Alpha S. Traore

Fort Thomas, KY 41075 alpha.s.traore@wmich.edu
517-512-8299 www.linkedin.com/in/alphatraore/

PROFESSIONAL SUMMARY

Statistical Analyst & Biostatistician with 8+ years' experience in clinical and non-clinical research, including PK/PD analysis. Skilled in experimental design, advanced modeling, and GLP/GCP-compliant studies. Proficient in SAS, R, and CDISC standards. Active CDISC Pediatric User Network (CPUN) member with a strong track record in consulting and team development.

CORE SKILLS

- PK/PD modeling
- Languages: SAS, R
- *CDISC standards: SDTM, ADaM, Define-XML*
- Statistical Consulting & Training
- Experimental Design, Mixed Models, Categorical Data Analysis
- GLP / GCP Compliance
- Team Leadership and Project Management
- Version control & reproducibility: Git, Jupyter Notebooks

PROFESSIONAL EXPERIENCE

Sr data Scientist; Biostatistician
BioSTAT Consultants Inc., Mattawan, MI
08/2024 – Present | 07/2017 – 04/2019
Reviewed study protocols and authored Statistical Analysis Plans (SAPs) to ensure alignment with study objectives and regulatory standards, including sample size determination and statistical power calculations to support study design decisions.

- Protocol & SAP Development:

Reviewed study protocols and authored Statistical Analysis Plans (SAPs) to ensure alignment with study objectives and regulatory standards.

- Dataset & Output Specifications:

Drafted specifications for analysis datasets and created mock shells for tables, figures, and listings (TFLs).

- Data Quality & Programming:

Conducted Data Quality Assessments and developed SAS/R programs for randomization, dataset generation, and TFL production.

- Advanced Statistical Methods:

Applied a range of statistical techniques, including Mixed Models for Repeated Measures, logistic regression, survival analysis, and tumor data analysis from carcinogenicity studies.

- Reporting & Validation:

Compiled comprehensive Statistical Analysis Reports and validated TFLs produced by peers, ensuring adherence to quality control procedures.

Senior Statistical Programmer
Precision for Medicine, Bethesda, MD
08/2021 – 05/2024
Successfully managed multiple projects. Supported team inquiries on study documentation, provided key references to improve efficiency, and contributed to over 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.

- 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:

Alpha S. Traore

Fort Thomas, KY 41075 alpha.s.traore@wmich.edu
517-512-8299 www.linkedin.com/in/alphatraore/

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

Biostatistician
PPD, NC
10/2020 – 07/2021
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

Biostatistician
CTI Clinical Trial & Consulting Services, Covington, KY
04/2019 – 10/2020
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 crossfunctional 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).

EDUCATION AND PROFESSIONAL DEVELOPMENT

Master of Science in Statistics
Western Michigan University, MI

Master of Science in Economics
University of Ouagadougou, Burkina Faso

Alpha S. Traore

Fort Thomas, KY 41075
517-512-8299
alpha.s.traore@wmich.edu
www.linkedin.com/in/alphatraore/

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*