

# Rennie Okoro

## Senior Clinical Research Associate

Houston, TX

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**Regulatory Compliance | Site Management | Multi-tasking | Effective Communicator**

### QUALIFICATION SUMMARY

Experienced Senior Clinical Research Associate with over 14 years of monitoring clinical trials across all phases of clinical research and over 20 years in the Pharmaceutical and biotech industry. Demonstrates exceptional organizational and problem-solving skills with a proven ability to manage multiple complex tasks efficiently. Skilled in various EDC systems (Rave, Inform, Veeva Vault), Clinical Data Management, GCP, CTMS systems (Oracle, Impact, Veeva Vault), CDMS BOX, eTMF, CRIO. Excels in cross-functional collaboration, consistently demonstrating the ability to work effectively with multidisciplinary teams. Background includes oversight of over 20 clinical programs, Lead CRA responsibilities, and mentoring over 30 junior CRAs. Experienced in both field-based and remote monitoring, with full availability for up to 70% domestic and international travel. Frequently assigned as the rescue CRA for underperforming and high-risk sites, with a strong track record in risk-based monitoring and site remediation.

### KEY SKILLS

- |                                 |                             |                                        |
|---------------------------------|-----------------------------|----------------------------------------|
| ✓ On-Site, Remote Monitoring    | ✓ Problem Solving           | ✓ Excellent Communicator               |
| ✓ Risk Mitigation               | ✓ Safety Reporting          | ✓ Source Data Verification             |
| ✓ Patient Recruitment/Retention | ✓ Critical Thinker          | ✓ Quality Control & Assurance          |
| ✓ Query Resolution              | ✓ Clinical Trial Management | ✓ Risk Based Monitoring (RBM), KPI/KQI |

### Therapeutic Indications

- |                    |                              |                      |
|--------------------|------------------------------|----------------------|
| ✓ Cardiovascular   | ✓ Respiratory                | ✓ Infectious Disease |
| ✓ Gastroenterology | ✓ Oncology                   | ✓ Device             |
| ✓ Endocrinology    | ✓ Immunology                 | ✓ Dermatology        |
| ✓ Neurology        | ✓ Ophthalmology              | ✓ Rheumatology       |
| ✓ Women's Health   | ✓ In-Vitro Diagnostics (IVD) | ✓ Vaccine            |

### RELEVANT PROFESSIONAL EXPERIENCE

#### Senior Clinical Research Associate

Innovaderm

Contract CRA

*Atopic Dermatitis (Phase 2), Psoriatic Arthritis (Phase 2), Acne (Phase 3), Osteoarthritis (Phase 2), Psoriasis (Phase 2, 3)*

01/2024-present

Montreal, Quebec

- Conducts site qualification, initiation, monitoring, and close-out visits for research sites according to the monitoring plan, Innovaderm and sponsor SOPs, ICH CGP guidelines and applicable regulations
- Participates in investigator meetings
- Builds productive relationships with investigators and site staff to achieve study objectives, including patient recruitment targets.

- Performs source data verification, ensured on-site study drug storage, dispensing, and accountability, data collection, and regulatory document collection
- Maintain eTMF completeness in Veeva Vault through periodic reconciliation with site ISFs, collecting and filing essential documents to ensure audit-ready status.
- Apply risk-based monitoring (RBQM) strategies, leveraging site-level dashboard review to assess KRIs, prioritize monitoring focus on critical data points, and drive compliance improvements across assigned sites.
- Serves as a rescue CRA for underperforming sites, addresses critical compliance gaps, resolves outstanding corrective actions, and restores protocol adherence at sites flagged for elevated risk or poor enrollment performance.
- Serves as Lead CRA on Rheumatology Program; creates Monitoring Plan, reviews investigator packages, monitors clinical trial supplies, develops & initiates Communication Plan, reconciles Core Informed Consent Documentation with IRB & Legal Requirements
- Reviews and approves site visit reports
- Tracks site visit and trip report metrics and escalates issues to project teams
- Recommends potential solutions to identified issues and work with the project managers to find resolution
- Supports in the development of annotated site visit reports, clinical monitoring plans, and monitoring tools
- Supports in the preparation and development of materials related to the training of CRAs
- Mentors junior CRAs through structured co-monitoring visits and ongoing coaching, providing feedback on monitoring technique, documentation standards, and site management skills.
- Conducts on-site co-monitoring and oversight visits with CRAs

