Wanda Pérez-Díaz

Clinical Research Associate

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Summary

Clinical Research Associate with research experience in academia, clinical trials, and non-profit settings, including working with national, pharmaceutical, and foundation sponsored research studies. Academic background in both public health and biology, as well as lab and social science research skills. Strong knowledge of remote and risk-based monitoring, adept organizational skills, attention to detail, and the capacity to adapt quickly to new environments. Adept at working with FDA, ICH-GCP guidelines, organizational standard operating procedures (SOPs), as well as ensuring proper implementation of a written protocol. Skilled at creating an atmosphere of diversity and inclusion where all members are valued and embraced.

Core Competencies

- Communication
- Knowledge of clinical trial and research design
- Knowledge of ethical and participant safety considerations
- Knowledge of medicine development and regulation
- Risk-Based Monitoring
- Management of Remote Centralized Monitoring
- Conduct of site initiation, periodic, and final monitoring on-site visits
- Research & Analysis
- Project Management
- Investigational Product (IP) Reconciliation
- Site Management
- Essential Regulatory Document Review
- Query Resolution
- Relationship Building

Education

Bachelor of Arts in Public Health — 2008 - 2013

University of Rochester

Bachelor of Arts in Public Health with a concentration in Health, Behavior, and Society

Professional Experience

DOCS Global — January 2018 - Present

Clinical Research Associate, Amgen FSP

Clinical Research Associate dedicated to fulfilling Amgen's monitoring and site management activities and obligations for 18 different sites in relation to clinical studies. Ensures subject safety, regulatory compliance, and data integrity at the site level for 4 different cardiology protocols (GALACTIC, GOULD, OSLER, FOURIER-OLE). Travels 60% of the time for clinical trial site visits per monitoring plan schemas. In addition, works according to and complies with relevant ICON/DOCS procedures and processes.

Key elements of my duties include, but are not limited to:

- Ensuring clinical study sites are conducting Amgen clinical trials in compliance with the respective protocol, Amgen SOPs and applicable ICH/GCP guidelines and regulations.
- Providing input into feasibility, identifying clinical investigators, and conducting site evaluations post-feasibility to determine site suitability and selection.
- Conducting Investigator Profile Visits.
- Conducting Clinical Site Initiation visits.
- Facilitating subject enrollment at the site level with focused patient recruitment strategies and action plans.
- Identifying site needs and site-related issues, escalating them and/or initiating corrective

Certifications

- **Human Subject Protection Program (HSPP), CITI** – Greater than Minimal Risk (Biomedical)
- **Good Clinical Practice (GCP), CITI**
- **Danger Assessment Certification** – Johns Hopkins Medical Center

Language and Technological Proficiencies

- Fluency in Spanish - Reading, Writing, Speaking
- Microsoft Office Suite
- eRecord - EPIC electronic medical record system
- SPSS - statistical software package
- Research Electronic Data Capture (REDCap)
- eClinical - electronic data capture system/clinical trials management system
- Medidata Rave - electronic data capture system
- Veeva Vault - document management system
- Intralinks -secure document sharing (safety reports)
- Cognos Analytics Reports
- TIBCO Spotfire Reports

actions when necessary, providing solutions for site staff to facilitate the clinical trial process.
- Assisting in and conducting ongoing site personnel training.
- Providing input into case report forms and study-related documents as requested.
- Ensuring appropriate safety reporting as well as tracking and reporting of adverse events (AEs and SAEs).
- Verifying case reports and source documentation.
- Facilitating the resolutions of clinical queries to investigative staff in accordance to the study specific monitoring plan.
- Reporting Important Protocol Deviations (IPDs) and developing issue resolution plans.
- Reviewing, collecting, and maintaining essential documents, submititting to CTA for processing.
- Developing site visit plans and conducting monitoring visits.
- Providing input into Clinical Monitoring Plans as requested.
- Preparing reports for Investigator and Site Evaluations, Clinical Site Initiation, Clinical Site Monitoring, and Clinical Site Close-Out.
- Assisting in preparing sites for audits, reviewing audit reports, and contributing to resolve findings.
- Avoiding major or critical audit or inspection findings not previously documented by CRA.
- Building and maintaining solid and long-term professional relationships with investigators and site staff.
- Assisting other staff, on an as needed basis, to resolve workload/monitoring backlogs.
- Ensuring timely communication of information between Medical Department and site staff.
- Inputing and maintaining electronic site management systems, eg. eClinical, CDSS/CDSS-R, GST, IVRS.
- Implementing new technologies and systems at clinical sites, eg. EDC systems.
- Performing investigational product accountability and reconciliation. Maintaining site supplies.
- Executing clinical supplies management at sites in a compliant manner.
- In conjunction with Clinical Operations Manager (COM), providing study leadership as required.
- Sharing “best practices” in conducting studies to increase site productivity.
- Interacting with other Amgen field staff (eg. RMLs) to optimize relationship with clinical study sites.
- Maintaining expertise through familiarity with clinical and scientific literature and participation in professional activities.
- Providing back-up cover for vacation and other absence.
- Conducting Clinical Site Close-Out visits.

