



Imani Pacheco

Clinical Research Associate II

Certified Clinical Research Associate with 6 years of experience managing multi-site oncology, cardiology, and respiratory trials across Phases II and III. Closed 97.74% of open action items within 14 days during 38 audit-readiness reviews of site-level TMF binders while training 27 site staff members on informed consent procedures and CTMS data entry workflows.

CONTACT INFORMATION



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Medford, OR 12345

KEY SKILLS

- ICH-GCP Guidelines
- FDA Regulatory Compliance
- Electronic Data Capture (EDC)
- CTMS
- Medidata
- Trial Master File (TMF) Management
- Site Monitoring Visits
- Protocol Compliance Auditing
- HIPAA
- Source Data Verification
- IRB Submissions

Professional Experience

CLINICAL RESEARCH ASSOCIATE II | ROGUE VALLEY CLINICAL SCIENCES, MEDFORD, OR

2023 - PRESENT

- Completed 87 clinical trial audits across 4 Phase II and Phase III oncology studies, resolving 34 findings before sponsor deadlines.
- Managed 11 clinical sites spanning 3 states, coordinating monitoring visit schedules and maintaining ICH-GCP compliance documentation in the TMF.
- Shortened trial setup time by 19 days for a cardiology study by standardizing site qualification templates and IRB submission packets.
- Trained 27 site staff members on updated informed consent procedures and CTMS data entry workflows over 9 months.

CLINICAL RESEARCH ASSOCIATE I | CASCADE RIDGE THERAPEUTICS, GRANTS PASS, OR

2021 - 2023

- Conducted independent monitoring visits at 8 clinical sites, verifying source data against EDC entries for 3 concurrent trials.
- Reduced trial setup time from 46 days to 33 days by creating a reusable regulatory binder checklist adopted across the CRA team.
- Performed 38 audit-readiness reviews of site-level TMF binders, closing 97.74% of open action items within 14 days.
- Coordinated IRT configuration and drug shipment tracking for a Phase III respiratory trial enrolling 214 participants.

CLINICAL RESEARCH ASSISTANT I | UMPQUA BASIN HEALTH RESEARCH, ROSEBURG, OR

2020 - 2021

- Supported 6 clinical sites during a Phase II dermatology trial, preparing visit reports and filing 412 essential documents in the TMF.
- Verified 173 adverse event entries in Medidata against source records, flagging 9 discrepancies for medical monitor review.
- Reduced site activation delays by 7 days by pre-screening regulatory packets for missing FDA Form 1572 signatures.

Education

- BS in Biology
Southern Oregon University, Ashland, OR | 2016 - 2020

Certifications

- Certified Clinical Research Associate | Academy of Clinical Research Professionals | 2022