Breaking Into the Clinical Research Field
A How-To Guide to Jump Start your Clinical Research or Regulatory Career
October 30, 2014
Diedre Ribbens, PhD
Kristen Maynard, PhD
Joy Frestedt, PhD, RAC, CCTI, FRAPS
Disclosure

The presenters for today’s session have no relevant financial relationships with respect to this educational activity.

Dr. Ribbens is a Technical Writing Specialist for Frestedt, Inc.

Dr. Maynard is a Clinical Data Analyst for Frestedt, Inc.

Dr. Joy Frestedt is the Founder, President and CEO of Frestedt, Inc.
Share Fair Learning Objectives

Upon completion of this educational activity, you should be able to:

- Describe aspects of clinical research practice that exemplify a broad range of contemporary concerns presented at The Share Fair
- Review differing approaches to the clinical research collaborative process, from the viewpoints of Sponsors and of clinical facilities
- Determine whether a technique applied by colleagues to a specific clinical research issue pertains to your research process
Learning Objectives

Upon completion of this presentation, participants should be able to:

- Recognize the various roles and responsibilities in the clinical research field
- Use the specific suggestions to investigate opportunities
- Describe the types of skills needed for a clinical research position
Clinical research jobs often list experience as a prerequisite, so how can you land that initial job? Background on the clinical research field and types of clinical research jobs will be explained, followed by some general suggestions of how to improve the experience section on your resume and some specific examples of internships and volunteer opportunities in the Twin Cities area and elsewhere.
Dr. Ribbens is currently a Technical Writing Specialist with Frestedt, Incorporated in St. Louis Park, MN. She received her PhD in Cell Biology from The Johns Hopkins School of Medicine in 2013 and previously worked as a technical editor and freelance science writer.

Dr. Maynard is currently a Clinical Data Analyst with Frestedt, Incorporated in St. Louis Park, MN. She received her PhD in Chemistry from Boston College in 2003 and previously worked in type I diabetes research at the University of Minnesota Schulze Diabetes Institute.
Joy L. Frestedt, PhD, CCTI, RAC, FRAPS
founded Frestedt Incorporated in 2008 and
Alimentix, the Minnesota Diet Research
Center in 2012. Dr. Frestedt has managed
clinical, regulatory, and quality affairs for
over 30 years in companies like Johnson
and Johnson, Medtronic, Mayo Clinical Trial
Services, AstraZeneca and Orphan Medical.
Dr. Frestedt is among the “100 Most
Inspiring People in the Life Sciences
Industry” (PharmaVOICE, 2011) and the top
25 “Industry Leaders” (Minneapolis/St. Paul
Agenda

1. How Do I Enter the Clinical Research Field?
2. Identify the type of clinical research job that interests you
3. Network and meet people to gain opportunities and access
4. Internships and entry-level positions to build resume
Key Stakeholders in Clinical Research

- Sponsor
- Study Subject (healthy volunteer, or patient with a medical need)
- Vendor (CRO, contractor, service provider)
- Regulatory Authority
- Clinical Research Investigator/Study Site
- Health Care Provider
- IRB/EC/HRC
- Public

Source: ACRP “How to Enter the Clinical Research Field” September 5, 2014
How Do I Enter the Clinical Research Field?

<table>
<thead>
<tr>
<th>Network to find internship opportunity</th>
<th>Be prepared to start at entry-level or lateral position; consider transferrable skills and experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seek education to acquire new knowledge and skills in science, medicine</td>
<td>Education is useful but not enough, experience with processes and regulations are required</td>
</tr>
</tbody>
</table>

No single answer to this question

Source: ACRP “How to Enter the Clinical Research Field” September 5, 2014
Clinical Research Coordinator (CRC)

- Works at a clinical research site with study subjects under direction of Principal Investigator
- Conducts clinical trials using Good Clinical Practices (GCPs)
- Perform essential duties such as obtaining informed consent and adhering to protocol
- Certifications:
  - Certified Clinical Research Coordinator (CCRC)
  - Certified Clinical Research Professional (CCRP)
- Other titles:
  - Study Coordinator
Clinical Research Associate (CRA)

- Supervises, monitors and supports administration of a clinical trial on behalf of sponsor
- May be employed directly or indirectly by sponsor
- May work at pharmaceutical companies, medical research institutes or government agencies
- Certifications:
  - Certified Clinical Research Associated (CCRA)
  - Certified Clinical Research Professional (CCRP)
- Other titles:
  - Study monitor
  - Clinical monitor
  - Trial monitor
Principal Investigator (PI)

- Serves as the primary, sub- or co-investigator on a clinical trial
- Accepts full responsibility for safe and ethical conduct of clinical trial
- Holds doctoral-level degree: PhD, PharmD, DNP; DO, MD, DDS or equivalent
- Monitors, supervises or designs clinical trials
- Certifications:
  - Certified Physician Investigator (CPI)
Clinical Data Coordinator

