The Contemporary Clinical Research Coordinator (CRC) Career Path: An Evolution of Professional Development

Session T201: 10:30 AM – 11:30 AM

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OBJECTIVES

- Recognize the importance of creating an individualized career development plan.
- Identify strategies for professional development and career advancement to promote workforce development for the Clinical Research Coordinator (CRC).
Poll #1

What is your job title (position)?

a. Clinical Research Coordinator/Research Assistant or Associate
b. Clinical Research Nurse
c. Research Administrator/Research Manager
d. Other
Poll #2

How long have you been in a research position?

a. 1 – 4 years
b. 5 – 10 years
c. 11-15 years
d. 16-20 years
e. More than 20 years
Poll #3

How would you best describe your Organization?

a. Academic Medical Center
b. University
c. Hospital or Health System
d. Independent Research Site
e. Other
Poll #4

Does your organization provide funding to support attendance at research educational or training programs/seminars/webinars?

a. Yes
b. No
c. Other
A Clinical Research Coordinator works at a clinical research site under the direct supervision of a principal investigator whose research activities are conducted under GCP regulations.

(Association for Clinical Research Professionals – ACRP)
Evolution of the Role

- Over time, the role of the CRC has evolved to include more complex and specialized functions.
- The CRC role has evolved as a profession and now must be recognized within the context of leadership.
- The trends of increasing administrative burdens has the potential to cause gaps in participant protections.
- Contemporary models need to expand the definition of “business unit” from individual investigator-coordinator teams to department or division enterprises adopting resource sharing of personnel focused on specific administrative tasks.


# Job Satisfaction

<table>
<thead>
<tr>
<th>Top Positives About the Job</th>
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<tbody>
<tr>
<td>Patient/Subject Interaction</td>
<td>29%</td>
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<tr>
<td>Multitasking/diversity</td>
<td>18%</td>
</tr>
<tr>
<td>Contribution to medical advancement</td>
<td>16%</td>
</tr>
<tr>
<td>Flexibility and Autonomy</td>
<td>15%</td>
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<table>
<thead>
<tr>
<th>Top Negatives About the Job</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Overworked and Inadequate Pay</td>
<td>20%</td>
</tr>
<tr>
<td>Paperwork, budgets, billing</td>
<td>14%</td>
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<thead>
<tr>
<th>Top Motivations for Leaving the Job</th>
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<tbody>
<tr>
<td>Better Salary</td>
<td>23%</td>
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<tr>
<td>Career Advancement</td>
<td>17%</td>
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Greater than 75% of CRCs described their work as both professionally and personally fulfilling.

41% of CRCs reported no opportunity for career advancement or development.

Lack of career advancement was reported as one of the top reasons for leaving CRC positions.

63% of surveyed institutions do not have programs for CRC development or recognition.

CRC Responsibilities

Core Responsibilities:

• Adherence to an IRB approved protocol
• Participation in the proper consenting of study subjects
• Support of the safety of clinical research subjects
• Coordination of clinical treatment, study visits, and follow-up care
• Subject screening, recruitment, and enrollment
• Maintenance of study source documents
• Proper reporting of adverse events

CRC Responsibilities (continued)

**Additional Responsibilities:**

- Submissions to regulatory authorities (e.g., IRB, FDA, etc.)
- Regulatory documentation development and management
- Completion of case report forms (paper & electronic data capture)
- Coordination of pre-study, initiation, and monitoring visits
- Collection, processing, and shipping of laboratory specimens
- Maintenance of drug accountability documentation
- Study budget and coverage analysis preparation
- Management of study finances (i.e., resolving study subject billing issues)
- Acting as liaison for participants, investigator, IRB, sponsor, etc.

Critical Trends

- Numerous factors impact CRC retention and job satisfaction: reasonable workload, advancement of new therapies, working with participants/families, recognition, salary and a formalized career ladder.
  - Reinforcement of these factors is necessary to improve CRC retention and job satisfaction.
- The continuum of learning for CRCs should include opportunities beyond the basic (mandatory) regulatory training.
  - CRCs should receive advanced levels of research education and ethical training to strengthen their role in protecting participants and promoting research integrity.
- CRCs are generally satisfied with their roles even though important issues remain to be clarified.
  - The evolving role of the CRC should be researched and more formally recognized as a profession.

Types of Training

- Peer Mentoring
- Shadowing
- Institution/Department based Orientation
- Online HSP* Course (e.g., CITI, NIH)
- Web-based Training Modules
- Online Certifications, Degrees
- National/local Courses and Conferences
- Graduate Courses

* HSP = Human Subjects Protection
Education & Training

• 45% of CRCs reported they received appropriate training however, gaps in initial and ongoing training were also reported.

