Curriculum Vitae

Name: Zehui Bai **E-mail**: zehuibai@outlook.com **Tel.**: +491746279208

Qualification Highlights

- Solid training in theoretical and applied statistics with concentration in Biostatistics
- Hands-on experience in study designs, protocol reviewing and input, ADaM data conversion, SAP creation and review, data analysis, execution results interpretation, protocol reviewing and report writing.
- Familiar with evaluation and programming with SAS and R, proficient in statistical computing: 4+ years of experience in SAS and R, ability to work with SQL, Python and Git
- Experienced data visualization using SAS, R, R Shiny, Advanced MS Excel, visualization tool Highcharts and Apache ECharts
- Accustomed to critical thinking, communicating, and collaborating effectively with people of diverse organizational backgrounds.
- Detail oriented, think outside the box, and be able to problem solve, and trouble-shoot.
- Constantly learning every week, every month, every year for broad knowledge, continuing to broaden knowledge boundaries and stepping out of comfort zone

EXPERIENCE

ARO Experience (German Breast Group)

Biostatistician Oct.2022—Feb.2023

- Planning, monitoring, and evaluation of clinical trials in the field of breast cancer
- Advice on experimental design, research approaches, statistical requirements, and scientific standards
- Development of study proposals (including expertise on case numbers and randomization) and discussion with cooperation partners
- Management of statistical tasks related to clinical trials, including creation of statistical section of study protocols, SAP, mock TLFs, sample size
- Preparation and presentation of study data for IDMC
- Creation of the statistical analysis plan (SAP) and its implementation
- Programming, evaluation and processing of statistical results and creation of reports
- Analysis of biomarker projects
- Development and Verification of SAS Macros
- Data Transfer and Data Transformation in Compliance with MetaDB Requirements

CRO Experience (GCP-Service International Ltd. & Co. KG)

Biostatistician Mar.2020—Sep.2022

- More than 20 of executed international projects (Oncology, Ophthalmology, Respiratory Disease, Chronic Pain, Allergology, Chronic inflammatory, Wound care, Aesthetic Medicine, COVID-19 etc.)
- Lead multiple complex projects as lead biostatistician by building study design, consulting, and programming to implement analytic plans
- Communicate directly with sponsors and participate in budget discussions
- Host Data Review Meeting and drive other meetings to provide effective findings and recommendations to multiple levels of researchers
- Assist submission and obtaining approval for the study protocol from the EC, prepare feedback to discrepancy letter from EC

Curriculum Vitae

- Create randomization plans and generate randomization lists for multiple studies using SAS (block randomization, stratified variable block randomization)
- Conduct sample size calculation and prepare statistical analysis plans for more than 10 studies
- Carry out data clean and manipulation. Conduct data analysis of clinical, laboratory, survey measured data applying standard and non-standard statistical methodology from exploratory analysis to final model building, sensitivity analysis, diagnosis, necessary post-hoc subgroup analysis etc.
- Good knowledge of SAS (SAS BASE/SAS STAT/SAS GRAPH), efficient SAS macro programming to create standard RTF Output for TFLs
- Analyze data using statistical models in SAS and R, such as logistic regression, mixed model, classification, random forest, survival analysis, meta-analysis, cross-validation and bootstrapping, regularization, propensity score matching, Bayesian analysis
- Explore data as a data-loving member and identify key elements, perform model selection and diagnosis, and various visualization tasks
- Prepare Centralized Statistical Monitoring (CSM) Plan and implement
- Prepare Quality Risk Management Plan, conduct clinical trial within Clinical Quality Management System (CQMS) conceptual framework
- Experience in converting SDTM to ADaM data under the CDISC standard, and using ADaM data for programming to generate TFLs
- Provide support for academic conferences and publications
- Assist medical writing in the statistical part for more than 10 projects
- Produce questionnaires under FDA standard

Epidemiology Institute (Leibniz-Institut für Präventionsforschung und Epidemiologie - BIPS)

Intern (Biometry and Data Management) and Master Thesis Aug.2019—Sep.2020

- Participate in the largest cohort study of overweight children and adolescents in Europe: IDEFICS/I.Family
- Organization and management of complex workflow data in R and SAS
- Conduct multiple imputation and diagnosis
- Predictive mean matching for multiple imputation (MICE)
- Explore the application of machine learning method (random forest) in MICE

EDUCATION

University of Bremen (Germany) Oct.2018—Sep.2020

M.Sc. Medical Biometry/Biostatistics

Tianjin University (China) Aug.2013—Jul.2017

B.Sc. Biological Engineering (Major)

LL. B. Law (Minor)

SKILL

Training	ICH GCP, ISO 14155, CDISC ADaM Training
Language	Chinese – native, English– advanced, German – advanced
Computer	MS office, Several EDC systems (QCTMS EDC/Castor/ Viedoc)
	SAS BASE/SAS STAT/SAS GRAPH/SAS MACRO
	R, LaTeX, Markdown, Python, SQL and MySQL, Machine learning

Curriculum Vitae

Qualification	Senior Nutritionist Qualification
	IBM Data Analyst Professional Certificate (Python and SQL)
	IBM Data Science Professional Certificate (Python and SQL)
	IBM Data Analytics with Excel and R Professional Certificate (R and Excel)
	University of Harvard, Data Science-Machine Learning Certificate (R)
	University of California, SQL for Data Science Certificate (SQL)
	University of California San Diego, Drug Development Product Management Specialization
	Google Data Analytics Professional Certificate
	Google Fundamentals of Digital Marketing
	LVMH Inside Certificate
	CFI-Statistics Fundamentals, Data Science Fundamentals
	MSI-Project Management Essentials Certified (PMEC)