POSITION DESCRIPTION

Position Title: Senior Biostatistician  
Classification: SO  
Group: Clinical Trials and Biostatistics Unit  
Department: Population Health  
Program: Mental Health and Complex Disorders  
Location: Herston

POSITION OBJECTIVES

The purpose of this position is to contribute in design and analysis of clinical studies, undertake clinical biostatistical research, provide biostatistical consulting to clinical and basic science researchers, and participate in associated activities such as research supervision and mentoring. At the senior level you will have the opportunity to take a leadership role within the Unit, to lead statistical aspects of projects and mentor junior staff and students.

ORGANISATIONAL CONTEXT

QIMR Berghofer is a statutory body under the QIMR Act (1945). The mission of QIMR Berghofer is to promote the wellbeing of humankind through medical research, to maintain within the State of Queensland an internationally recognised Centre for Medical Research, to develop that Centre as the primary focus of Medical Research within the State and to cooperate with, and where possible assist the work of other medical research establishments within the State and throughout the world.

The Clinical Trials and Biostatistics Unit (CTBU) is a specialised research unit within QIMR Berghofer. CTBU designs and conduct early and late phase clinical trials in different therapeutic areas, apart from leading clinical, clinical epidemiological and biostatistical methodological research projects, with both academic and industry collaborators. All professionals of the Unit are GCP trained, and conduct clinical studies strictly following the regulatory requirements and pharmaceutical industry standard. The Unit is currently running several Phase 1, -2 and -3 clinical trials in various therapeutic areas. Specific research services include study design and protocol development, database development and management, specialised analyses for safety reporting, as well as statistical and clinical reporting. CTBU also provides high quality research consulting services to clinical researchers and bio-pharmaceutical companies.

The Unit has achieved international prominence through numerous collaborations with international academic research groups and multinational pharmaceutical companies. CTBU currently leads a programme of clinical research studies in the fields of diabetes and cardiovascular disease. Some of our current research activities include: evaluation of the cardiometabolic effects of new anti-diabetes drugs; clinical and pharmaco-epidemiological studies combining clinical trials and large real world data to understand disease pathophysiology in the fields of metabolic diseases; and statistical methodological developments to address the challenges in dealing with large real-world primary care level data.
The Unit is now playing a pivotal role in the development of Australia’s translational research capabilities, and is one of the principal members of Therapeutic Innovation Australia – QLD Node.

**REPORTING STRUCTURE**

The position reports to Professor Sanjoy Paul, Head of the Clinical Trials and Biostatistics Unit.

**PRIMARY RESPONSIBILITIES**

Specific duties and responsibilities include, but are not limited to:

**Development of the Unit’s research profile**
- Contribute to development of research program(s) in areas of biostatistics and clinical epidemiology - related to design, conduct and analysis of data from clinical trials and large multinational longitudinal primary care databases
- Collaborate in research projects within the Institute and beyond
- Develop grant applications to support research activities in collaboration with multidisciplinary teams
- Publish high quality research papers in leading scientific journals

**Research**
- Act as Project Statistician on various clinical trials and non-trial projects
- Be responsible for all statistical tasks on assigned projects (e.g. clinical trial design and planning, statistical analysis plan, reporting activities, exploratory analyses and additional analyses to support publications)
- Develop expertise in understanding and analysis of safety data and provide relevant support to DSMBs associated with trials being conducted by the Unit
- Track clinical project activities and milestones and ensure high quality of all CTBU deliverables for the assigned projects
- Adhere to CTBU and project specific protocols as well as other regulatory requirements (e.g. SOPs, SAP, GCP and standard regulatory guidelines) to ensure project standards are maintained
- Establish and maintain sound working relationships and effective communication within the Institute and with national and international collaborators

**Consulting**
- Provide statistical consultancy to clinical and basic science researchers.

**Service**
- Support the Unit’s Clinical Data Manager and Project Manager to ensure timely and high quality support services are delivered in relation to clinical studies conducted by the Unit
- Participate in organisations external to the Institute in relevant areas, and where this is likely to contribute to research activities of the Unit
- Take part in relevant consultancy activities that can also contribute to research activities of the Unit

**Administration**
- Serve on relevant committees as required.

**Occupational Health and Safety:**
- Ensure work practices comply with the requirements of the Work Health and Safety Act, related legislative requirements and the Institute’s WH&S policies and procedures.
KEY SELECTION CRITERIA

Qualifications
- Post-graduate qualifications in Biostatistics, Statistics, Mathematics, or related fields with a strong methodological background.

Knowledge and Skills
- Strong quantitative skills and research experience in the fields of epidemiology, biostatistics, clinical trials, or other relevant disciplines.
- Good statistical programming skills, with programming expertise in at least two of the standard software packages: SAS, STATA & R
- Demonstrated experience with statistical analyses including interpretation and presentation of results
- Sound knowledge of advanced biostatistical methods in clinical studies
- Sound understanding of survival analysis, multivariate modeling and exploratory data analysis is essential
- Ability to work on a variety of collaborative clinical trials and epidemiological studies in a wide range of therapeutic areas
- Excellent time management skills, with the ability to prioritise multiple tasks as well as flexibility to meet changing team priorities and research project deadlines
- Familiarity with international regulatory/research guidelines on drug development, GCP, and statistical principles (especially ICH guidelines)
- Excellent written skills and ability to produce clear reports and manuscripts for publication in clinical and scientific journals
- Excellent communication skills, including the ability to conceptualise and report verbally on project matters

Experience
- Minimum 3 years of experience in clinical data analysis (i.e. clinical trials). Experienced Biostatisticians from pharmaceutical or biotech industries with strong research interests are also welcome to apply.

Personal Qualities
- Ability to work independently as well as collaboratively and effectively within a team, including national and international collaborators
- Proactivity and ability to learn new analytical techniques and methods to address project needs
- Reliable, trustworthy and able to maintain confidentiality