Senior Statistician, DOCS

Durham, NC

Supports teams through contributions to the design, planning, execution, analysis, and reporting of clinical and non-clinical studies, with a view toward establishing the conditions essential for determining safety, efficacy, and marketability.

- Complete understanding and wide application of technical principles, theories, and concepts in the statistical field.
- Under general supervision lead scientific development of protocols for multiple projects.
- Independent operational and technical leadership of multiple protocols or non-clinical experiments in one or more therapeutic areas.
- Under general supervision, lead analyses and inputs into regulatory filings for all phases of development.
- Ensure and manage quality, timeliness, and efficiency for all support and deliverables for designated studies or projects.
- Liaise with and provide needed guidance to statistical programmers and Statistical Operations associates assigned in support of project and trial deliverables.
- Establish and maintain working relationships with relevant team functional representation.

**Key Performance Indicators**

- Understanding and wide application of statistical principles, theories, and concepts in the field.
- Biostatistics go-to person for clinical trials sub-team or non-clinical counterpart.
- Determines and develops approaches to solutions as issues arise on study. Proposed solutions are imaginative, realistic, practicable, and consistent with organization and project objectives.
- Completed work is reviewed in terms of meeting the study or project objectives and schedules.
- Quality and timeliness of all deliverables for studies and projects.
- Compliance with internal and external standards as measured by audit findings.
- Works under general supervision of supervisor or project statistician who is responsible for the overall statistical design strategy for the project.

**Background**

Education: – Doctoral degree in statistics or biostatistics. Master’s degree with sufficient relevant experience.

Experience: – At least 5 years with Doctoral degree or at least 10 years with Master’s degree in the pharmaceutical or device industry or equivalent.

- Excellent knowledge in statistics and clinical trial methodology.
- Sound knowledge of product clinical development and relevance to study design.
- Limited Health Authority expertise.
- Excellent written and oral communication.

https://www.statsjobs.com/jobs/senior-statistician-docs/