Alpha S. Traore

Portfolio: https://alphatraore.github.io/ | LinkedIn: linkedin.com/in/alphatraore/
alpha.s.traore@wmich.edu | 517-512-8299 | Fort Thomas, KY

PROFESSIONAL SUMMARY

Biostatistician and Statistical Scientist with 8+ years of experience in clinical and non-clinical research. Skilled in experimental design, advanced statistical modeling, statistical programming, and GLP/GCP-compliant studies, with experience in statistical consulting, cross-functional collaboration, mentoring, and team development.

CORE SKILLS

- Advanced SAS Programming; hands-on experience with R; basic familiarity with Python
- Statistical Methods: Experimental design, mixed models, regression modeling, survival analysis, categorical data analysis, and sample size and power analysis
- CDISC Standards: SDTM, ADaM, and Define-XML
- PK/PD Modeling and Clinical Pharmacology Data Analysis
- GLP/GCP Compliance and Regulated Research Environments
- Applied understanding of AI methods for AI-enabled analytics, automation, and decision-support solutions
- Version Control and Reproducible Workflows: Git, Jupyter Notebooks, and Quarto
- Statistical Consulting, Training, and Cross-Functional Collaboration
- Team Leadership, Mentoring, and Project Management

PROFESSIONAL EXPERIENCE

BioSTAT Consultants Inc. — Mattawan, MI
Principal Statistical Scientist | Mar 2026 – Present
Senior Statistical Scientist / Statistical Programmer | Aug 2024 – Mar 2026
Biostatistician / Statistical Programmer | Jul 2017 – Apr 2019

- Study Design:

Contribute to study design through selection of appropriate designs, randomization schemes, stratification strategies, endpoint definitions, and sample size and power calculations to support scientific rigor and regulatory compliance.

- Protocol & SAP Development:

Review study protocols and author Statistical Analysis Plans (SAPs) to align study objectives, endpoints, and statistical methodology with regulatory standards.

- Dataset & Output Specifications:

Draft specifications for analysis datasets and develop mock shells for tables, figures, and listings (TFLs) to support traceable, review-ready reporting.

- Data Quality & Programming:

Conduct data quality assessments and develop SAS/R programs for randomization schedule generation, analysis dataset creation, and TFL production.

- Advanced Statistical Methods:

Apply statistical methods including Mixed Models for Repeated Measures, logistic regression, survival analysis, and analyses of carcinogenicity study endpoints.

- Reporting & Validation:

Prepare Statistical Analysis Reports and validate peer-produced TFLs in accordance with quality control standards.

Precision for Medicine — Bethesda, MD
***Senior Statistical Programmer** | Aug 2021 – May 2024*
Successfully supported multiple clinical studies by managing cross-functional teams, resolving study documentation questions, providing key references, and improving workflow efficiency across more than 20 studies.

- CRF & Dataset Specifications:

Created and reviewed annotated Case Report Forms (CRFs). Developed SDTM and ADaM specifications, including ADaM-like analysis datasets for DSURs.

- Programming & Validation:

Developed and validated QC and primary SAS programs for safety and efficacy analyses using ADaM and SDTM datasets. Created, tested, and documented global utility programs aligned with validation standards.

- Oncology & Pharmacokinetics:

Collaborated on oncology-specific SDTM domains for early-phase trials and developed efficacy datasets and outputs for efficacy endpoints. Programmed PK SDTM domains (PC, PP) and ADaM datasets (ADPC, ADPP) across 6+ studies.

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- Regulatory Submissions:

Contributed to NDA submission studies by developing specifications and programming integrated ADaM datasets for ISS and ISE. Provided essential support for ISS/ISE TLF programming.

- Define.xml & Documentation Support:

Supported the creation and review of Define.xml files and reviewer guides (SDRG, ADRG). Collaborated with statisticians to review and create table mockups.

PPD — North Carolina
Biostatistician | Oct 2020 – Jul 2021
Led cross-functional teams (4–8 members), overseeing timelines, resource planning, team meetings, and sponsor communications. Collaborated with programmers and data managers on database maintenance and documentation.

- Dataset Development & Specifications:

Developed ADaM specifications and ADaM-like analysis datasets tailored to specific outputs. Created detailed table and listing specifications with clear implementation guidance.

- Programming & Validation:

Programmed and validated statistical tables, focusing on efficacy endpoints. Provided thorough documentation and oversight of programming and validation activities.

- Reporting & Documentation:

Prepared and reviewed interim and final reports, including Integrated Clinical and Statistical Reports and Integrated Summaries of Safety and Efficacy (ISS/ISE). Contributed to statistical methods sections and ensured consistency and completeness.

- Cross-Functional Collaboration:

Collaborated with senior statisticians on multiple Quality Tolerance Limits (QTL) specification studies. Reviewed project budgets and scopes, proactively communicating anticipated changes

CTI Clinical Trial & Consulting Services — Covington, KY
Biostatistician | Apr 2019 – Oct 2020
Participated in sponsor meetings to present biostatistics updates across multiple studies. Reviewed CRFs, developed and reviewed SDTM/ADaM specifications and mock TLFs and created QC SAS programs for datasets and outputs.

- Client & Team Collaboration:

Actively contributed insights during meetings with clients and cross-functional internal teams.

- Statistical Planning:

Developed Statistical Analysis Plans (SAPs) and Interim Analysis Plans (IAPs) in alignment with study protocols.

- Data Collection & Review:

Reviewed Case Report Forms (CRFs) to ensure accurate protocol data capture; provided input on data structure and editing prior to database lock.

- Programming & Specifications:
    - Created program specifications, including ADaM dataset specs and mock Tables, Figures, and Listings (TFLs).
    - Independently developed SAS programs for derived/analysis datasets and TFLs.
- Regulatory Submissions:

Supported NDA studies by programming integrated ADaM datasets and TFLs for ISS and ISE submissions.

- Quality Assurance:

Validated outputs from statistical programmers/statisticians per SOPs.

- Compliance:

Executed all tasks in accordance with CTI SOPs, project conventions, and regulatory guidelines (GCP, ICH).

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EDUCATION AND PROFESSIONAL DEVELOPMENT

Master of Science in Statistics
Western Michigan University, MI

Master of Science in Economics
University of Ouagadougou, Burkina Faso

CERTIFICATIONS

https://www.credly.com/users/alpha-traore.da7afca9

- Certara Certified PK/PD Modeler using Phoenix
- Certara Certified NCA Analyst using Phoenix
- SAS Certified Advanced Programmer for SAS®9
- CDISC Standards Certification *Certified by CDISC*
- MS Power BI Data Analyst Specialization
- R Programming (Johns Hopkins University)
- Experimental Design (Arizona State University)

PRESENTATIONS/ADDITIONAL EXPERIENCE

- ***Speaker, "CDISC Implementation Experiences Using R,"*** *CDISC Pediatric User Network (CPUN), https://wiki.cdisc.org/display/PEDUN/Pediatric+User+Network+Meetings July 16, 2025*
- ***Speaker – "Fundamental Terminologies in CROs & Introduction to CDISC Data Standards"*** *Western Michigan University Colloquium — 2018*
- ***Presenter – "Pareto Distribution and the 80–20 Rule"*** *Western Michigan University — 2015 & 2016*
- ***Researcher – "Wage Incentives and Labor Supply Dynamics"*** *Western Michigan University — 2015*