## **Lead Principal Clinical Research Associate**

11/2016 –

02/2024

PPD, Part of Thermo Fisher

Austin, TX

*Performed and coordinated all aspects of the clinical trial monitoring in accordance with ICH GCP.*

*Performed monitoring in all phases of clinical trials and all forms of monitoring visits; PSSVs, SIVs, IMVs, and COV.*

*Major Depressive Disorder (Phase 3), Lower Back Pain (Phase 2), IBS (Phase 3), CAR-T (Phase 2), NSCLS (Phase 3), COPD (Phase 3), Alzheimer's (Phase 3), Dementia (Phase 3), Macular Degenerative Edema (Phase 2), COVID-19 (Phase 2,3), Diabetes (Phase 2, 3)*

- Led site monitoring visit activities for over 30 clinical trials, ensuring a high level of compliance with study protocols and regulatory requirements, which contributed to the successful completion of 5 major drug development programs.
- Led monitoring activities for 4 NIH Government funded clinical trials, ensuring stringent adherence to ICH GCP, FDA guidelines, local regulations, and PPD Global SOPs, leading to a 100% audit pass rate and zero critical findings across consecutive regulatory audits.
- Served as Lead CRA on multiple projects, coordinating monitoring activities across regional site portfolios, reviewed trip reports for quality and consistency, and provided direct support to Clinical Study Managers, including monitoring visit report review, site trend analysis, and managerial task coordination.
- Participated in Investigator recruitment & provided a final recommendation

- Efficiently applied Risk-Based Monitoring strategies, analyzing key risk/performance/quality indicators (KRI, KPI, KQI) to identify and address potential issues, enhancing overall site performance and contributing to a significant reduction in protocol deviations.
- Initiated and lead regular site management calls, utilizing strong interpersonal skills, ensuring continuous engagement with trial sites to evaluate adherence to protocol and regulatory standards, discuss recruitment and retention, and facilitate the seamless execution of global project deliverables.
- Contributed to the development and review of over 10 clinical trial protocols and study materials, enhancing study efficiency and data quality.
- Mentored and trained over 30 junior clinical research associates, resulting in an increase in team productivity and monitoring effectiveness.
- Conducted comprehensive on-site and remote monitoring visits, achieving a 98% on-time completion rate for all required monitoring reports and follow-up letters.
- Demonstrated advanced monitoring skills through the conduct of Interim monitoring visits and site management to assess protocol adherence and regulatory compliance, managing study documents to ensure audit readiness.
- Participated in the site selection process of over 40 sites, providing critical oversight and feedback, facilitating in the selection of quality sites for awarded studies
- Developed and maintained effective working relationships with clinical sites, fostering clear communication and collaboration across multiple protocols.
- Actively participated in Investigator Meetings and business development meetings, showcasing strong communication and presentation skills.
- Support quality management by preparing for internal audits and facilitating corrective and preventive action (CAPA) implementations.

### **Senior Clinical Research Associate**

9/2015 – 8/2016

DOCS Global/ICON

Durham, NC

*Contract CRA performing all aspects of clinical trial monitoring primarily in phase II and phase III studies.*

*Lymphoma (Phase 3), Influenza (Phase 3), Glaucoma (Phase 2), Breast Cancer (Phase 2)*

- Executed both onsite & remote monitoring tasks, ensuring study required activities were conducted efficiently across multiple protocols.
- Led efforts in site management to enhance protocol adherence and regulatory compliance, directly contributing to the project's success by maintaining audit-ready status.
- Engaged in study team meetings, demonstrating strong communication skills and a commitment to quality.
- Played a key role in fostering an effective team environment, mentoring junior team members, and promoting agile and adaptable project management practices.
- Conducted over 90 onsite monitoring visits, achieving 95% data integrity and compliance across multiple studies.
- Established and maintained effective working relationships with clinical sites, leading to improved communication and support for project goals and requirements.
- Delivered presentations at 4 Investigator Meetings and conferences, enhancing company and sponsor visibility and showcasing clinical operations achievements.

