NoNO Inc.

Position:	**Director of Biostatistics**
Reports to:	**CEO and President**
Status:	**Permanent**

NoNO Inc. is accepting applications for the position of **Director of Biostatistics** to be based in our office in Toronto.

The successful candidate will perform duties of a Project Statistician to support our key clinical development projects. Provide statistical input into the design of clinical trials and marketing application strategies. Provide statistical expertise necessary to design, analyze, interpret and communicate the results of Phase 3 clinical trials. Take on the key statistical responsibility in the planning and preparation of NDA and Health Canada regulatory submissions. Represent the company as required before regulatory agencies and other organizations in defense of statistical methodologies and data analyses related to our products. Represent the company on external independent data monitoring committees (IDMCs). Work with external CROs on the Data Management and Statistics deliverables to ensure compliance with FDA and Health Canada requirements.

RESPONSIBILITIES INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING:

- Perform duties of a Project Statistician to support global Phase 3 clinical trials. Participate in the Project Teams in the role of a Project Statistician. Collaborate with project team members in the planning of the clinical programs, outlining protocols and marketing applications and publication strategies.
- Advise on the design of valid, efficient and cost effective clinical trials. Prepare statistical methodology sections for protocols and Statistical Analysis Plans.
- Prepare accurate, high quality reports of complex clinical trials for registration and publications.
- Take on the key statistical responsibility in the planning and preparation of regulatory submissions as required.
- Attend regulatory agency meetings and respond to questions to support the statistical analysis results of clinical trials on behalf of the company.
- Provide and organize statistical support for regulatory meetings, questions and submissions.
- Represent the company on external IDMCs.
- Act as the primary contact for CROs for statistics deliverables.
- Prepare specifications for data analyses by outside vendors. Assure compliance of the data with the specifications.
- Work with external vendors on the analysis of data including responsibility for program validation. Direct exploratory analyses to discover or define possible drug effects or claims.

- Ensure achievement of statistical deliverables and milestones in coordination with other functions including Clinical Development, Quality Assurance, Safety, and external vendors.
- Ensure outsourced data management activities and databases are compliant with FDA, Health Canada and other regulatory agencies requirements for marketing applications.
- Generate reports for internal safety review meetings and annual safety updates.
- Ensure that protocol objectives are met and project standards are maintained.
- Ensure good communication between team members.
- Provide statistical consultancy for NoNO personnel.
- Train NoNO employees on good statistical practices, as needed.

QUALIFICATIONS

- Masters or Ph.D. in statistics, biostatistics, or biometry; at least 8 years experience in pharmaceutical clinical trials, in the pharmaceutical industry and/or Regulatory Authorities.
- Ability to successfully plan and conduct a submission project, including interactions with regulatory authorities on statistical issues.
- Sound knowledge of statistical methodology; ability to critique devised hypotheses and results interpretation.
- Previous experience with NDAs/CTDs and authoring SAPs.
- Ability to challenge methodological issues.
- Ability to manage deliverables outsourced to a CRO.
- Excellent interpersonal skills with the ability to interact effectively with people, internally and externally.
- Expertise with the requirements of 21 CFR Part 11 and ensuring vendor compliance
- Proficiency in SAS programming.
- Excellent communication, presentation, interpersonal skills, both written and spoken (English), with an ability to inform, influence, convince, and persuade.
- Must be legally authorized to work in Canada without restriction.
- Ability to travel may be required (approximately 5%).
- Salary commensurate with experience.

Applications to:

CDjobs@nonoinc.ca

Subject: Director Biostatistics