An Introduction to Clinical Research

Presented by: Sabrina Ramkellawan
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Getting Started in Clinical Research

This webinar is for anyone interested in learning more about the clinical research field and how to enter and get started in Clinical Research.
Presenter

Sabrina Ramkellawan is the Vice President of Operations at Apollo Applied Research. In this capacity, she oversees collaborative research partnerships and the conduct of research studies with the goal to advance research in medical cannabis. Sabrina is also a Professor and the Program Coordinator of the Clinical Research Program at Seneca College. Prior to joining Apollo Applied Research, she was the Director of Operations at INC Research overseeing the operations of the Contract Research Organization in Toronto. In this capacity, she was responsible for the conduct of phase I clinical trials. In addition, Sabrina has Nursing experience in various areas including Critical Care, Pediatrics and Mental Health.

Learning Objectives

Upon completion of this Webinar, attendees should be able to:

• Determine whether clinical research is a good fit for you
• Describe the various roles and positions within the clinical research industry and how these roles fit within the drug development process
• Discuss the required qualifications and competencies of clinical research professionals
• Discuss the types of certifications available for various roles and positions within the clinical research industry
• Describe what is it like to work in clinical research through “A day in the life” interviews with research professionals in the field
• Utilize interview tips to prepare and plan for upcoming interviews
• Utilize networking and social media to make professional connections, improve your brand and get noticed.
Are you a good fit for clinical research?

Take the short quiz
Are you a good fit for clinical research?

- Team work
- Flexible and adaptable to changing priorities
- Leadership & Professionalism
- Knowledgeable in regards to regulations, guidelines, Good Clinical Practice, Good Documentation Practices
- Being detail-oriented is critical and can’t be understated.

The different roles and positions in clinical research
The different roles and positions in clinical research

Roles & Positions

- Clinical Research Coordinator (CRC)
- Principal Investigator (PI)/Medical Monitor
- Clinical Research Associate (CRA)
- Project Manager (PM)
- Regulatory Affairs (RA)
- Medical Writer/Data Management/Informatics
- Biostatistics/Statistician/Research Scientist
- Quality Assurance (QA)/Quality Control (QC)
- Medical & Laboratory Staff
- Clinical Trial Administrator (CTA)
- Pharmacovigilance
- Other Specialist/Roles e.g. Patient Recruitment Specialist, IRB Staff, Budgets & Contracts

Positions related to the drug development process

- Drug Discovery
  - This process starts with an idea and a target compound is identified
  - Position(s): Research Scientist, Informatics

- Preclinical Testing
  - Preclinical Testing includes both in vitro and in vivo testing
  - Position(s): Research Scientist; Medical Writer, Informatics

- Regulatory Approval
  - Application to Regulatory Body to test in Humans
  - Position(s): Regulatory Affairs, Project Manager

- Clinical Trials I-III
  - Clinical Trials are done to show that the drug is safe and works
  - Position(s): See next Slide

- Regulatory Approval
  - Application to Regulatory Body to approve the drug to market
  - Position(s): Regulatory Affairs, Project Manager

- Post Market-Clinical Trials Phase IV
  - Clinical Trials are done to show that the drug continues to be safe
  - Position(s): See next Slide
## Positions Related to the Clinical Trial Process Flow

<table>
<thead>
<tr>
<th>Study Definition</th>
<th>Study Preparation</th>
<th>Patient Enrollment</th>
<th>Data Collection</th>
<th>Data Analysis</th>
<th>Submission</th>
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<tbody>
<tr>
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### What is it like to work in clinical research?

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What is it like to work in clinical research?

“A day in the life”

Elizabeth Hollingdrake    Gregory Staios

Types of organizations that hire clinical research professionals
Types of organizations that hire clinical research professionals

- Contract Research Organization
- Hospital
- Vendor/Consultant
- IRB/Ethic Committee
- Medical Clinic
- Pharmaceutical Company
- Medical Device Company
- Regulatory Agency
- Biotech Company
- Clinical Research Professional Organization
- Academic Center/University
- Laboratory
- Site Management Organization

Competencies, experience and certifications
Experience

- If you are looking to enroll in a clinical research program, look for schools that offer a work placement. This is a great way to gain some experience.
- Be flexible as you will likely need to apply for an entry-level position to get your foot in the door.
- It’s best not to “get set” on the specific company or type of company.
- Don’t be limited by geography. A great opportunity may require that you travel for an hour or even relocate.
- Look for job shadow or internship opportunities.
## Certifications

<table>
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<tr>
<th>Association</th>
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<tr>
<td>ACRP (Association of Clinical Research Professionals)</td>
<td>CCRA (Certified Clinical Research Associate)</td>
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<td>CCRC (Certified Clinical Research Coordinator)</td>
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<td></td>
<td>CPI (Certified Principal Investigator)</td>
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<td>RAPS (Regulatory Affairs Professional Society)</td>
<td>RAC (Regulatory Affairs Certificate)</td>
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<td>SOCRA (Society of Clinical Research Associates)</td>
<td>CCRP (Certified Clinical Research Professional Certificate)</td>
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<tr>
<td>ASQ (American Society for Quality)</td>
<td>CQA (Certified Quality Auditor)</td>
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<td>PMI (Project Management Institute)</td>
<td>PMP (Project Management Professional)</td>
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<td>Society for Clinical Data Management</td>
<td>CCDM (Certified Clinical Data Manager)</td>
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## Salaries
### Salaries

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<tr>
<th>Job Title</th>
<th>Salary Range</th>
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<tr>
<td>Clinical Research Coordinator</td>
<td>$33,869 - $65,597</td>
<td>$46,354</td>
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<tr>
<td>Clinical Research Associate</td>
<td>$41,218 - $84,477</td>
<td>$60,880</td>
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<tr>
<td>Principal Investigator</td>
<td>$64,564 - $190,347</td>
<td>$102,119</td>
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<tr>
<td>Clinical Research Nurse</td>
<td>$50,602 - $87,588</td>
<td>$64,553</td>
</tr>
<tr>
<td>Project Manager</td>
<td>$54,447 - $120,403</td>
<td>$84,214</td>
</tr>
<tr>
<td>Research Scientist</td>
<td>$45,676 - $110,541</td>
<td>$75,508</td>
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<tr>
<td>Medical Writer</td>
<td>$49,445 - $112,505</td>
<td>$72,227</td>
</tr>
<tr>
<td>Statistician</td>
<td>$46,444 - $107,866</td>
<td>$72,114</td>
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<tr>
<td>Data Manager</td>
<td>$35,829 - $98,351</td>
<td>$53,621</td>
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<tr>
<td>Regulatory Affairs Manager</td>
<td>$57,801 - $122,733</td>
<td>$87,738</td>
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Reference: Payscale.com (funds are in US Dollars)
Networking and social media

- Two types of networking: in-person and online so utilize both options
- Your network is larger than you think!
- Reach out to your network
- Focus on building relationships

Using social media

- LinkedIn
- Twitter
- Facebook
- Google +(Plus)
References

- A New Approach to developing the CRA workforce
- 2015 Career and Salary Benchmark Reports
- Moving from Compliance to Competency

A Harmonized Core Competency Framework for the Clinical Research Professional