### **Clinical Research Associate**

01/2015 - 06/2015

Scientific Search

The Woodlands, TX

*Contract CRA dedicated to Lexicon Genetics. Performed all aspects of monitoring.*

*Bladder Cancer (Phase 3), In Vitro Diagnostic Device Class III,*

- Managed site monitoring and closure activities
- Reviewed EDC systems and source documents extensively to support accurate data entry, adherence to Data Management plans.
- Specialized in clinical monitoring of various therapeutic areas, applying medical/therapeutic area knowledge and monitoring skills for effective execution of clinical trial protocols.
- Demonstrated proficiency in computer literacy, including MS Office, sponsor specific portals, CTMS and EDC systems, to manage documentation and ensure data integrity.
- Worked with sites to adapt, drive and track subject recruitment plan in line with project needs to enhance predictability.
- Assisted with site audits and site quality management activities as needed
- Emphasized a committed to quality approach in all tasks, applying critical thinking to evaluate situations and craft novel solutions for site management challenges.

**Clinical Research Associate**

12/2014 - 02/2016

Beaufort

Houston, TX

*Contract CRA. Performed all aspects monitoring, to include pre-study visits, site initiation visits, interim monitoring visits and close out visits.*

*Cardiac Stent Class II Device, Hypertension (Phase 3), Asthma (Phase 3), Multiple Sclerosis (Phase 2), COPD (Phase 3)*

- Led site selection and initiation processes for over 5 cardiovascular studies
- Managed and monitored clinical trial sites, ensuring a high level of compliance with study protocols and FDA regulations across over 35 sites, reducing protocol deviations by 40%
- Implemented innovative patient recruitment strategies, which contributed to exceeding enrollment targets by 30% for twelve consecutive months, significantly accelerating study timelines.
- Facilitated effective training for site staff on GCP and protocol adherence, improving site performance metrics by 35% and enhancing overall study quality.
- Developed strong relationships with site personnel, leading to a 90% satisfaction rate among site staff and investigators, as measured by end-of-study feedback surveys.
- Contributed to the development and review of study protocols and documentation, ensuring all materials met regulatory standards and were implemented efficiently, shortening protocol approval times by 15%.

**Clinical Research Associate**

01/2013 – 12/2014

PRA

Raleigh, NC

*Pulmonary Arterial Hypertension (Phase 3), Psoriasis(Phase2), Parkinsons Disease (Phase 2), Influenza (Phase 3), Coronary Artery Disease (phase 3), Afib (Phase 2), Glaucoma (Phase 3), Type 2 Diabetes (Phase 2/3)*

- Led site visits (PSSV, SIV, IMV, COV), demonstrating exceptional monitoring skills and ensuring protocol adherence and regulatory requirements were met to maintain audit-ready status.
- Collaborated effectively within the Clinical Operations department at PRA, contributing to internal initiatives and the development of standard operating procedures for clinical trial administration and monitoring.
- Showcased agility and adaptability in managing multiple sites and protocols simultaneously, ensuring effective project goals and critical requirements communication.
- Ensured protocol and regulatory compliance across multiple interim monitoring visits, directly contributing to the on-time completion of 4 large-scale clinical trials.

- Facilitated a 10% improvement in site selection efficiency and feedback processes through detailed analysis and reporting, leading to faster study start-up phases

**Research Associate II**  
The Henry M. Jackson Foundation

04/2011 – 12/2012  
Dayton, OH

- Supported the administration and monitoring of clinical trials through proactive site management and documentation practices.
- Enhanced operational efficiency and compliance by contributing to the development of 5 new SOPs and internal training programs, which were adopted across the organization.
- Served as primary contact for site personnel and vendors for non-medical questions
- Issued, followed and resolved clinical queries and issues
- Maintained clinical and research databases, logs and records in compliance with study, IRB, and organizational requirements; ensured that paperwork was properly stored/maintained according to regulations
- Conducted site management calls according to project monitoring plan
- Liaised with CRA to prompt collection of documents, review of data points, findings from EDC and file reviews
- Assisted in ensuring audit ready files and contributed to company, client, and federal/local regulatory requirements/audit responses as needed
- Collected and processed study related data and assisted with data coding, data analysis, QA/QC, and other study-related administrative procedures

## **EDUCATION**

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**MBA**  
Texas A&M University-Commerce

Commerce, TX

**B.S. in Clinical Research Administration**  
The George Washington University

Washington, DC