



Understanding Our Profession—At This Moment

This special issue of *The Monitor* is dedicated to increasing the understanding of our readers from both the membership of ACRP and from the general public, who have access to these articles online, regarding the wide range of career opportunities that exist in the clinical research enterprise. In the ever-changing global environment that shapes our profession, it is good that, from time to time, we ask ourselves if we understand—at this moment—who the “clinical research professional” is and how the definition has changed as our community continues to grow.

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The traditional roles and accountabilities for clinical research professionals have expanded and transitioned with the changing needs for the profession. For example, the role of vendor manager has been identified as an area of expertise with growing demand as contract research organizations have become vital players in the clinical research cycle.

The clinical research professional is described by a variety of sources as an individual who functions as administrator, coordinator, consul-

tant, educator, and/or researcher in the management of clinical trials. These professionals come from an impressive variety of backgrounds with even more varied job descriptions and practices in settings that cover the gamut from the clinic to the corporate framework.

Good clinical practice standards require that clinical researchers must be qualified by education, experience, and training. The learning path followed by physicians and nurses from their schooling and on into continuing education lends itself to career opportunities in clinical research, due to the

similarities of clinical care and clinical research activities that involve human subjects. Similarly, expertise and education in the scientific arena provide an understanding of the disciplined framework for clinical research development and implementation. Other professional domains within the clinical research community include medical technology, business administration, health information management, statistics, biology, project management, teaching, and communications, to name a few.

Much of the training in our enterprise comes in an on-the-job fashion or through specialized venues that teach fundamental skills in the administration and progress of a clinical trial, with an understanding of the ethical and legal ramifications for all stakeholders being part and parcel of the experience. Areas of expertise required include protocol development, data collection, analysis, monitoring, recording, auditing, teaching, communications, diplomacy, ethics and regulations, and liabilities and responsibilities of conducting research with human subjects.

The professional standards of excellence required for achieving professional development and implementation of best practices bring with them the need for certification. ACRP currently offers independently accredited certification programs for clinical research associates and clinical research coordinators, and the Association has applied for accreditation of the certification program for physicians who are principal investigators of clinical studies.

The ACRP website describes the importance of certification in this fashion:

For employers, *Certification* can serve several purposes from providing evidence of experience and qualifications of a research team to the FDA *or other regulatory bodies* [italics mine] during an inspection, to validating com-

petency when considering a new employee. Recently, evidence has indicated that regulators believe *Certification* reduces risk to research subjects. There are fewer errors, lower costs, more rapid turnaround, and greater safety in clinical trials when *Certified* professionals are involved.

Feedback from the industry is clear—*Certification* is invaluable.

So how does one get started? It so often seems to be a Catch-22 that you can't get a job without experience and you can't get experience without a job. Over my years of working in the clinical research community, I have learned that being in the right place at the right time is a big part of serendipity, which is when someone is delighted to find something that they weren't expecting to find. Proactively managing a job search involves flexibility and creativity, so it is important to first learn the skills that are required and then accommodate to the

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needs of potential places of employment. If you want to get your foot in the door, it's a good idea to develop your potential in partnership with the companies or clients to whom you are offering your services.

With all of these definitions and aspirations as background, the September issue of *The Monitor* offers a grand sweep of articles about the clinical research profession and professionals that will hopefully spark your imagination, whatever your particular stage of professional development happens to be at this moment. As you will see from the collected wisdom of our contributing authors, we are fortunate that the fundamental premises of learning and development form a strong foundation for the success of clinical research professionals today

and in the years ahead—even as our quest for learning continually grows.

One more thought: As the speed and scope of transition accelerates in the world, we need to consider the changing environment and become chameleons—artists of amazing and quick change! Whatever changes you are facing or could soon face in your career, we hope that you will enjoy the articles in these pages and think reflectively about your place or the place you hope to have in the community of clinical research professionals. Think also about what you can give back to enhance and support the advancement of the profession and the care of people who need it most—the volunteer subjects who are rightly the focus and star attractions of all that urges us up, and keeps us on, this fascinating career path. **ACRP**

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