GENE THERAPY PROGRAM

Catalyzing the development of gene therapeutics from concept to clinic

Robust end-to-end capabilities ensure that promising technologies are efficiently translated into clinical therapeutics.

With a strong fundamental research program and a diverse portfolio of partnered programs, we are currently working towards treatments for more than 30 diseases.

Biostatistician

The Gene Therapy Program (GTP) is entering a new era of unprecedented opportunity with the great potential to reshape the face of medicine as we know it. Our discoveries have set the stage for successful treatments and possibly even cures for devastating genetic diseases.

The laboratory of Dr. Jim Wilson, at GTP of the University of Pennsylvania, has been a leader in the development of innovative vector technology for close to three decades. We have emerged as the "go-to" organization for public and private partners, who want to participate in the gene therapy space. Currently, we are positioned to lead another round of vector innovation and establish pre-clinical and clinical proof-of-concept in therapeutic applications of in-vivo genome editing.

We are currently looking for a **Biostatistician** to provide statistical design and data analysis for pre-clinical studies and clinical trials, performing secondary data analysis to support our programs.

As a **Biostatistician,** you will partner with senior staff on the design and conduct of pre-clinical and clinical studies; the evaluation, interpretation, and reporting of study results; regulatory submissions to the FDA, as required, and; the development of quality study protocols, schema, and reports per agreed timelines. You will work with project teams to determine statistical methodology and will advise on the development of randomization schedule, sample size and power calculations. You will be assuring that statistical tables and data listings are compiled and accurate to assure that statistical input is incorporated into reports or decisions. You will offer advisement on the development of alternative analysis strategies when changes are needed, identifying and correcting errors in result interpretation. You will oversee data managers to assure compiled data is normalized for analyses.

You will review all project protocols, writes the statistical analysis sections, and generates study randomization, collaborating in the preparation and review of clinical assessments and is directly responsible for their statistical integrity, adequacy, and completeness. Authoring statistical analyses in clinical study report(s) and peer-reviewed publications. You will attend professional meetings and present authored work as invited. Assist in preparing development programs for new drug indications. Provide statistical consultation to other disciplines related to the use of statistics in biologic applications.

You will be assuring the accuracy in describing biostatistics to explain pre-clinical or clinical data in any of the following areas: clinical trials management, the submission of analyses associated with regulatory filings, clinical communications, clinical pharmacology, publications, and/or quality management.

Successful candidates must have a comprehensive understanding of biology and the application of statistical methods in experimental design, assay qualification, and quality control. You must be proficient in statistical software language (Non-Clinical/Stat-specific). Having an understanding in bioinformatics would be helpful but not required.

As a Top candidate for this role, you will possess:

- Master's Degree in statistics, mathematics or equivalent and 3 years of experience required;
- Ability to communicate effectively at all levels
- Strong team contributor with effective leadership abilities
- Excellent communication skills, especially in communicating statistical concepts to non-statisticians
- Broad experience in statistical data analysis, and expertise in areas such as experimental design, linear/nonlinear models, mixed effect models, data mining, Bayesian methods, and statistical learning
- Experience with bioinformatics helpful but not required
- Programming proficiency and Experience with relevant software tools and; thorough understanding of cell biology and human physiology.

Interested in Applying? Please email your updated CV to Jennifer Royal (jenroyal@upenn.edu) for further consideration

For more information regarding our research and services please visit our website: http://gtp.med.upenn.edu/

"We are at the beginning of a revolution in the treatment of patients with rare diseases. The commitment of the staff and scientists at GTP to the development of treatments for rare disease patients inspires me every day I come into work."

James M. Wilson, MD, Ph. D.
Director, Gene Therapy Program

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