• The majority of institutions (61%) with formalized education offer online, full-day/ or longer in-house education and written training programs.

• Growing trend of graduate degree programs nationally.

Core Competencies Framework

## Domain 2

<table>
<thead>
<tr>
<th>2</th>
<th>Ethical Considerations, Patient Care and Safety: Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial</th>
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<tbody>
<tr>
<td>2.1</td>
<td>Compare and contrast clinical care and clinical management of research participants</td>
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<tr>
<td>2.2</td>
<td>Define the concepts of “clinical equipoise” and “therapeutic misconception” as they relate to the conduct of a clinical trial</td>
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<tr>
<td>2.3</td>
<td>Compare the requirements for human subject protection and privacy under different national and international regulations and ensure their implementation throughout all phases of a clinical study</td>
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<tr>
<td>2.4</td>
<td>Explain the evolution of the requirement for informed consent from research participants and the principles and content of the key documents that ensure the protection of human participants in clinical research</td>
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<td>2.5</td>
<td>Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards</td>
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<td>2.6</td>
<td>Evaluate and apply an understanding of the past and current ethical issues, cultural variation and commercial aspects on the medicines development process</td>
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<td>2.7</td>
<td>Explain how inclusion and exclusion criteria are included in a clinical protocol to assure human subject protection</td>
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<tr>
<td>2.8</td>
<td>Summarize the principles and methods of distributing and balancing risk and benefit through selection and management of clinical trial subjects</td>
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Career Ladder

• A career ladder is a formal process within an organization that allows employees to advance their careers to higher levels of salary, responsibility or authority. Once employees meet certain criteria, they are eligible to move into higher level roles.
• Clinical Ladders are commonly designated as professional development tools to reward nurses for education and certification, research, clinical skills and leadership. (Smailes et al, Clinical Researcher, December 2017)
• “Novice to expert”: novice, advanced, beginner, competent, proficient, expert (Brenner)
Career Ladder: Retain, Motivate and Develop

- When organizations have career ladders in place, they show employees the organization values them. The career ladder is a formal mechanism whereby employees gain **knowledge, skills, and abilities** that make them more useful to the employer.

- The organization equips employees to do their jobs better over time. Career ladders facilitate this in methodical ways. Each rung of the ladder has **training requirements** for moving to the next rung. The training prepares employees for the tasks, assignments, and projects they will work on once they reach the next level of the career ladder.
What is Workforce Development?

“Workforce development, an approach to economic development, attempts to enhance a region's (organization’s) economic stability and prosperity by focusing on people rather than businesses. It essentially develops a human-resources strategy.”

Wikipedia, 2017
“Workforce development consists of a constellation of activities from orientation to the work world, recruiting, placement, mentoring, to follow-up counseling and crisis intervention (Harrison & Weiss, 1998).

It provides individuals with occupational preparation necessary for employment, including technical, basic, and academic competencies (Gruber, 1999).
Practical Definition: Training and Development

- What do we mean by Training and Education: It is about learning something new and should be very skill focused:
  - Responsible Conduct of Research Classes and Seminars
  - Core curriculum for all areas of Research Administration
  - Regulatory Affairs Training
  - Experiential Learning (hands on approach)

- What do we mean by Professional Development: It is about individual growth and competency Development:
  - Society for Research Administrators International
  - Certificate Programs
  - Degree Programs (theoretical learning)
There is Opportunity: Simple Next Steps

Training Opportunities

- Organizational Seminar Series and Education Sessions
- On the job training and Stretch Assignments
- Teamwork
- Funding Announcements
- Federal Regulations
- Organizational Policies and Procedures
- Tracking organizational objectives and mission
- Cross Training
  - Clinically (where applicable)
  - Various Research Administration Roles
There is Opportunity: Simple Next Steps (continued)

Professional Development Opportunities

• Life Cycle Mentorship (and/or Coaching)
  • Find a Mentor
  • Become a Mentor
• Professional Societies (Build Relationships and Networks!)
  • Society of Research Administrators International (SRA)
  • Public Responsibility in Medicine & Research (PRIM&R)
  • Association of Clinical Research Professionals (ACRP)
• Degree Seeking Programs
  • Certificates in Leadership or Research Administration
  • Masters in Research Administration or Regulatory Affairs
  • Doctorate in Research Management
There is Opportunity: More Complex Next Steps

