



Nia Toure

Senior CRA

Monitoring activities across Phase II and Phase III trials in oncology, immunology, and metabolic therapeutic areas over 12 years of clinical research experience have supported 4 drug approvals through FDA submission milestones. Restructuring query resolution workflows in EDC improved data accuracy by 22.19% across 2 Phase III immunology studies. Mentorship of 6 junior CRAs on ICH guidelines and source data verification reinforced team-wide compliance standards.

CONTACT INFORMATION

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EDUCATION

BS, Biology
South Dakota State University,
Brookings, SD
2010 - 2014

KEY SKILLS

- ICH-GCP Compliance
- FDA Regulations
- HIPAA
- Medidata
- EDC Query Management
- CTMS
- Source Data Verification
- TMF Management
- IRT Drug Supply Reconciliation
- Recruitment Plan Development
- Monitoring Visit Execution

PROFESSIONAL EXPERIENCE

Senior CRA | Prairie Bluffs Clinical Sciences, Sioux Falls, SD
2020 - Present

- Supported 4 drug approvals over 6 years by leading monitoring activities for Phase II and Phase III trials in oncology and immunology, each progressing through FDA submission milestones on schedule.
- Improved data accuracy by 22.19% across 2 Phase III immunology studies by restructuring query resolution workflows in EDC and reducing median query age from 9 days to 3 days.
- Developed 4 participant recruitment plans for multi-site oncology trials, producing site-specific enrollment forecasts that guided investigator outreach across 7 locations.
- Mentored 6 junior CRAs on ICH guidelines and source data verification procedures, conducting monthly review sessions over 18 months.

Clinical Research Associate | Missouri River Health Research, Pierre, SD
2016 - 2020

- Raised case report form data accuracy from 83.8% to 98.18% over 14 months by introducing a dual-review process for all EDC entries in Medidata.
- Developed 3 participant recruitment plans for a Phase II metabolic trial, tailoring outreach materials to each site's patient demographics and boosting screening volume by 41 candidates in 6 months.
- Verified 1,460 source documents per quarter against CTMS records and regulatory binders, ensuring HIPAA-compliant handling at every visit.
- Coordinated IRT drug supply reconciliation for 2 concurrent trials, resolving 17 inventory discrepancies within 24 hours of detection.

Clinical Research Associate I | Black Hills Therapeutics Group, Rapid City, SD
2014 - 2016

- Improved data accuracy by 44.4% for a Phase I cardiovascular study by auditing 780 EDC fields monthly and escalating unresolved queries to the data management team within 48 hours.
- Filed and maintained 594 essential documents in the TMF for 2 active protocols, passing all 3 sponsor quality reviews with zero critical findings.
- Prepared pre-visit monitoring reports summarizing enrollment targets, outstanding queries, and regulatory document status for 5 investigator sites.