University of Rochester Medical Center 2006 - 2017

Clinical Research Associate, Clinical Trials Coordination Center (October 2016-December 2017)

Clinical Research Associate for Parkinson's Disease clinical trials: STEADY-PD III, a National Institute of Neurological Disorders and Stroke (NINDS) sponsored Phase 3 clinical trial with 54 sites with 330 active subjects and NILO-PD, a Michael J. Fox Foundation (MJFF) sponsored Phase 2 clinical trial with 25 sites enrolling 135 subjects throughout the U.S. and Canada. Traveled to sites to ensure subject safety, data integrity, and site regulatory compliance.

Key elements of my duties included, but were not limited to:

- Conducting periodic on-site monitoring visits, which included the review of source documents, case report forms and logs for all subjects, review of essential regulatory documents, and IP accountability and authorization for destruction per the STEADY-PD III and NILO-PD protocols, organizational SOPs and ICH/GCP guidelines.
- Managing the remote centralized process for verification of database derived protocol deviations as well as completion of action items from previous on-site monitoring visits for all sites as part of the risk-based monitoring process.
- Tracking of investigational product (IP) disposition as well as management of IP reconciliation.
- Collaborating with the risk-based monitoring team (project managers, data manager, medical monitor) to work with 'high-risk' sites on resolution of issues present in a timely manner.

Clinical Research Coordinator

Department of Psychiatry (May 2015 - September 2016)

Coordinated the Realizing Opportunities for Self-Empowerment project (Project ROSE) at UR Medicine Women's Health Practice. The study aimed to reduce depression and improve quality of life in socioeconomically disadvantaged women with depression, sponsored by the Patient Centered Outcomes Research Institute (PCORI). Had latitude for creativity and independent judgement, provided direction, guidance and leadership in planning and delivery of project implementation. Screened and recruited prospective research study participants, coordinated and conducted assessments with study participants, collected, cleaned and managed data, compiled basic descriptive statistics and handled correspondence and other miscellaneous tasks relative to the goals of the project.

Key elements of my duties included, but were not limited to:

- Collecting and documenting data per ICH/GCP guidelines while prioritizing ethics and subject safety.
- Enrolling 225 subjects and ensuring retention in a three-year study.
- Collecting information on adverse events as well as serious adverse events at each assessment visit (3 visits over a 10 months period, per subject).
- Conducting suicide assessments when subjects endorsed suicidality and ensuring subject safety, including informing the subject health care provider. Provided subjects with out-of-study mental health care resources.
- Conducting a Danger Assessment (Johns Hopkins University) for cases involving domestic violence. Provided subject with additional out-of-study resources for domestic violence situations, including the in-clinic social worker.

Research Assistant

School of Nursing (October 2013- April 2015)

Assisted in National Institute of Nursing Research (NINR) sponsored study: Learning about Eating and Diet in Women of Mexican Origin (LEAD) project, an exploratory study to develop a phone application to track disordered eating behaviors real-time. Duties included: weekly strategic planning meetings with bioinformatics team at Indiana University; Testing of application; Document preparation with English-Spanish translation and data collection: training a low-literacy population to use cell phone application, administration of health literacy tests and collection of personal information for 60+ women in their homes throughout Western New York.

Key elements of my duties included, but were not limited to:

- Enrolling 60 subjects throughout Western New York and ensuring retention in an exploratory study using a health care application in a migrant farm worker population.
- Conducting follow-up assessments in subject home, including a Spanish discussion on healthful eating.
- Training a low-technology literacy population to use a cell phone application to record disordered eating behaviors real-time.
- Liaising with bioinformatics team at Indiana University to troubleshoot all issues with the cell phone application.

Earlier Experience 2006 - 2013

University of Rochester Medical Center

Technical Assistant in Medicine in Psychiatry Service (MIPS)

- June 2012 – August 2013: Transferred medical records from 2005 and prior to an electronic database for 800+ patients, updated patient provider and advanced directives information. Provided Spanish-speaking patients with translation services. Created health education materials in Spanish and English.

Research Assistant in the Department of Community and Preventive Medicine

- November 2010 – May 2011: Assisted in National Institute of Health (NIH) sponsored study, Proyecto Doble T, a tobacco research and capacity building project in 6 economically disadvantaged communities in the Dominican Republic. Duties included: participation in weekly conference calls, oral and written translations from (Spanish/English), literature reviews, attendance of intervention development meetings and a variety of office duties.

Neuro-Engineering Research Assistant in the Department of Neurobiology & Anatomy

- June 2006 – September 2007: Conducted research for 3 National Science Foundation (NSF) sponsored pre-clinical studies. Duties included: data collection, performance of lab experiments involving a small procedure on tissue from the rat brain, and data entry/analysis. Co-authored for research presented at National Biomedical Engineering Society (BMES) conference.