NICHODEMUS AMOLLO

Senior Biostatistician | Clinical Research Lead

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PROFESSIONAL SUMMARY

Senior Biostatistician with over 8 years of experience in clinical study design, data analysis, and regulatory reporting within healthcare and research environments (KEMRI, Georgetown). Proven expertise in developing Statistical Analysis Plans (SAPs), calculating sample sizes, and conducting rigorous data quality control for multi-site clinical trials. Proficient in SAS, R, and Python for CDISC-compliant data manipulation and TLF (Tables, Listings, Figures) generation. Demonstrated leadership in cross-functional collaboration with data management and clinical teams to ensure data integrity and audit readiness. Committed to driving clinical excellence through statistical rigor and innovation.

TECHNICAL SKILLS

- **Statistical Software:** R (Expert), SAS (Proficient), Python (Pandas/Statsmodels), SPSS, Stata.
- **Standards & Tools:** CDISC knowledge (SDTM/ADaM concepts), SQL, Git/GitHub, REDCap, ODK.
- **Analysis Methods:** Generalized Linear Models, Survival Analysis, Mixed Effects Models, Bayesian Methods.

CORE COMPETENCIES

Clinical Study Design: Sample Size Calculation, Randomization, Protocol Development, Case Report Form (CRF) Design

Statistical Analysis: SAP Development, TLF Generation, Survival Analysis, Regression Modeling, CDISC Standards

Data Management: Data Quality Control (QC), Audit Trails, Data Cleaning & Validation, query resolution

Programming: SAS (Base/Advanced concepts), R (Tidyverse, Survival), Python, SQL

Regulatory & Compliance: GCP Guidelines, ICH Standards, Ethical Research Compliance, Audit Preparation

PROFESSIONAL EXPERIENCE

Lead Biostatistician | Georgetown University East Africa (gui2de)
Nairobi, Kenya | Apr 2025 – Present

- **Study Design & Protocol:** Lead the statistical design for multi-site health intervention studies, including power analysis, sample size determination, and stratified randomization schemas.
- **Statistical Analysis Plans (SAPs):** Author and review SAPs for longitudinal health studies, defining primary/secondary endpoints and derived datasets in alignment with study protocols.
- **Data Quality & QC:** Oversee data validation and quality control procedures, writing SAS/R programs to identify discrepancies and ensure database lock readiness.
- **Reporting:** Generate and validate Tables, Listings, and Figures (TLFs) for interim and final clinical study reports (CSRs), presenting findings to Principal Investigators and safety monitoring boards.

Senior Statistician & Research Officer | Kenya Medical Research Institute (KEMRI)
Nairobi, Kenya | Apr 2023 – Mar 2025

- **Clinical Data Management:** Collaborated with Data Managers to design Case Report Forms (CRFs) and separate CRF completion guidelines, ensuring robust data capture for oncology and infectious disease trials.

- **Statistical Programming:** Developed reusable R and SAS macros for standard safety and efficacy analysis, reducing programming time for routine datasets by 40%.
- **Audit & Compliance:** Maintained rigorous study documentation and audit trails for all statistical programs, ensuring full compliance with GCP and institutional review board requirements.
- **Cross-Functional Collaboration:** Served as the statistical point of contact for clinical operations teams, resolving data queries and providing statistical input for protocol amendments.

Biostatistical Consultant | Various Clinical Research Projects (Global Fund, MMV)
Remote / Kenya | 2023 – 2024

- **Global Fund PMTCT Study:** Designed the statistical framework and analysis plan for a multi-country HIV effectiveness study, ensuring data harmonization across diverse sites.
- **MMV (Medicines for Malaria Venture) Study:** Conducted quantitative analysis on patient uptake data, producing validation reports and statistical summaries for regulatory submissions.

Data Analyst & MEAL Specialist | LERIS Hub
Kenya | Sep 2017 – May 2021

- **Outcome Analysis:** Conducted survival analysis and logistic regression modeling to evaluate health program outcomes, directly informing adaptive management strategies.
- **Data Integrity:** Implemented automated data quality checks using SQL and R, significantly reducing data entry errors in large-scale health surveys.

EDUCATION

MSc – Statistics & Data Science (Biostatistics Focus) (Expected 2026)
Jaramogi Oginga Odinga University of Science & Technology
Thesis: Financial Determinants & Health Outcomes Modeling

BSc (Honours) – Statistics
University of Nairobi

CERTIFICATIONS

- **Biomedical Research Ethics (CITI Program)** - GCP & Human Subjects Research
- **Monitoring & Evaluation for Global Health** – University of Washington
- **Advanced Data Analysis with R** – Johns Hopkins University