

Kaito Monroe

Clinical Research Associate

Certified Clinical Research Professional with 6 years of experience monitoring up to 6 studies simultaneously across oncology, cardiology, neurology, and autoimmune therapeutic areas. Reduced trial errors by 43.8% by implementing a standardized source data verification checklist, and identified 67 protocol deviations across multiple investigator sites. Skilled in Medidata, CTMS, ICH-GCP Guidelines, and Trial Master File Management.

PROFESSIONAL EXPERIENCE

2023 - Present

Clinical Research Associate | Edisto Creek Clinical Research, Orangeburg, SC

- Reduced trial errors by 43.8% across 3 Phase III autoimmune studies by implementing a standardized source data verification checklist used during all monitoring visits.
- Monitored 9 studies simultaneously across oncology and endocrinology therapeutic areas, completing 6 to 8 on-site visits per month.
- Identified 37 protocol deviations during 14 months of monitoring, categorizing each by severity and submitting corrective action reports within 72 hours.
- Reviewed 1,840 case report form pages per quarter in Medidata, resolving open queries an average of 2.3 days ahead of sponsor deadlines.

2021 - 2023

Clinical Research Associate | Congaree Valley Therapeutics, Columbia, SC

- Monitored 6 studies simultaneously spanning Phase II cardiology and neurology protocols, conducting on-site and remote visits across 7 investigator sites over 24 months.
- Identified 19 protocol deviations at 4 investigator sites by cross-referencing visit logs against CTMS scheduling records and eligibility criteria.
- Decreased trial documentation errors from 31 to 18 per quarter by creating a pre-visit preparation guide adopted by 13 fellow CRAs.
- Verified informed consent forms and regulatory documents for 128 enrolled subjects, filing corrected entries in the TMF within 48 hours.

2020 - 2021

Clinical Research Coordinator | Santee Basin Health Research, Sumter, SC

- Monitored 4 studies simultaneously during a Phase II respiratory trial period, maintaining visit schedules and tracking enrollment milestones in CTMS.
- Identified 11 protocol deviations during screening and randomization phases by auditing IRT logs against source records.
- Prepared and shipped 86 regulatory document packages to sponsor and IRB offices, meeting 98.15% of submission deadlines over 18 months.

EDUCATION

B.S., Biological Sciences

University of South Carolina, Columbia, SC | 2016 - 2020

CERTIFICATIONS

Certified Clinical Research Professional, Society of Clinical Research Associates, 2022



CONTACT INFORMATION

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 Orangeburg, SC

KEY SKILLS

- ICH-GCP Guidelines
- FDA Regulations
- HIPAA Compliance
- Medidata
- CTMS
- Electronic Data Capture
- Source Data Verification
- Protocol Deviation Reporting
- SAE Reporting
- Trial Master File Management
- Site Monitoring Visits