



Title: Director, Biostatistics

Hiring Manager: Vice President, Biometrics

Function: Biostatistics

Location: Waltham, MA

Position Summary:

The Director, 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.

About Upstream Bio:

Upstream Bio is a public company based in Waltham, MA. We are developing verekitug, the only known antagonist currently in development that targets the receptor for Thymic Stromal Lymphopoietin (TSLP). We have advanced this highly potent monoclonal antibody into separate Phase 2 trials for the treatment of severe asthma and chronic rhinosinusitis with nasal polyps (CRSwNP) and plan to initiate development in chronic obstructive pulmonary disease (COPD). Our experienced team is committed to maximizing verekitug's unique attributes to address the substantial unmet needs for patients underserved by today's standard of care. Learn more about us at upstreambio.com.

Interested candidates, please contact:

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