Pharmaceutical Lead

Summary

Work directly for some of the biggest pharmaceutical companies in the industry and gain exposure to a wide range of clinical studies while feeling valued and supported in your day-to-day work.

Personality

- Independent
- Self Starter
- Enjoys guiding and mentoring teams
- Good communicator across multiple teams and levels

Responsibilities

- Act as the lead statistician on behalf of the client for one or more clinical studies within a clinical program or across multiple clinical programs.
- Understand the regulatory requirements related to design and analysis of studies.
- Participate in the protocol summary development. Give input into the study design, efficacy and safety parameters and the planned statistical analyses. Perform sample size calculations and study design simulations.
- Participate in protocol development, review and approval.
- Review data management related documents.
- Author/review the Statistical Analysis Plan (SAP).
- Work closely with the lead biostatistician at the assigned CRO to oversee the statistical deliverables for the client.
- Participate in data review/evaluation meetings and other study-related meetings and activities.
- Perform exploratory analyses.
- Review the clinical study report and provide input on interpretation of results.
- Review and input into regulatory documents and interactions.
- Contribute and review abstracts posters, presentations, and manuscripts for publication and ensure accuracy of all biostatistical aspects of such documents.
- Support and mentor more junior statisticians on the team.

Opportunities

- Presenting at conferences.
- Developing and executing innovative study design and/or efficiency optimisation ideas.
- Line management and peer mentoring.
- Contributing to business process improvements and authoring/presenting internal training.
- Contributing to initiatives that consider employees, the environment and our local communities as part of our B Corp accreditation.

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- Understanding of clinical drug development process, relevant disease areas, endpoints and different study designs.
- Awareness of industry and project standards & ICH guidelines.
- Interpersonal/teamwork and communications skills for effective interactions.
- Proficiency in data handling using SAS or other statistical software (e.g. R).
- Self-management skills with a focus on results for timely and accurate completion of competing deliverables.
- Demonstrated problem solving ability and attention to detail.
- Ability to work independently and as part of a team.