• Vision about your career and write down your expectations
• Invest in yourself – “personal business plan”
• Work on emotional and social self-awareness
  ➢ Ideal Self – who you want to be*
  ➢ Real Self – who you are*
  ➢ Ought self – who you think others want you to be*
  ➢ Gaps – what you need to change with intention*
• Understand your strengths and weaknesses and work to close gaps
• Be proactive and flexible about opportunities
• Ask questions and be open to feedback
Examples of Research Job Families

- **Vice President or Associate VP**
  - Science Operations Leader
    - Med. Director
    - IRB Chair(s)
    - Leadership
  - Pre-Award Director
    - Specialist I
    - Specialist II
    - Specialist II
    - Coordinator
    - Intern
  - Research Finance Director
    - Specialist 1
    - Specialist 2
    - Specialist 3
    - Coordinator
    - Intern
  - Post Award Director
    - Finance Accounting
      - Accountant 1
      - Accountant 2
      - Accountant 3
      - Coordinator
      - Intern
Research Job Families (continued)

- **IRB Director**
- **Clinical Research Unit Director**
- **Compliance and Education Director**
- **Technology Transfer Director**

**Ethical Review**
- Specialist I
- Specialist II
- Specialist III
- Coordinator
- Intern

**Study Conduct**
- Nurse I
- Nurse II
- Nurse III
- Nurse IV

**Regulatory Training**
- Specialist I
- Specialist II
- Add text III
- Coordinator
- Intern

**IP Protection**
- Licensing I
- Licensing II
- Licensing III
- Coordinator
- Intern
“If you fail to plan, you plan to fail.”
Benjamin Franklin
2015 CenterWatch-ACRP Career and Salary Survey: The Clinical Research Coordinator Perspective

REPORT PREPARED APRIL 2015
If your current role has changed substantially in the past year, without a formal job change, what have been the most significant changes?

- Expectation of company to take on more responsibility in current role: 38% (Clinical Study Site), 42% (Private Practice), 38% (Academic Medical Center)
- Informal morphing of job functions: 19% (Clinical Study Site), 23% (Private Practice), 30% (Academic Medical Center)
- Formal integration of one or more job functions: 12% (Clinical Study Site), 14% (Private Practice), 17% (Academic Medical Center)
- Change of role due to technology integration: 3% (Clinical Study Site), 7% (Private Practice), 5% (Academic Medical Center)
- Other: 3% (Clinical Study Site), 8% (Private Practice), 6% (Academic Medical Center)
- Current role has not changed: 39% (Clinical Study Site), 39% (Private Practice), 39% (Academic Medical Center)

Base: Total (n=612), Academic Medical Center (n=267), Private Practice (n=191), Clinical Study Site (n=154), Sample Size = 612
Company Policy on Education & Training

What is your company's policy on educational meeting attendance and external training/development of employees?

- My company has an in-house training/development department: 21% (Clinical Study Site), 26% (Private Practice), 26% (Academic Medical Center)
- My company allows employees to take advantage of educational opportunities: 44% (Clinical Study Site), 58% (Private Practice), 63% (Academic Medical Center)
- My company pays for certification examination(s): 55% (Clinical Study Site), 51% (Private Practice), 58% (Academic Medical Center)
- My company pays for employee meeting/training/development attendance: 41% (Clinical Study Site), 43% (Private Practice), 51% (Academic Medical Center)
- My company pays for maintaining my certification(s)/membership(s): 51% (Clinical Study Site), 55% (Private Practice), 55% (Academic Medical Center)
- My company allows employees to take advantage of educational opportunities: 12% (Clinical Study Site), 94% (Private Practice), 1% (Academic Medical Center)
- My company does not currently support employee training/development programs: 3% (Clinical Study Site), 4% (Private Practice), 1% (Academic Medical Center)
- I don't know/Not applicable: 3% (Clinical Study Site), 4% (Private Practice), 2% (Academic Medical Center)
- Other: 2% (Clinical Study Site), 2% (Private Practice), 2% (Academic Medical Center)

Base: Total (n=612), Academic Medical Center (n=267), Private Practice (n=191), Clinical Study Site (n=154), Sample Size = 612
Best Path to Increase Salary & Upward Mobility

Which one of the following options do you consider the best way to increase your salary and move upward in your profession?

- Obtain a promotion within my current dept from current employer
- Obtain a position outside my current department from my current employer
- Obtain a new position from a new employer
- Become self-employed
- All Other

Base: Total (n=612), Academic Medical Center (n=267), Private Practice (n=191), Clinical Study Site (n=154), Sample Size = 612
Clinical Research Coordinators (CRCs)

- We are unique!
  - Multiple Responsibilities
  - Self-Directed
  - Highly Specialized

- Hard to find and retain IF your office culture doesn’t support employee values.
Questions?

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