

Curriculum Vitae

Name: Zehui Bai



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Tel.: +491746279208



Location: Hamburg,
Germany

QUALIFICATION HIGHLIGHTS

- Enjoys leading, problem solving, detail oriented, building and working within high performing teams to ensure quality deliverables and successful project delivery.
- Accustomed to critical thinking, communicating, and collaborating effectively with people of diverse organizational backgrounds.
- Hands-on experience in study designs, protocol reviewing and input, ADaM data conversion, SAP and shells 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: 5+ years of experience in SAS and R, ability to work with SQL, Python and Git.
- Constantly learning every week, every month, every year for broad knowledge, continuing to broaden knowledge boundaries and stepping out of comfort zone.

EXPERIENCE

CRO Experience (ICON plc)

Senior Biostatistician II

Dec.2023—Present

Senior Biostatistician I

Mar.2023— Nov.2023

Clinical Trials As a lead statistician, led multiple international clinical trials and participated in deep support for over 10 clinical programs across multiple therapeutic areas including Oncology, Neurology, Hepatology, Immunology, Hematology and Endocrinology studies.

Lead BST Statistical oversight of the entire clinical study, Responsible for the quality and delivery of the Table, Figure, and Listing packages (TFL), Contributions to Protocol Risk Evaluation and Planning (PREP), Performing validation of TFLs, table datasets, and derived datasets, Manages statistics and programming projects to high quality, within budget, and on-time completion.

Communication Establishes and maintains effective working relationships with (external) clients and (internal) project team members, including data management personnel, statistical programmers, and clinical research personnel.

Training Training and instruction of new or younger statisticians in statistical methods and business processes.

Regulatory Assists in the preparation of biostatistics input to research proposals, Contribute to and review clinical study protocols, Supports responses to regulatory questions (EMA, FDA) on the design of the program, and any labelling claims following submission.

Randomization Verification of simple to complex randomization specifications and dummy randomization schemes.

Sample Size Calculation Performing sample size calculations ranging from general to complex study designs using R and SAS, visualization and illustration of results using R Shiny App and ggplot2 Package.

As a Subject Matter Expert (SME), providing guidance and validation of sample size calculations using R for other biostatisticians.

SAP Holding SAP Kick off Meeting, Development of multiple statistical analysis plans and report specifications for simple to complex clinical studies, Review multiple SAP as a SME.

Programming Use SAS for complex inference macro programming, for efficacy analysis of study endpoints. Validation and review of ADaM Derivation and TFLs Outputs using R.

CDISC Review of Annotated Case Report Form (aCRF), SDTM Spec, Study Data Reviewer's Guides (SDRG), ADaM Spec, Analysis Data Reviewer's Guide (ADRG) and Define.

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Quality Management Documents and archives analysis and programming work to ensure a complete audit trail.

Medical Writing Preparation of in-text tables and Contribution to the statistical sections of Clinical Study Reports (CSRs).

Academic Experience (German Breast Group)

Biostatistician

Oct.2022—Feb.2023

Clinical Trials Planned, monitored, and evaluated clinical trials in the field of breast cancer.

Lead BST Served as the lead statistician for two cancer sub-studies, providing advice on experimental design, research approaches, statistical requirements, and scientific standards for planned clinical trials.

Communication Facilitated communication and development of study proposals, demonstrating expertise in case numbers and randomization, and engaging in discussions with cooperation partners. Additionally, responsible for preparing and presenting study data to the Independent Data Monitoring Committee (IDMC).

SAP Successfully completed two SAPs and mock TLFs.

Programming Conducted comprehensive analyses as outlined in two SAPs, including logistic regression, survival analysis, cutoff analysis, and biomarker analysis. Also performed scientific plotting in line with publication standards.

SAS Macro Development Independently developed a survival analysis macro for generating survival probabilities and censoring information at specified time points, adaptable for various subgroup analyses. Enhanced the Kaplan-Meier Plot macro to provide more detailed information, including median survival times and survival probabilities at specific time points.

CDISC Converted external data compliant with the SDTM into metadata sets that meet internal company standards.

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

Biostatistician

Mar.2020—Sep.2022

Clinical Trials Successfully executed over 30 international projects across diverse therapeutic areas, including Oncology, Ophthalmology, Respiratory Disease, Chronic Pain, Allergology, Chronic Inflammatory Conditions, Wound Care, Aesthetic Medicine, and COVID-19 studies.

Lead BST Spearheaded more than 15 complex projects as a lead biostatistician, overseeing study design, preparing SAPs and shells, providing insightful consultations, and skillfully programming to implement SAPs.

Communication Directly communicated with sponsors and participated in budget discussions, hosted Data Review Meetings, and led other meetings to deliver effective findings and recommendations to various research levels.

Regulatory Navigated the regulatory landscape, assisting in protocol submissions and obtaining study protocol approval from Ethics Committees (ECs), addressing feedback, and resolving discrepancies raised by ECs.

Randomization Prepared randomization plans and generated randomization lists for multiple studies using SAS.

Sample Size Calculation Conducted sample size calculations for over 20 studies using SAS, R, and nQuery.

SAP Gained experience in over 15 SAPs spanning Phase 1 to Phase 3 in drug and medical device trials, and reviewed junior biostatisticians' SAP drafts.

Programming Proficient in SAS macro programming for standard RTF output for TFLs, and analyzed data using

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statistical models in SAS and R, including logistic regression, mixed models, GEE, survival analysis, meta-analysis, cross-validation, bootstrapping, regularization, propensity score matching, and Bayesian analysis.

CDISC Programmed and converted data from SDTM to ADaM under the CDISC standard, and prepared and reviewed ADaM specifications.

Quality Management Developed Centralized Statistical Monitoring (CSM) Plans and Quality Risk Management Plans, ensuring clinical trials adhered to Clinical Quality Management Systems (CQMS).

Medical Writing Contributed to the statistical sections of CSRs for more than 10 studies.

Academic Experience (Leibniz-Institut für Präventionsforschung und Epidemiologie - BIPS)

Intern (Biometry & Data Management) and Master Thesis

Aug.2019—Sep.2020

- Participated in the largest cohort study of overweight children and adolescents in Europe: the IDEFICS/I.Family study
- Conducted multiple imputation and diagnosis, showcasing expertise in advanced statistical techniques.
- Implemented predictive mean matching within the framework of Multiple Imputation by Chained Equations (MICE)
- Explored the application of machine learning methods, specifically random forest, in the context of 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

BASE/SAS STAT/SAS GRAPH/SAS MACRO

R and R Shiny, LaTeX, Markdown, Python, SQL and MySQL, Machine Learning

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
