Title: Director of Biostatistics
Hiring Manager: VP of Biometrics
Function: Biostatistics
Location:

Position Summary:

Upstream Bio is developing innovative therapeutics to treat inflammation. We are a nimble company with solid financial backing having raised $400M from high-quality investors. We have a clinical stage asset, verekitug, focusing on two Phase 2 studies in 2024 in asthma and chronic rhinosinusitis with nasal polyps (CRSwNP) and plans to expand into other therapeutic areas. Our offices are in Waltham, MA. We have a hybrid working model, with Tuesdays-Thursdays in the office and Mondays and Fridays flexible to work remotely if desired.

The Director of Biostatistics will provide strategic input and operational leadership for all biostatistical activities related to our clinical trials. Collaborating closely with cross-functional teams, this role requires a seasoned professional with deep expertise in biostatistics, clinical trials, and regulatory requirements. The Director will ensure the integrity, quality, and compliance of statistical analyses, contributing to the successful development and approval of new therapies.

Key Responsibilities:

- Collaborate with cross-functional teams, to align biostatistical strategies with clinical development goals.
- Be accountable for statistical aspect of the design and analysis of clinical trials, including the development of statistical analysis plans (SAPs) and the execution of statistical analyses.
- Oversee vendor performance, ensuring deliverables meet quality and compliance standards. Ensure the accurate and timely delivery of high-quality statistical outputs, including tables, listings, figures, and clinical and regulatory documents including CSRs, INDs, NDAs/BLAs.
- Conduct statistical analyses to support clinical trial design, result exploration, and publications.
- Represent Biostatistics at relevant governance/review forums and in Regulatory correspondence where appropriate.
- Communicate effectively across all functional areas so that deliverables and interdependencies are clear.

Qualifications:

- PhD or Master's degree in Biostatistics, Statistics, or a related field.
- Minimum of 10 years of experience in biostatistics within the biotech or pharmaceutical industry.
- Proven expertise in the design and analysis of clinical trials, including phase I-IV studies.
- Strong knowledge of regulatory requirements (e.g., FDA, EMA, ICH-GCP) and industry best practices.
- Experience with statistical software (e.g., SAS, R) and data management systems.
- Excellent leadership, communication, and interpersonal skills.
- Strong analytical and problem-solving abilities.
- Ability to work collaboratively in a fast-paced, dynamic environment.