JOB DESCRIPTION (DRAFT)

Job Title	Associate Director, Biostatistician
Grade	Associate Director, Biostatistician
Reports to	Head of Biometrics
Department	Clinical Operations
Hours	35
Location	London (White City)

About Autolus

Autolus is a clinical-stage biopharmaceutical company developing next-generation, programmed T cell therapies for the treatment of cancer. Using a broad suite of proprietary and modular T cell programming technologies. The company is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognise cancer cells, break down their defence mechanisms and eliminate these cells. Autolus has a pipeline of product candidates in development for the treatment of haematological malignancies and solid tumours.

Role Summary

We are actively looking for a permanent Associate Director Biostatistician to join our offices in White City.

This will be a high profile role where your expertise will be applied across the Oncology clinical trial portfolio. You will collaborate with Clinical Development colleagues and other functional groups via the project team to ensure timeliness and quality of study deliverables for biostatics.

You will have demonstrated experience in experimental design, statistical methodologies, analysis and reporting of clinical data mainly using SAS.

Key Responsibilities

- Collaborate with Clinical Sciences, regulatory affairs and other functions on protocol development, including choosing an appropriate study design and statistical methodology, defining endpoints, calculating sample size, and writing statistical sections of the protocol.
- Develop statistical analysis plans.
- Collaborate with statistical programming to ensure that appropriate programs and
- documentations are being developed for datasets development and outputs generation, and ensure the statistical analyses specified in scientific protocols and/or analysis plans are conducted appropriately.
- Collaborate with data management and clinical operations over the course of trials to provide statistical input to study conducts and database development as well as data collection/cleaning.
- Collaborate with clinical pharmacology and biology and provide analysis support for their projects
- Collaborate with medical affairs on publications
- Interact with medical writing and other functions on regulatory documents containing
- statistical information and clinical data (e.g. Clinical Study Reports, Summary

- documents for NDA submissions
- Contribute to the development of functional-level standards, SOPs, and templates.
- Represent biostatistics on study/project teams.
- Establish and maintain effective working relationships with study/project teams.

Demonstrated skills and competencies

E – Essential
P – Preferred

Experience

- Oncology drug development experience is preferred
- Excellent verbal and written communication skills are required.
- Good interpersonal and project management skills are essential.
- Ability to effectively represent Biostatistics in multidisciplinary or cross-functional meetings
- Broad knowledge and superior understanding of advanced statistical concepts and techniques

Qualifications

- Ph.D. or M.S. in statistics, biostatistics, or related field with minimum 5 (Ph.D.) - 10 (M.S.) years of experience as biostatistician in the biotech/pharmaceutical industry or medical research. Ph.D. preferred. (E)