- Plans, directs or coordinates clinical research projects
- Ensure compliance with protocols and overall objectives
- Evaluate and analyze clinical data
- Work in academia or industry
- Training:
  - Bachelor’s degree
  - Clinical background or experience in healthcare field
Biostatistician

- Aid in design and analysis of clinical trials
- Develop statistical plan for clinical trial
- Training:
  - Bachelor’s degree with mathematics, biology and statistics courses
  - Master’s of Public Health (MPH)
  - Master’s or PhD in Statistics/Biostatistics
- Other titles:
  - Statistical Programmer
  - Data Manager
  - Trial Manager
Clinical Safety Specialist

- Draft, review and QC safety documents and protocols
- Help document and reconcile severe adverse events (SAEs)
- Training:
  - Bachelor’s degree
- Other titles:
  - Clinical Safety Manager
  - Trial Safety Surveillance Specialist
Other Careers

- **Consultant**
  - Help design, manage, monitor, audit, write, etc.
  - Flexibility and variety

- **Clinical Quality Assurance Auditor (CQA)**
  - Inspect documents and processes for a study to assure compliance with GCPs

- **Medical Writer**
  - Write documents to apply for funding or disseminate results

- **Regulatory Affairs Specialist**
  - Collaborate with clinical study team and regulatory agencies
  - Act as liaison
Different Strategies for Action

**LOOK**
- Find opportunities

**APPLY**
- Entry level
- Lateral

**NETWORK**
- Find a project where you can help a leader

**LEARN**
- Clinical research landscape
- Grow skill set to match

**VOLUNTEER**
- Build experience
- Demonstrate skills

**PARTICIPATE**
- Informational meetings
- Shadow professionals

**PLAN**
- Get certified

**KEEP AN OPEN MIND**
- Be flexible
- Be patient

**LAND YOUR JOB!**

Source: ACRP “How to Enter the Clinical Research Field” September 5, 2014
Networking Opportunities

- **Professional Organizations**
  - ACRP and the Share Fair!
  - Society of Clinical Research Associates (SOCRA)
  - LifeScience Alley
  - Graduate Women in Science (GWIS)
  - American Medical Women’s Association (AMWA)
  - Drug Information Association (DIA)
  - Regulatory Affairs Professional Society (RAPS)

- **Career events/resources**
  - Job fairs
  - Introductions via LinkedIn
  - Informational interviews
Internships – Local and National

NATIONAL

- NIH Clinical Center Summer Internships
  - [http://clinicalcenter.nih.gov/training/students/summer_internships.html](http://clinicalcenter.nih.gov/training/students/summer_internships.html)
- Mayo Clinic Clinical Research Internship Study Program (CRISP) (FL)
  - [http://www.mayo.edu/mshs/careers/clinical-research-internship-study-program/clinical-research-internship-study-program-florida](http://www.mayo.edu/mshs/careers/clinical-research-internship-study-program/clinical-research-internship-study-program-florida)
- Part-time work, such as this ad for Project Manager:
  - [http://www.internships.com/biotech/Project-Manager-I1913492](http://www.internships.com/biotech/Project-Manager-I1913492)
- Or this one for a Senior Intern in Clinical Trial management:

LOCAL

- FRESTEDT, INC!
- Applied Business Training (ABT) program Fellowships (LifeScience Alley/BioBusiness Alliance)
Work Towards Your Dream Clinical Research Role

GOAL: Clinical Research Job Found!

Learn and master new knowledge, skills and processes based on global and local regulatory requirements before moving up the career ladder!

Source: ACRP “How to Enter the Clinical Research Field” September 5, 2014
Agenda

1. How Do I Enter the Clinical Research Field?
2. Identify the type of clinical research job that interests you
3. Network and meet people to gain opportunities and access
4. Internships and entry-level positions to build resume
Questions?

Contact Us!

- Visit our website: www.frestedt.com
  - Slides from this presentation available

- Email: info@Frestedt.com
Resources

“Launching Your Career”
Association of Clinical Research Professionals (ACRP)

April 2013 Issue of The Monitor (ACRP) – Careers in Clinical Research
Association of Clinical Research Professionals (ACRP)
http://www.acrpnnet.org/MainMenuCategory/Resources/TheMonitor/April-2013.aspx

About the Regulatory Profession
Regulatory Affairs Professionals Society (RAPS)
http://www.raps.org/about/regulatory-profession/

Getting Started in Clinical Research
ACRP Panel September 5, 2014

DIA Clinical Research Certificate Program
Resources

Considering a Career in Medical Research
Association of American Medical Colleges
https://www.aamc.org/students/research/

“Tooling Up: Clinical Trial Careers”
Science Careers Career Magazine
http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2011_08_19/caredit.a1100083

“Toolkit For New Medical Writers”
American Medical Writers Association
http://www.amwa.org/toolkit_new_med_writers

American College of Healthcare Executives Career Resources
http://www.ache.org/carsvcs/career_development_resources.cfm