Director – Biostatistics

- Sanofi, Bridgewater, NJ, US

**Apply**

Provide leadership and guidance as the statistical expert on a project team or within a therapeutic area. For one or more projects, be accountable for all statistical aspects of clinical studies and submissions, including quality, relevance to regulatory perspective, and scientific validity. Act as key statistical consultant within company. Responsible for project staffing, resource planning and allocation within therapeutic area(s). Responsible for facilitating career development of team members and assisting Group Manager with creation and implementation of policies. May have regional or global management responsibility. In some cases incumbent could serve as department leader in specific technical area.

**Major Duties And Responsibilities**

- Oversee statistical support to multiple project teams. Collaborate with clinical and regulatory leads in defining general strategic approach, creating clinical development plans (CDP), and producing individual protocols. Work independently, or with other statistical departmental members or consultants, to develop effective statistical approaches applicable to project.
- Statistically valid CDP involving one or more studies designed to lead to a key decision point or submission. CDP, related protocols, and statistical analysis plans (SAP) consistent with overall project objectives. CDPs have degree of optimality in terms of timing, use of resources, and probability of success.
- Oversee execution of statistical analyses, preparation of the statistical methods and results sections for clinical study reports (CSR), and production of overall summaries. Review and approve key results memos and statistical conclusions. Provide guidance to the clinical and regulatory teams regarding conclusions and inferences from the data package. Ensure statistical representation at regulatory or other external meetings.
- Completed data package relevant for submission or making key decisions. Statistical deliverables consistently compliant, in timing and quality, with SOPs and departmental standards.
- Provide general guidance on definition and documentation of key derived variables needed to support production of tables, listings, and graphs (TLG). Effect consistency of data collection and analysis across project or area.
- Analysis datasets that are quality controlled, sufficient to produce TLG for reports, and consistent within projects. General compliance with Sanofi-aventis standard data models, e.g. CIDSC.
- Plan and track project activities, timelines, and resource use across projects. Provide justification for planned resource needs. Seek to optimize resource utilization and capacity.
• Accurate plans, well-managed projects, capacity to apply extra resources in urgent situation.
• Ensure mentoring and development of staff. Encourage personal development in the context of project work. Learn and apply techniques to promote teamwork, quality, and motivation. Manage conflict.
• Productive work environment, individual growth, development of strong contributors. Staff compliance with SOPs and departmental policies.
• Maintain awareness of industry standards, regulatory requirements, and departmental guidelines and SOP. Within area of control, update procedures or practices as needed to remain in compliance.
• Procedures and practices meet industry standards and are consistent with internal SOP.
• Serve as departmental representative on division or corporate-wide teams. Advocate application of statistical thinking in decision-making. Work effectively with leaders in other functional areas.
• Effective corporate use of statistical thinking. Efficient processes in clinical development and operations.

**Required Education/Experience**

• PH.D. (MS) in statistics or related discipline
• 10+ (12+) years of pharmaceutical experience, including significant interactions with regulatory bodies, history of successful management (4+ years), and expertise in one or more therapeutic areas
• Demonstrated knowledge of general HR policies and management
• Demonstrated leadership, project management, and interpersonal skills
• Excellent verbal, writing, and presentation skills
• Experience managing direct reports, assembling teams, and implementing working relationships with external agencies, such as CRO, consultant groups, and research committees
• Ability to recruit, retain, motivate, and develop highly qualified persons; projects and reinforces corporate values
• Broad knowledge and superior understanding of advanced statistical concepts and techniques
• Innovatively applies technical principles, theories, and concepts to pharmaceutical clinical development and life cycle management
• Proven success, through previous submissions or interactions, in meeting regulatory guidelines and requirements for drug development
• In-depth understanding of the regulatory drug submission / approval process regionally and globally
• Ability to effectively represent Biostatistics and Programming in multidisciplinary or cross-functional meetings
• Ability to work in a fully self-directed manner
Preferred Experience

- Knowledge of regulatory laws / procedures outside of US and Europe
- Leadership role in societies or committees relevant to drug development or statistics
- Ability to contribute to advancement of statistical or applied specialized area of knowledge

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We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions. With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

https://www.statsjobs.com/job/director-biostatistics/