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ProTrials Research, Inc.
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QUALIFICATIONS

- 29 years of experience in the health care industry
- Over 17 years clinical research experience
- Phase experience includes II-IV
- Excellent verbal and written communication skills
- Adherence to FDA and ICH Good Clinical Practice

THERAPEUTIC AREAS

- **Human Growth Hormone**
- **IBD** (Crohn's Colitis)
- **Infectious Disease** (HIV, Hepatitis)
- **Oncology** (Lung Cancer, Metastatic Melanoma, Hematological)
- **Respiratory**
- **VTE Prevention** (CHF, pneumonia, COPD, UTI, cellulites, CVA)

PROFESSIONAL EXPERIENCE

ProTrials Research, Inc: San Jose, CA **2014 - Present**
Sr. Clinical Research Associate

- Monitor clinical studies, including evaluation, initiation, routine, site qualification visits and close out site visits
- Manage and train site personnel on therapeutic area, protocol requirements, proper source documentation, and case report form completion
- Manage, prepare, send, track, and return investigational supplies at individual sites
- Monitor trial by reviewing and reporting on the following: site enrollment and termination updates, monitoring visits, protocol deviation/exceptions, serious adverse events and laboratory abnormalities
- Review source data and case report forms for accuracy, completeness, and integrity of the data, and identifying and resolving ongoing data issues
- Review data queries and listings, and working with the study centers to resolve data discrepancies
- Maintain complete and accurate study files, and reviewing files to ensure all appropriate documentation is present
- Maintain consistent contact with the study centers, investigators, coordinators, client personnel, and other individuals involved in clinical trials
- Presented at the APEX Regional Meeting with the client's Director of Clinical Operations and the Clinical Trial Liaison on April 17, 2015. Attendees included Investigators and study coordinators. The client's CEO also attended the meeting.
- Conducted protocol training and discussed recruitment strategies with the client's clinical trial liaison at various APEX sites.

Westat: Rockville, MD **2004 - 2013**

Senior Clinical Research Associate (2012–2013)

Clinical Technical Advisor: Clinical Research Support Services
Client: Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases

- Conduct site assessments for DAIDS funded research sites outside of the U.S. to evaluate a site's overall capabilities for the conduct of human subjects research and for the conduct of specific categories of clinical trials/studies
- Review and provide comments for site Clinical Quality Management Plans
- Provide oversight of close-out visits
- Review and provide input for revisions to existing quality management tools

Site Monitoring Manager (2009 - 2012)

Pediatric HIV / AIDS Cohort Study
Client: National Institute of Child Health and Human Development, NICHD

- Conducted monthly site monitoring meetings with the clinical research associates
- Conducted close-out visits
- Conducted site monitoring visits to ensure that studies were being conducted according to the protocol, applicable regulations, and the principles of ICH-GCP
- Modified the site monitoring plan, developed a site visit report work instruction, and tracked site visits, and report distribution
- Reviewed site visit reports
- Conducted training visits for new clinical research associates
- Attended and participated in two Network meetings each year
- Evaluated and approved site Quality Assurance Plans

Site Monitoring Manager (2011)

Phase IV Observational Study of Recombinant Protein to Treat Endocrine Disorders
Client: Commercial Client

- Collaborated with the project manager to develop a Risk Management Plan
- Presented at the Investigator Meeting
- Reviewed site monitoring reports
- Conducted site monitoring meetings with the clinical research associates
- Conducted site monitoring visits (remotely and on-site) to ensure that the study was being conducted according to the protocol, applicable regulations, and the principles of ICH-GCP
- Conducted site initiation visits
- Developed and trained Clinical Research Associates on the Site Monitoring Plan
- Participated in a biweekly call with the client.

Senior Clinical Research Associate (2010)

Implementation of Programs for the Prevention, Care and Treatment of HIV / AIDS in the Federal Republic of Nigeria Under the President's Emergency Plan for AIDS Relief, PEPFAR
Client: Vanderbilt University

- Worked with the project director to develop a Clinical Quality Assurance Plan and tools for the clinics participating in the PEPFAR program
- Piloted in-service training at three locations in Nigeria

Senior Clinical Research Associate (2010)

Multicenter, Double-Blind, Randomized, Placebo-Controlled, Dose-Ranging Trial Evaluating the Safety and Efficacy of Study Drug in Respiratory Syncytial Virus (RSV)-Infected Patients at Risk of Severe RSV Illness
Client: Commercial Client

- Conducted site monitoring visits to ensure that studies were being conducted according to the protocol, applicable regulations, and the principles of ICH-GCP
- Conducted site initiation visits
- Conducted close-out visits
- Conducted site monitoring meetings with the clinical research associates
- Reviewed Site Monitoring Reports
- Participated in calls with the client

Quality Control Monitor (2008 - 2010)

- Conducted quality control visits for new clinical research associates
- Conducted annual quality control visits for experienced clinical research associates

Clinical Research Associate (2004 - 2009)

International and Domestic Pediatric and Maternal HIV Studies Network Coordinating Center
Client: National Institute of Child Health and Human Development

- Conducted site monitoring visits to ensure that studies were being conducted according to the protocol, applicable regulations, and the principles of ICH-GCP
- Provided oversight of monitoring activities for five sites in Brazil
- Conducted close-out visits
- Revised Westat's procedures handbook, monitor manual, and two project-specific standard operating procedures
- Conducted a site visit for an investigator initiated study in Tororo, Uganda

Clinical Research Associate (2005)

Clinical Research Operations and Monitoring Center (CROMC) Contract
Client: Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID)

- Reviewed and edited site visit reports

Georgetown University Medical Center: Washington, DC **1986 - 2004**
Study Coordinator (1998 – 2004)

- Planned, coordinated, supervised, and controlled all resources to ensure effective patient care
- Reduced costs and improved physician productively and patient satisfaction by implementing in-office treatments and policies
- Administered Remicade infusions which increased referrals from area practices
- Managed innovative video capsule program after FDA approval in 2001 by screening patients for eligibility and performing the procedure
- Managed research activities for studies conducted in the Department of Gastroenterology. Areas of research included Hepatitis B and C, gastrointestinal bleeding, and reflux.
- Prepared and submitted initial and annual renewal submissions to the Institutional Review Board (IRB)
- Provided education seminars for the Crohn's and Colitis Foundation and served on the Washington DC/Virginia Chapter board for three years

Endoscopy Nurse (1990 – 1998)

- Supervised five rooms simultaneously, six nurses, and one technician
- Trained nurses from other U.S. sites on conscious sedation administration

Charge Nurse (1986 – 1990)

- Managed patient care for up to 16 patients with various diagnoses

Northeastern University: Boston, MA **2009 - Present**
Instructor

- Part-time instructor in the Graduate Biopharmaceutical Regulatory Affairs Program

EDUCATION

Master of Science in Biopharmaceutical Regulatory Affairs, Northeastern University
Bachelor of Science in Nursing, George Mason University
Associate Degree in Nursing

CERTIFICATIONS

IV Certification Course – Centacor-Sponsored Course (2001)
Certification: Research Coordinator Certificate, Georgetown University (1999)

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