Introduction To Medpace & Clinical Research Overview
Medpace Overview

- We are a Contract Research Organization (CRO)
- Work closely with biotech, pharma, and device companies
- Full Service Model
- US Campus and Global HQ – Cincinnati, US
- >2,400 employees
  - Operations in 35 countries
  - 29 offices in 23 countries
- Well-established reputation of 25 years in industry
- IPO – August 2016
Our mission is to accelerate the global development of safe and effective medical therapeutics.
Strategically Mapped for Global Trials

Operations in over 35 Countries

Operations
- Offices
- Offices with labs or standalone lab
Therapeutic Areas

- Provides Phase I-IV core development services for drug, biologic, and medical device programs

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<thead>
<tr>
<th>Therapeutic Areas</th>
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<td>Cardiovascular</td>
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<td>Endocrine and Metabolic</td>
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<td>Gastroenterology</td>
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<td>Hematology and Oncology</td>
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<td>Infectious Disease/Vaccines</td>
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<td>Nephrology</td>
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- Rapid growth over the past couple of years
- Medical Monitor therapeutic expertise
Overview of Opportunities at Medpace
Clinical Research Associate (CRA)

- Also know as a clinical monitor
- Visits the study sites to ensure:
  - The investigators are following the protocol
  - Compliance with Good Clinical Practice (GCP) Guidelines
  - The appropriate collection and documentation of data
- CRA travels approximately 60-80% of the time
- CRA is assigned approximately 2-3 protocols with ~15 sites total
What is a clinical research site?

- A clinical research site is independently contracted to participate in a clinical research study
  - Privately owned physician office, university institution, hospital, research only facility, etc.
- Led by the Principal Investigator (PI) and the Clinical Research Coordinator (CRC)
- Recruits trial subjects, conducts informed consent, performs study visit procedures, and oversees subject safety
CRA Responsibilities: Onsite

- There are 4 types of monitoring visits:
  - Qualification
    - Performed prior to final selection of site
  - Study Initiation
    - Performed prior to screening any subjects at the site
  - Routine Monitoring
    - Performed periodically based on Sponsor request and site activity (e.g., every 8 weeks)
  - Study Site Closeout
    - Performed at the completion of a study or at the request of the Sponsor (e.g., site is a low recruiter)
CRA Responsibilities: In-house

- Schedule future monitoring visits
- Prepare for upcoming visits
- Contact sites regularly to ensure the study is progressing without problems
  - Includes recruitment discussion and answering protocol questions
- Check the electronic data capture system to ensure sites are entering data in a timely fashion
- Complete the visit report and follow-up letter for a completed visit
- Complete expense reports
- Attend study meetings and trainings
PACE CRA Training Program

- **Professionals Achieving CRA Excellence**
  - In-House training
    - SOP and Clinical Trial Management System (ClinTrak)
    - Therapeutic Introductions
    - Independent Electronic Training Modules
  - Mock Practicum
  - Field-Based Training

- **PACE Rotations**
  - Initial training + core departmental rotations
    - Project Coordination, Study Start-up/Regulatory, Data Management, Feasibility
Project Coordinator (PC) Responsibilities

- Similar background as CRAs, without the travel
- Engage with Clinical Trial Management on day-to-day operations, working closely with the CTM
- Maintenance of project management databases
- Coordinate project meetings and produce quality minutes
- Interact with Sponsors, study sites, and internal associates
- Compile and maintain project-specific status reports
- Responsible for routine departmental support including maintaining supplies, shipping, archiving, filing, and faxing
Regulatory Submissions Coordinator (RSC) Responsibilities

- Provide day-to-day departmental support activities to Regulatory Submissions Managers and other Coordinators;
- Maintain database and spreadsheets as necessary to facilitate tracking and documentation of departmental activities;
- Collect, review, organize, and assemble regulatory start-up submissions; and,
- Perform other tasks as needed.
Clinical Trial Manager (CTM) Responsibilities

- The CTM position performs as project lead for multiservice full service global clinical trials.
- The position interacts with sponsors and manages the timeline and all project deliverables.
- This role coordinates all services contracted for the study.
- CTMs are also responsible for leading a team of CRAs and managing project coordinators.
- Common career path for experienced CRAs.
Qualifications

- CRA/PC/RSC Qualifications:
  - Bachelor of Science/Life Sciences, Allied Health, Nursing, etc.
  - Masters in science related field
  - PhD/PharmD
  - Relevant healthcare related work experience preferred but not required

- Backgrounds of current employees:
  - Pharmacy, Nursing, Biomedical Engineering, Chemical Engineering, Chemistry, Biology, Neuroscience, Allied Health, Nutritional Sciences, Laboratory, etc.

- Training – We will train those with no clinical research experience
Why Work at Medpace?
Opportunities

- Fast-paced, challenging, and rewarding work
- Being offered the tools and training to succeed
- Opportunity to grow professionally
  - Well established career paths
  - New opportunities
- Global presence
- Growing industry in which your work has a large impact
- Stable, growing company
Perks

- Dynamic working environment, with varying responsibilities day-to-day
- Expansive experience in multiple therapeutic areas
- Work within a team of therapeutic and regulatory experts
- Defined promotion and growth ladder with potential for mentoring and management advancements
- Competitive pay and opportunity for bonus
- Business causal dress; Free lunch; Gym
- Potential to work from home
- Named a Top Cincinnati Workplace for 2015, 2016, and 2017 by the Cincinnati Enquirer
Any Questions?