Roche Canada
Title: Associate Statistical Scientist- 1 Year Contract (Biostatistician Level 2)
Department: Biostatistics
Location: Mississauga Head Office

Multiple Positions Available

Objective:
The Associate Statistical Scientist partners with senior scientists in biostatistics, clinical, safety, epidemiology, regulatory, research, and manufacturing on clinical development projects, research applications, development science applications, and/or product manufacturing applications. This typically includes partnering with senior scientists in the creation of strategies to address drug development needs and designing experiments, and evaluating and preparing study results for health authorities and the medical/research community. Within Clinical Development, this also entails effective collaboration with Operations, Data Management, and Statistical Programming personnel.

Responsibilities:
1. Clinical Development

- A member of cross-functional Study Management Teams
- Study Planning: With assistance of senior statistical scientists, reviews study protocols, authors statistical sections of protocols
- With assistance of senior statistical scientists develops independent data monitoring and endpoint committee charters.
- Develops the statistical and data analysis plans, and prepares the study randomization
- Study Conduct: Reviews case report forms to ensure protocol objectives are met and project standards are maintained. Develops statistical programs as necessary to perform analyses, Review and approve analyses produced by statistical programming, ensuring the accuracy and validity of results.
- Analysis & Reporting: Author the clinical study report, and with assistance of senior scientists and cross-functional team members provides input into global health authority documents and regulatory response for health authority submissions
- Contributes to study publications and presentations, and provides analytical support for exploratory activities such as personalized healthcare biomarker development and PK/PD modelling.
2. Nonclinical Statistics

- **Study Planning:** With assistance from senior staff, provides experimental design and analysis strategies to nonclinical projects in Research, Preclinical Development Science, Bioprocess Development and Manufacturing.
- **Analysis and Reporting:** With assistance from senior staff, performs statistical analyses for nonclinical studies, provides input to IND and BLA submissions and to regulatory response to global health authority investigations related to marketed products, and contributes to publications and presentations.
- **Statistical Consulting:** With assistance from senior staff, provides statistical advice to nonclinical investigators and contributes to the development of statistics courses.

3. Functional Area

- Understand and apply business requirements and processes. Participates in functional training.
- Keep abreast of new developments in statistics, drug development, and regulatory guidance through literature review, conference attendance, etc.

**Qualifications:**

Minimum MSc in statistics, biostatistics, mathematics or similar areas of academic discipline + 2 years of experience in:

- Experience using statistical software.
- Solid knowledge of theoretical and applied statistics
- Developing knowledge and experience applying statistical methods to drug development
- Developing understanding of regulatory guidelines in a pharmaceutical research setting

**Skills:**

- Good Communication and Collaboration Skills (including statistical consulting skills, interpersonal skills to contribute effectively in cross-functional team settings, ability to influence others without authority, ability to build strong collaborative relationships with scientific and non-scientific partners)
- Evident Project management skills (including ability to manage scope and effectively delegate to other functions, staff, contractors and external vendors)
- Evident Strategic Agility (including problem-solving and critical thinking skills, ability to drive drug development strategies, agility that extends beyond statistical aspects)
- Evident Drive for Results (Demonstrates interest and ability to learn new things, takes initiative, welcomes problems as challenges; finds solutions to technical problems)
- Understands and applies Business requirements and processes
- Understands and respects cultural differences when interacting with colleagues in the global work place
- Accomplishes responsibilities with supervision
- Good knowledge of English in a business environment.

**Qualified candidates are encouraged to submit cover letter and resume no later than January 16, 2018.**

*This position is not eligible for relocation support.*

*This position is open to applicants legally authorized to work in Canada.*

If you are interested, please click on the link to apply: [Associate Statistical Scientist- 1 Year Contract](#)

**NOTE:** All employment is conditional upon the completing and obtaining a satisfactory background check, including educational, employment, references and criminal records (for which a pardon has not been granted) checks.

Roche is an equal opportunity employer and prohibits unlawful discrimination based upon any legally protected ground. Roche will make a good faith effort to accommodate the individual needs of applicants with disabilities in our recruitment process.

**AGENCY NOTICE:** Please note that Roche Canada does not accept unsolicited resumes from recruiters or employment agencies. In the absence of a signed Services Agreement with agency/recruiter, Roche Canada will not consider or agree to payment of any referral compensation or recruiter fee. In the event a recruiter or agency submits a resume or candidate without a previously signed agreement, Roche Canada explicitly reserves the right to pursue and hire those candidate(s) without any financial obligation to the recruiter or agency.

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