

Executive Director/Vice President, Biostatistics

Position Overview:

AirNexis is seeking an exceptional Executive Director/Vice President, Biostatistics to lead and define the statistical strategy for our next-generation COPD inhalation program. This is a high-impact leadership role where you will help shape clinical development, influence regulatory strategy, and directly engage with the FDA and global health authorities.

This is a high-visibility role with executive and board-level exposure. As a key member of the leadership team, you will build and lead the biostatistics function, driving innovative study designs and data-driven decision-making in a fast-paced, entrepreneurial environment.

Responsibilities:

- Establish and lead the biostatistics function, setting strategy, standards, and infrastructure
- Serve as a trusted advisor to executive leadership on clinical and regulatory strategy
- Design and lead statistical strategy for Phase II/III trials, including endpoints, estimands, and analysis plans
- Directly represent biostatistics in FDA and global regulatory interactions
- Drive innovative and efficient study designs to maximize probability of success
- Oversee statistical deliverables including protocols, SAPs, TFLs, and CSRs
- Lead interpretation of clinical data and translate insights into strategic recommendations
- Collaborate cross-functionally across Clinical, Regulatory, and Pharmacology teams
- Oversee and manage CROs and external partners
- Build and mentor a high-performing biostatistics team as the company grows

Requirements:

- Ph.D. in Statistics or Biostatistics (required)
- 12–15+ years of experience in the pharmaceutical or biotechnology industry
- Proven leadership experience in late-stage (Phase II/III) clinical development
- Strong track record of direct FDA and global regulatory interactions
- Experience in respiratory diseases; COPD strongly preferred
- Experience with inhalation or drug-device combination products preferred
- Advanced proficiency in SAS, R, or similar statistical tools
- Ability to thrive in a fast-paced, startup environment
- Excellent communication and stakeholder management skills.

Send your resume and cover letter to HR@airnexus.com to apply.