

Preparing Clinical Research Associates for the 21st Century

Janet F. Zimmerman, MS, RN, Clinical Research Training Consultant, Newtown, PA

DURING THE ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS' (ACRP's) 1998 annual meeting in Anaheim, CA, we facilitated a session titled "Preparing CRAs for the 21st Century." The session was designed to provide an open forum to identify the knowledge and skills that clinical research associates (CRAs) will need to perform effectively in the new millennium and to recommend a strategy to prepare monitors for the challenge. Four questions provided the impetus for a series of lively information-gathering exercises: (1) What factors will affect CRAs in the 21st century?; (2) What competencies will CRAs need to function efficiently?; (3) How can CRAs prepare themselves?; and (4) What strategies can CRA managers and trainers implement to ensure their CRA workforce is ready for the new millennium?

Participants, who included CRAs, CRA managers and trainers, made thoughtful predictions of what monitoring drug, biologic, and device studies will be like in the 21st century. Since many of the predictions are already in effect, a primary objective was to recommend action plans for self-directed CRAs and for CRA managers and trainers.

Three factors were predicted as having consequences for clinical monitors in the new millennium: technology, globalization, and health care. During the ensuing discussions, 10 essential competencies (or knowledge and skill areas) emerged.

TECHNOLOGY

One major factor that will affect CRAs in the 21st century is technology growth, which is sweeping and

endless. CRAs will use computers, peripherals, and a myriad of electronic, digital, cellular, and optical equipment on the job, allowing them to be

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"wired" in their offices, in their cars, and in their briefcases. CRAs will monitor studies for investigational medical devices as well as review data obtained using standard tests and procedures that are all technology-based.

Required competencies will be:

1. Skills in using and troubleshooting hardware – computers, peripherals and other office apparatus;
2. Knowledge of multiple software programs – standard word processing, database, project management, productivity programs and custom-designed intranet software programs;
3. Knowledge of diagnostic and therapeutic technologies – laboratory tests and imaging examinations;
4. Skills in using and troubleshooting the investigational device – technology-driven medical devices and instruments.

GLOBALIZATION

Another factor that will transform CRAs is globalization of clinical trials. Many drug, biologic, and device companies sponsor clinical research worldwide to expedite marketing approvals. CRAs will work on global projects, interfacing and monitoring internationally. CRAs will meet people with different cultural and societal perspectives.

Required competencies will be:

5. Multiple Language Skills – English and other common languages;

6. Knowledge of Different Countries – the unique cultural, social, religious, political, legal, and ethical characteristics of the countries where trials are conducted and the sponsor is based;

7. Project Management Skills – international project team management;

8. Negotiating Skills – multicultural project team collaboration.

HEALTH CARE

Health care is also shaped by technology and globalization; its

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juxtaposition with clinical research will expose CRAs to many different health care systems and standards. Sponsors will focus on developing breakthrough products to prevent or treat universal illnesses. CRAs will work on a variety of therapeutic projects.

Required competencies will be:

9. Knowledge of diverse health care systems – global disparities in access to health care and standards of care;

10. Knowledge of different therapeutic areas – cross-training in different diseases.

STRATEGIES:

CRAs, CRA Managers and Trainers

This list of 10 competencies CRAs will need to perform effectively in the 21st century is not intended to be inclusive, but rather as a starting point for evaluation and planning.

CRAs may use this competency list as a self-assessment exercise. Areas of weakness would become priority goals on a personal development plan. Strengths would be emphasized during job searches and performance appraisals.

CRA managers may use this information as a guide for hiring and managing monitors. CRA trainers may want to design and implement training programs to develop these competencies.

We have a limited amount of time to plan for the changes that technology, globalization, and health care will bring. Our goal is to be visionary, proactive and prepared for the 21st century. Good luck!

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