make the monitoring job easier with real-time review of data and correction of errors before they multiply. Monitors now concentrate more on the conduct of the study at the site, instead of on data checks.

Q As you think about all of the clinical research professionals you have mentored and all those just entering the field, what advice do you have for them, in terms of how to further advance their career?

A There are many paths you can take in a clinical research career, so explore what most interests you. If you love the clinical and patient aspect, work at investigator organizations. You can obtain additional clinical training and education to be a higher level clinician, such as a nurse practitioner or physician, or you can get an MBA and work on the management side of the clinical research site or hospital.

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If you prefer being on the monitor side, you can learn the skills and knowledge to move into clinical research management and project management in industry organizations such as biopharmaceutical companies or CROs.

If you love data, you can move into data management, clinical analysis of data, or medical writing.

The bottom line is that you can use your best skills and knowledge and develop any career path in clinical research. Some of the current jobs didn't even exist five years ago, so you may be able to create your own position! Keep an open mind.

Q As you think about the future generation of clinical research professionals, what three "lessons learned" would you like to share?

A Keep current on GCP requirements worldwide. They are the foundation of any work in clinical research. If you are knowledgeable about GCPs, you will succeed in your career.

Also, be creative and knowledgeable about your career path. Research where the industry is going and what skills and knowledge you will need in three to five years. Be ready for the next new role before anyone else. Don't get locked in.

Finally, network in the industry. Join professional organizations, attend conferences, join groups, and meet lots of the great people in the industry. You never know where connections can lead. Some of my connections opened new career paths for me.

Q Do you have any closing thoughts you would like to share?

A It's hard to believe that I have been in clinical research for more than 30 years! I love my career, which is why I can't believe so much time has passed. My advice would be to do what you love to do and be good at it! Good luck!

Lorraine, on behalf of ACRP and all the clinical research professionals whose careers you have touched and influenced over the years, let me thank you for your dedication and contributions. We wish you another 30 years of success! **ACRP**

Beth D. Harper, MBA, is the president of Clinical Performance Partners, Inc., a clinical research consulting firm specializing in enrollment and site performance management. Previously she was the chief clinical officer of Centerphase Solutions, Inc., a technology-enabled consultancy specializing in protocol optimization services, as well as senior vice president at D. Anderson and Company, a firm specializing in patient recruitment and retention. She can be reached at bharper@clinicalperformancepartners.com.

To submit names of potential interview subjects or additional questions for future installments of this column, please contact Beth Harper at ***bharper@clinicalperformancepartners.com.***

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