

Company: inVentiv Clinical www.inventivclinical.com stock symbol: VTIV
Title: Associate and Director of Statistics and SAS Programming
Duration: Permanent
Location: Indianapolis, IN

JOB SUMMARY

The Director of Statistics and SAS Programming is responsible for oversight, leadership and direction of all statistical and SAS programming activities.

The Director of Statistics and SAS programming oversees work performed by the respective Managers of Statistics and SAS Programming to ensure compliance to FDA and ICH regulations and guidelines.

He/she is also responsible for staff retention, team performance, milestone, and deliverable compliance, training compliance, customer satisfaction, and adherence.

DUTIES AND RESPONSIBILITIES

Has management responsibility for a group of biostatisticians and statistical programmers in one or more therapeutic areas, including setting employee goals and doing performance reviews

Responsible for the statistical input provided by the group to all major documents, including clinical development plans, protocols, statistical analysis plans, clinical study reports, and summaries of clinical safety and efficacy.

Provides review and guidance on statistical aspects of all FDA interactions, including FDA meetings, responses to FDA questions, and Advisory Committee meetings.

Works closely with management to ensure a coordinated approach to statistical work.

Maintains comprehensive knowledge of theoretical and applied statistics and regulatory guidelines regarding clinical trial analysis and reporting. Applies new statistical procedures as appropriate.

Responsible for all on- and off-boarding activities for the statistics staff.

EDUCATION, TRAINING AND PRIOR EXPERIENCE REQUIREMENTS

Ph.D is a MUST with at least 4 years experience.

Comprehensive understanding of theoretical and applied statistics; extensive experience in clinical trials. Comprehensive understanding of regulatory guidelines in a clinical research setting.

Proven experience with creation of CDISC-compliant SAS data structures is expected.

Regulatory submission experience in a clinical setting required. Ability to effectively collaborate, communicate, and influence throughout all levels of the organization. Strong leadership abilities are expected.

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