

Job Description (Contact: Kevin Li, Kevin_Li@topalliancebio.com)

Position Title: Senior Biostatistician - Principle Biostatistician	Reports to: Head of Biostatistics
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Qualifications

- PhD (or Master) in Statistics, Biostatistics, or other statistics-related majors (3+ years of experiences in pharmaceutical industry for master's degree)
- Accomplishment of responsibilities with appropriate supervision
- Good problem-solving and critical thinking skills, ability to drive drug development strategies
- Effective communication and collaboration skills : including statistical consulting skills and interpersonal skills to contribute effectively in cross-functional team settings
- Rich experiences in using statistical software such SAS and R
- Good knowledge of statistical concepts and methods that are commonly used in the drug development
- Good understanding of regulatory guidelines

Responsibilities

- Collaborate with Medical Science in preparation of clinical trial development plans with respect to the study design, particularly the study objectives, endpoints, sample size, stratification and randomization
- Review protocol and author statistical sections
- Review CRF design and external data specifications to ensure protocol objectives are met and project standards are maintained
- Develop statistical analysis plan and independent data monitoring charter
- Prepare the study randomization and participate in its implementation
- Organize data monitoring meetings
- Work closely with Statistical Programmers in dry runs, identify data quality issues for key efficacy and safety variables, and ensure high quality of final TFL's
- Review & author the clinical study report
- Support NDA/BLA by overseeing the generation of health authority submission datasets, outputs, and performing ad hoc analyses as needed
- Oversee the statistical deliverables from CROs
- Contribute to study publications and presentations.
- Participate in process improvement/development activities for standards, process, and guidelines